# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

## Amendment No. 2
## to
# FORM S-1
**REGISTRATION STATEMENT**
**UNDER**
**THE SECURITIES ACT OF 1933**

# Processa Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

| **Delaware** | **2834** | **45-1539785** |
|---|---|---|
| (State or other jurisdiction of incorporation or organization) | (Primary Standard Industrial Classification Code Number) | (I.R.S. Employer Identification Number) |

**7380 Coca Cola Drive, Suite 106**
**Hanover, Maryland 21076**
**(443) 776-3133**
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**David Young, Pharm.D, Ph.D.**
**Chairman and Chief Executive Officer**
**Processa Pharmaceuticals, Inc.**
**7380 Coca Cola Drive, Suite 106**
**Hanover, Maryland 21076**
**(443) 776-3133**
(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public:
**As soon as practicable after the effective date of this registration statement.**

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. [ ]

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering. [ ]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

| | | | |
|---|---|---|---|
| Large accelerated filer | [ ] | Accelerated filer | [ ] |
| Non-accelerated filer | [ ] | Smaller reporting company | [X] |
| | | Emerging growth company | [ ] |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act. [ ]

**CALCULATION OF REGISTRATION FEE**

| Title of Each Class of Securities to be Registered | Proposed Maximum Aggregate Offering Price [2] | Amount of Registration Fee |
|---|---|---|
| Common Stock, $0.0001 par value per share [1] | $ 20,892,625 | $ 2,712 |
| **Total:** | **$ 20,892,625** | **$ 2,712[3]** |

(1) Includes shares that the underwriters have the option to purchase to cover over-allotments, if any.

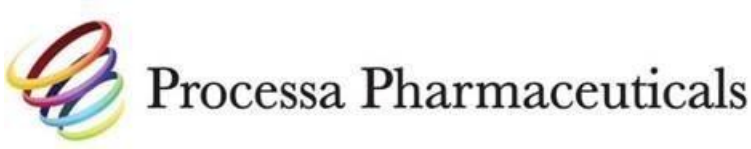
(2) Estimated solely for purposes of calculating the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended.

(3) Previously paid.

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS, SUBJECT TO COMPLETION, DATED SEPTEMBER 16, 2020




**2,150,000 Shares of Common Stock**

This is a firm commitment public offering of 2,150,000 shares of our common stock.

Prior to this offering, there has been a limited public market for our common stock on the OTCQB® Market, or OTCQB. On September 15, 2020, the last reported sale price of our common stock as reported on the OTCQB was $8.45 per share. We have applied to list our common stock on the Nasdaq Capital Market, or Nasdaq, under the symbol "PCSA" and our common stock has been approved for listing contingent on the completion of this offering. We have assumed a public offering price of $8.45, which represents the last reported sales price of our common stock as reported on the OTCQB on September 15, 2020. There is no assurance that this offering will be completed, or as to the terms of this offering. In addition, the closing sales price of our common stock as reported on the OTCQB may not be indicative of the final offering price or market price of our common stock on Nasdaq and there can be no assurance that a trading market will develop for our shares of common stock on Nasdaq. The final public offering price will be determined through negotiation between us and the underwriters in the offering and the recent market price used throughout this prospectus may not be indicative of the final offering price. In addition, quotes of stock trading prices on an over-the-counter marketplace may not be indicative of the market price on a national securities exchange.

On December 23, 2019, we effected a one-for-7 reverse split of our common stock, or the Reverse Split. Unless otherwise specified or the context otherwise indicates, the information contained in this prospectus has been adjusted to give effect to the Reverse Split.

**Investing in our common stock is highly speculative and involves a high degree of risk. See "Risk Factors" beginning on page 10.**

| | Per Share | Total |
|---|---|---|
| Public offering price | $ | $ |
| Underwriting discounts and commissions[(1)] | $ | $ |
| Proceeds, before expenses, to us | $ | $ |

(1) See "Underwriting" for a description of compensation payable to the underwriters.

We have granted the underwriters an option to purchase up to 322,500 additional shares of our common stock. The underwriters can exercise this option at any time within 30 days after the date of this prospectus.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

Delivery of the shares of common stock is expected to be made on or about , 2020.

*Joint Bookrunning Managers*

**Craig-Hallum Capital Group** **The Benchmark Company**

*Co-Manager*

**National Securities Corporation**

Prospectus dated , 2020

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You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus. We take no responsibility for and can provide no assurance as to the reliability of any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus we may provide to you in connection with this offering in any jurisdiction where action for that purpose is required, other than in the United States of America. Persons outside the U.S. who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of our common stock and the distribution of this prospectus and any such free writing prospectus outside of the U.S.

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations, market position and market opportunity, is based on our management's estimates and research, as well as industry and general publications and research, surveys and studies conducted by third parties. We believe that the information from these third-party publications, research, surveys and studies included in this prospectus is reliable. Management's estimates are derived from publicly available information, their knowledge of our industry and their assumptions based on such information and knowledge, which we believe to be reasonable. These data involve a number of assumptions and limitations which are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors." These and other factors could cause our future performance to differ materially from our assumptions and estimates.

This prospectus includes trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included in this prospectus are the property of their respective owners.

As used in this prospectus, unless the context indicates or otherwise requires, "the Company," "our Company," "we," "us," and "our" refer to Processa Pharmaceuticals, Inc., a Delaware corporation, and its consolidated subsidiary. For other defined terms, please see the Glossary on the following page.

## GLOSSARY OF CERTAIN SCIENTIFIC TERMS

The medical and scientific terms used in this prospectus have the following meanings:

"Active metabolite" means a drug that is processed by the body into an altered form which effects the body.

"Analog" means a compound having a structure similar to that of an approved drug but differing from it in respect to a certain component of the molecule which may cause it to have similar or different effects on the body.

"cGCP" is current Good Clinical Practices. The FDA and other regulatory agencies promulgate regulations and standards, commonly referred to as current Good Clinical Practices, for designing, conducting, monitoring, auditing and reporting the results of clinical trials to ensure that the data and results are accurate and that the rights and welfare of trial participants are adequately protected.

"cGMP" is current Good Manufacturing Practices. The FDA and other regulatory agencies promulgate regulations and standards, commonly referred to as current Good Manufacturing Practices, which include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation.

"CRO" means a Contract Research Organization.

"EMA" means the European Medicines Agency.

"FDA" means the Food and Drug Administration.

"IND" means an Investigational New Drug Application. Before testing a new drug on human subjects, the company must file an IND with the FDA. Information must be produced on the absorption, distribution, metabolism, and excretion properties of the drug and detailed protocols for testing on human subjects must be submitted.

"Indication" means a condition which makes a particular treatment or procedure advisable.

"Moiety" means an active or functional part of a molecule.

"NDA" means a New Drug Application submitted to the FDA. Under the Food, Drug, and Cosmetic Act of 1938, an NDA is submitted to the FDA enumerating the uses of the drug and providing evidence of its safety.

"NL" means Necrobiosis Lipoidica, a chronic, disfiguring condition.

"Osteonecrosis" means the death of bone cells due to decreased blood flow. It can lead to pain and collapse of areas of bone.

## PROSPECTUS SUMMARY

*This summary highlights selected information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making an investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our consolidated financial statements and the related notes thereto and the information set forth under the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this prospectus.*

### Overview

*Our mission is to develop drug products that improve the survival and/or quality of life for patients with high unmet medical needs.*

Processa Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on the development of drug products that are intended to provide treatment for and improve the survival and/or quality of life of patients who have a high unmet medical need condition or who have no alternative treatment. Our most advanced product candidate, PCS499, is an oral tablet that is a deuterated analog of one of the major metabolites of pentoxifylline (PTX or Trental®). We have completed the patient portion of our Phase 2A trial for PCS499 and are in the process of closing the trial, and we plan to begin recruiting for a Phase 2B trial in 2021. We also have four newly licensed drugs (PCS12852, PCS6422, PCS11T and PCS100) and will begin developing these products once adequate funding has been obtained.

### Our Strategy

Our vision is to develop drugs with potentially high return on investment and lower risk of development failure. Our portfolio drugs are focused on treating patients who do not have adequate treatment options for their conditions and have some clinical evidence supporting the efficacy of the drug, whether it be evidence with the drug itself or a drug with similar pharmacological properties. Given the prior success of our development team, the regulatory science approach that we employ not only allows us to develop drugs focused on FDA approval, but also allows us to select drugs for our portfolio which may have a greater chance for approval in a population of patients who need treatment options. The key pillars of our strategy to achieve our vision include:

(i) identifying drugs that have potential efficacy in patients with an unmet medical need, as demonstrated by some clinical evidence that the targeted pharmacology of the drug provides clinical efficacy in the targeted patient population;

(ii) identifying drug products that have been developed or approved for other indications but can be repurposed to treat those patients who have an unmet medical need; and

(iii) identifying drugs that can be quickly developed such that within 2-4 years, critical value-added clinical milestones can be achieved while advancing the drug closer to commercialization.

### Our Team

Our drug development efforts are driven by our extensive knowledge in applying rigorous regulatory science to the FDA approval pathway. We have assembled a seasoned management team with extensive experience in developing therapies, including advancing product candidates from preclinical research through clinical development and ultimately regulatory approval and commercialization. Together, our management team has completed over 30 FDA approvals. Our team is led by our Chairman and Chief Executive Officer David Young, Pharm.D., Ph.D., who has extensive experience in research, regulatory approval and business development and who served at Questcor for eight years as independent director and Chief Scientific Officer, helping lead to the ultimate sale of Questcor in 2014.

### Our Pipeline

The table below summarizes our clinical product pipeline. We have completed the patient portion of our Phase 2A clinical trial for PCS499, however, the finalization of the trial data and its closeout has been delayed due to the ongoing COVID-19 pandemic.

| Program | Indications | Pre-Clinical | Phase I | Phase II | Phase III | Key Upcoming Milestones |
|---|---|---|---|---|---|---|
| PCS499 | Necrobiosis Lipoidica | | | | | Enroll first patient in a Phase 2B study in the first half of 2021; release clinical data in the second half of 2022 |
| PCS12852 | POGD (Postoperative Ileus) | | | | | Enroll first patient in a Phase 2A in the first half of 2021; release clinical data in the second half of 2022 |
| PCS6422 | Colorectal (colon, metastatic), Metastatic Breast | | | | | Enroll first patient in a Phase 1B in the first half of 2021; release clinical data in the second half of 2022 |
| PCS11T | Small Cell Lung and Pancreatic Cancer | | | | | Complete the IND-enabling studies; submit the Phase 1B IND in the second half of 2022. |
| PCS100 | Fibrotic Disease | | | | | FDA meeting in 2021; GLP Tox |

***PCS499***

Our lead product, PCS499, is an oral tablet that is a deuterated analog of one of the major metabolites of pentoxifylline (PTX or Trental®). PCS499 is classified by FDA as a new molecular entity. PCS499 and its metabolites act on multiple pharmacological targets that are important in a variety of conditions. We have identified Necrobiosis Lipoidica (NL) as our lead indication for PCS499. NL is a chronic, disfiguring condition affecting the skin and the tissue under the skin typically on the lower extremities with no currently approved FDA treatments. NL presents more commonly in women than in men and occurs more often in people with diabetes. Ulceration occurs in approximately 30% of NL patients, which can lead to more severe complications, such as deep tissue infections and osteonecrosis threatening the life of the limb. Approximately 22,000 - 55,000 people in the United States and more than 120,000 people outside the United States are affected with ulcerated NL.

The degeneration of tissue occurring at the NL lesion site may be caused by a number of pathophysiological changes, which has made it extremely difficult to develop effective treatments for this condition. Because PCS499 and its metabolites affect a number of biological pathways, several of which could contribute to the pathophysiology associated with NL, PCS499 may provide a novel treatment solution for NL, a condition for which there are currently no FDA-approved treatments.

On June 18, 2018, the FDA granted orphan-drug designation for PCS499 for the treatment of NL. On September 28, 2018, the IND for PCS499 in NL became effective, such that we could move forward with a Phase 2A multicenter, open-label prospective trial designed to determine the safety and tolerability of PCS499 in patients with NL. The study initially had a six-month treatment phase and a six-month optional extension phase. In December 2019, we informed patients and sites that the study

would conclude after the treatment phase and there would no longer be an extension phase. The first enrolled NL patient in this Phase 2A clinical trial was dosed on January 29, 2019 and the study completed enrollment on August 23, 2019. The last patient visit took place in February 2020. Due to COVID-19 related restrictions at certain sites, study closeout and database lock have yet to be completed.

The main objective of the trial was to evaluate the safety and tolerability of PCS499 in patients with NL and to use the collected safety and efficacy data to design future clinical trials. Based on toxicology studies and healthy human volunteer studies, Processa and the FDA agreed that a PCS499 dose of 1.8 grams/day would be the highest dose administered to NL patients in this Phase 2A trial. As anticipated, the PCS499 dose of 1.8 grams/day, 50% greater than the maximum tolerated dose of PTX, appeared to be well tolerated with no serious adverse events reported. All adverse events reported in the study were mild in severity. As expected, gastrointestinal symptoms were the most noted adverse events and reported in four patients, all of which were mild in severity and resolved within 1-2 weeks of starting dosing.

Two of the twelve patients in the study presented with more severe ulcerated NL and had ulcers for more than two months prior to dosing. At baseline, the reference ulcer in one of the two patients measured 3.5 cm2 and had completely closed by Month 2 of treatment. The second patient had a baseline reference ulcer of 1.2 cm2 which completely closed by Month 9 during the patient's treatment extension period. In addition, while in the trial, both patients also developed small ulcers at other sites, possibly related to contact trauma, and these ulcers resolved within one month. However, the other ten patients, presenting with mild to moderate NL and no ulceration, had more limited improvement of the NL lesions during treatment. Historically, less than 20% of all the patients with NL naturally progress to complete healing over many years after presenting with NL. Although the natural healing of the more severe NL patients with ulcers has not been evaluated independently, medical experts who treat NL patients believe that the natural progression of an open ulcerated wound to complete closure would be significantly less than the 20% reported as the maximum percentage of patients who naturally heal over several years after NL presentation.

On March 25, 2020, we met with the FDA and discussed the clinical program, as well as the nonclinical and clinical pharmacology plans to ultimately support the submission of the PCS499 New Drug Application (NDA) in the U.S. for the treatment of ulcers in NL patients. With input from the FDA, we will be designing the next trial as a randomized, placebo-controlled trial to evaluate the ability of PCS499 to completely close ulcers in patients with NL. We initially planned to begin recruiting for the randomized, placebo-controlled trial in the fourth quarter of 2020, but we now expect to begin recruiting patients in 2021 due to the ongoing COVID-19 pandemic. This PCS499 NL study will be a randomized, placebo-controlled Phase 2B study to better understand the potential response of NL patients on drug and on placebo. After obtaining the results from this Phase 2B study, we expect to meet with FDA to discuss our Phase 2B drug and placebo response findings while further discussing the next steps to obtain approval.

***PCS12852***

On August 19, 2020, we entered into a License Agreement ("Yuhan License Agreement") with Yuhan Corporation ("Yuhan"), pursuant to which we acquired an exclusive license to develop, manufacture and commercialize PCS12852 (formerly known as YH12852) globally, excluding South Korea.

PCS12852 is a novel, potent and highly selective 5-hydroxytryptamine 4 (5-HT4) receptor agonist. Other 5-HT receptor agonists with less 5-HT4 selectivity have been shown to successfully treat gastrointestinal (GI) motility disorders such as chronic constipation, constipation-predominant irritable bowel syndrome, functional dyspepsia and gastroparesis. Less selective 5-HT4 agonists, such as cisapride, have been either removed from the market or not approved because of the cardiovascular side effects associated with the drugs binding to other receptors, especially 5-HT receptors other than 5-HT4.

We plan to meet with the FDA in early 2021 to further define the clinical development program required for the PCS12852 product and discuss a Phase 2A proof of concept randomized, placebo-controlled study for PCS12852 in a gastrointestinal (GI) motility dysfunction disorder (e.g., post-operative ileus also called gastrointestinal dysfunction (POGD), opioid induced constipation, chronic idiopathic constipation). The purpose of the Phase 2A trial would be to better define a dosage regimen of PCS128552 that could be potentially efficacious and safe in a larger pivotal study. The patients with these types of conditions have an abnormal pattern of GI motility in the absence of mechanical obstruction. For example, POGD is characterized by nausea, vomiting, abdominal distension and/or delated passage of flatus or stool, following surgery (most commonly with abdominal surgery). It is the most common cause of prolonged length of stay in hospital following GI surgery, leading to an increase in healthcare costs. The only FDA-approved drug to treat POGD is a mu-opioid receptor antagonist alvimopan (Entereg®), which is only available through a restricted program for short-term use due to the potential risk of myocardial infarction with long-term use.

Two clinical studies have been previously conducted by Yuhan with PCS12852. In the first-in-human clinical trial (Protocol YH12852-101), the initial safety and tolerability of PCS12852 were evaluated after single and multiple oral doses in healthy subjects. PCS12852 increased stool frequency with faster onset when compared to prucalopride, an FDA approved drug for the treatment of chronic idiopathic constipation. Compared to the group receiving prucalopride (an FDA approved drug for the treatment of chronic idiopathic constipation), the PCS12852 dose groups showed higher stool frequency for 24 hours following single dosing and had faster onset of spontaneous bowel movements (SBMs) with comparable or relatively higher Bristol Stool Form Scale score (lower stool consistency) for 24 hours following first dosing. In addition, based on an increase of $\geq 1$ SBM/week from baseline during 7-day multiple dosing, the PCS12852 dose group had a higher percent of patients with an increase than the prucalopride group. All doses of PCS12852 were safe and well tolerated and no serious adverse events (SAE) occurred during the study. The most frequently reported adverse events (AEs) were headache, nausea and diarrhea which were temporal, manageable, and reversible within 24 hours. There were no clinically significant changes in platelet aggregation or ECG parameters including no sign of QTc prolongation in the study. The second study conducted was a Phase 1/2A clinical trial (Protocol YH12852-102) to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of PCS12852 immediate release (IR) formulation and delayed release (DR) formulation after multiple oral dosing. PCS12852 was safe and well tolerated after single and multiple administrations. The most frequent AEs for both the IR and DR formulations of PCS12852 were headache, nausea and diarrhea, but the incidences of these AEs were comparable with those of the prucalopride 2 mg group. These AEs, which were transient and mostly mild in severity, are also commonly observed with other 5-HT4 agonists. Both formulations of PCS12852 also showed pharmacologic activity as assessed using various pharmacodynamic parameters for stool assessment.

Yuhan had also conducted extensive toxicological studies for the product that demonstrated that the product is safe for use and can be moved quickly into Phase 2 studies.

***PCS6422***

On August 23, 2020, we entered into a License Agreement ("Elion License Agreement") with Elion Oncology, Inc. ("Elion"), pursuant to which we acquired an exclusive contingent license to develop, manufacture and commercialize PCS6422 globally.

Elion acquired the eniluracil (PCS6422) product from Fennec Pharmaceuticals (formerly known as Adherex Technologies) in 2016. PCS6422 is an oral, potent, selective, and irreversible inhibitor of dihydropyrimidine dehydrogenase (DPD), the enzyme that rapidly metabolizes 5-FU, a common chemotherapy drug, to inactive metabolites, such as α-fluoro-β-alanine (F-Bal). F-Bal is thought to cause the neurotoxicity and Hand–Foot Syndrome (HFS) associated with 5-FU, and greater formation of F-Bal appears to be associated with a decrease in the antitumor activity of 5-FU. HFS can affect daily living activities, quality of life, and requires dose interruptions/adjustments and even therapy discontinuation resulting in suboptimal tumor effects. We believe that the inhibition of DPD by PCS6422 may significantly improve exposure to 5-FU and reduce 5-FU side effects related to F-Bal. One dose of PCS6422 irreversibly blocks DPD activity for up to two weeks until DPD levels recover via de novo synthesis of the DPD enzyme. Thus, we believe inhibition of tumor DPD will result in higher 5-FU intra-tumoral concentration and potentially better tumor response along with the decrease in F-Bal.

Fluoropyrimidines (e.g., 5-FU) are still the cornerstone of treatment for many different types of cancers, either as monotherapy or in combination with other chemotherapy agents by an estimated two million patients annually. Xeloda®, an oral pro-drug of 5-FU, is approved as first-line therapy for metastatic colorectal and breast cancer. However, its use is limited by adverse effects such as the development of HFS in up to 60% of patients.

Elion evaluated the potential for the combination of PCS6422 with capecitabine (Xeloda®, and, together with PCS6422, known as ECAPE) as a treatment of advanced gastrointestinal (GI) tumors. Nonclinical efficacy data indicated that in colorectal cancer models, pretreatment with PCS6422 enhanced the antitumor activity of capecitabine. PCS6422 increased the antitumor potency of capecitabine while not increasing the toxicity. The antitumor efficacy of the combination of PCS6422 and capecitabine was tested in several xenograft animal models with human breast, pancreatic and colorectal cancer cells. These preclinical xenograft models demonstrate that PCS6422 potentiates the antitumor activity of capecitabine and significantly reduces the dose of capecitabine required to be efficacious.

Elion met with the FDA in 2019 and agreed upon the clinical development program required for the combination of PCS6422 and capecitabine as first-line therapy for metastatic colorectal cancer when treatment with fluoropyrimidine therapy alone is preferred. Subsequently, an IND has been granted safe to proceed by FDA on May 17, 2020, for the Phase 1B study. This Phase 1B study will evaluate the safety and tolerability of several dose combinations of PCS6422 and capecitabine in advanced GI tumor patients and should be initiated in the first half of 2021.

Other DPD enzyme inhibitors (e.g. Gimeracil used in Teysuno® approved only outside the US) act as competitive reversible inhibitors. These agents must be present when 5-FU or capecitabine are administered to inhibit 5-FU breakdown by DPD in order to improve the efficacy and safety profiles of 5-FU. Given the reversible nature of their effect on DPD, over time 5-FU metabolism to F-Bal will return, decreasing the amount of 5-FU in the cancer cells and decreasing the potential cytotoxicity on the cancer cells. There is also evidence that administering DPD inhibitors directly with 5-FU may also decrease the antitumor effect of the 5-FU. Because PCS6422 is an irreversible inactivator of DPD, it can be dosed the day before capecitabine administration and its effect on DPD can last longer than the reversible DPD inhibitors and beyond the time 5-FU exists in the cancer cell. We believe this can optimize the potential cytotoxic effect and minimize the metabolism of 5-FU.

Prior to Elion's involvement, two multicenter Phase 3 studies were conducted in patients with colorectal cancer (CRC) with PCS6422 administered in 10-fold excess to 5-FU. Unfortunately, we believe the dose of PCS6422 during these trials was not optimal, and that PCS6422 was not administered early enough to irreversibly affect the DPD enzyme, thus the regimen tended to produce less antitumor benefit than the control arm with the standard regimen of 5-FU/leucovorin (LV) without PCS6422. Later preclinical work suggested that when PCS6422 was present at the same time as and in excess to 5-FU, it diminished the antitumor activity of 5-FU, which we believe supports the proposal of exploring clinically dosing PCS6422 several hours before 5-FU to allow its clearance before the administration of 5-FU.

***PCS11T***

On May 24, 2020, we entered into an exclusive License Agreement with Aposense, Ltd., ("Aposense"), pursuant to which we were granted a contingent license in Aposense's patent rights and know-how to develop and commercialize their next generation irinotecan cancer drug, PCS11T (formerly known as ATT-11T). The grant of license is conditioned on the following being satisfied within 9 months of May 24, 2020 (or the agreement shall terminate): (i) our closing of an equity financing and successful up-listing to Nasdaq and (ii) Aposense obtaining the approval of the Israel Innovation Authority for the consummation of the transactions contemplated by the agreement, which approval was obtained on August 24, 2020.

PCS11T is a novel lipophilic anti-cancer pro-drug that is being developed for the treatment of the same solid tumors as prescribed for irinotecan. This pro-drug is a conjugate of a specific proprietary Aposense molecule connected to SN-38, the active metabolite of irinotecan. The proprietary molecule in PCS11T has been designed to allow PCS11T to bind to cell membranes to form an inactive pro-drug depot on the cell with SN-38 preferentially accumulating in the membrane of tumors cells and the tumor core. This unique characteristic may make the therapeutic window of PCS11T wider than other irinotecan products such that the antitumor effect of PCS11T could occur at a much lower dose with a milder adverse effect profile than irinotecan. Despite the widespread use of commercially marketed irinotecan products in the treatment of metastatic colorectal cancer and other cancers resulting in peak annual sales of approximately $1.1 billion, irinotecan has a narrow therapeutic window and includes an FDA "Black Box" warning for both neutropenia and severe diarrhea. There is, therefore, a substantial unmet need to overcome the limitations of the current commercially marketed irinotecan products, improving efficacy and reducing the severity of treatment emergent adverse events. We believe the potential wider therapeutic window of PCS11T will likely lead to more patients responding with less side effects when on PCS11T compared to other irinotecan products.

Pre-clinical studies conducted to date showed that PCS11T demonstrated tumor eradication at much lower doses than irinotecan across various tumor xenograft models. PCS11T does not affect acetyl choline esterase (AChE) activity in human and rat plasma in vitro, which would suggest that PCS11T will show an improved safety profile, compared to irinotecan, which is known for its cholinergic-related side effects.

We are currently planning to manufacture the product at a GMP facility, conduct the required toxicological studies required to file the IND and initiate the Phase 1B study in oncology patients with solid tumors in 2022.

***PCS100***

On August 29, 2019, we entered into an exclusive license agreement with Akashi Therapeutics, Inc. ("Akashi") to develop and commercialize an anti-fibrotic, anti-inflammatory drug, PCS100 (formerly known as HT-100), which also promotes healthy muscle fiber regeneration. In previous clinical trials in Duchenne Muscular Dystrophy (DMD), PCS100 showed promising improvement in the muscle strength of non-ambulant pediatric patients. Although the FDA placed a full clinical hold on the DMD trial after a serious adverse event in a pediatric patient, the FDA has partially removed the clinical hold and defined how PCS100 can resume clinical trials in DMD. Once we have obtained adequate funding, we plan to develop PCS100 in rare adult fibrotic related diseases such as focal segmental glomerulosclerosis, idiopathic pulmonary fibrosis or Scleroderma. At the present time, we are evaluating the potential GMP manufacturing facilities and the potential indications for PCS100.

**Other Recent Developments**

***Line of Credit Agreements***

On September 20, 2019, we entered into two separate LOC Agreements ("LOC Agreements") with DKBK Enterprises, LLC ("DKBK") and CorLyst, LLC ("CorLyst", and, together with DKBK, collectively, "Lenders"), both related parties, which provide a revolving commitment of up to $700,000 each ($1.4 million total). Under the LOC Agreements, all funds borrowed bear interest at an annual rate of 8%. The promissory notes issued in connection with the LOC Agreements provide that the Lenders have the right to convert all or any portion of the principal and accrued and unpaid interest into our common stock on the same terms as our 2019 Senior Convertible Notes. Therefore, the Lenders may convert the outstanding debt under the LOC Agreements into our common stock at a conversion price equal to the lower of (i) $14.28 per share, (ii) a price per share equal to a 10% discount to the pre-money valuation of an equity sale of the Company's common stock for cash, or (iii) at an adjusted price; all as more particularly described in the 2019 Senior Convertible Notes.

Our Chief Executive Officer ("CEO") is also the CEO and Managing Member of both Lenders. DKBK directly holds 16,166 shares of Processa common stock and CorLyst beneficially owns 1,095,649 shares of our common stock.

In April and June 2020, we drew a total of $500,000 under the LOC Agreement with DKBK. On July 21, 2020, we drew an additional $200,000, bringing the total amount drawn under the LOC Agreement with DKBK to $700,000. We have not drawn any funds under the LOC Agreement with CorLyst. See "Transactions with Related Persons, Promoters and Certain Control Persons."

DKBK has informed us that they will convert the $700,000 principal amount and related accrued interest outstanding under the LOC Agreement with DKBK simultaneously with the closing of this offering into 92,574 shares of common stock. This assumes a conversion price of $7.61 per share, which, pursuant to the LOC Agreement, is a 10% discount on an assumed public offering price of $8.45 per share, which represents the last reported sales price of our common stock as reported on the OTCQB on September 15, 2020.

***Yuhan Investments in Our Company***

On July 14, 2020, we executed a non-binding indication of interest with Yuhan USA, a subsidiary of Yuhan. Pursuant to the non-binding indication of interest, Yuhan USA expressed its intent to purchase up to $3.0 million of our common stock in this offering at the public offering price. However, because indications of interest are not binding agreements or commitments to purchase, Yuhan USA may determine to purchase more, fewer or no shares in this offering.

The non-binding indication of interest with Yuhan USA is not a legally binding agreement and may be terminated or changed at any time. Accordingly, there can be no assurance that Yuhan USA will actually purchase any shares in this offering.

As consideration for the Yuhan License Agreement described above, we issued to Yuhan 250,000 shares of common stock (based upon an $8.00 per share price), subject to adjustment based on the offering price in this offering (but not less than 181,818 shares).

***Payroll Protection Program Loan***

In May 2020, we entered into a promissory note in favor of the Bank of America under the Small Business Administration Paycheck Protection Program of the Coronavirus Aid, Relief and Economic Security Act of 2020 (the "CARES Act"), for a $162,459 loan ("the PPP Loan"). We have used the loan proceeds for covered payroll costs in accordance with the relevant terms and conditions of the CARES Act. We anticipate the PPP Loan will be forgiven, in whole or in part, pursuant to its terms.

***Reduction in our Authorized Shares***

On June 25, 2020, we amended our Certificate of Incorporation reducing the number of authorized shares of our common stock from 100,000,000 to 30,000,000. We believe 100,000,000 authorized shares of common stock was disproportionately large in relation to the Company's outstanding common stock and our anticipated future needs, and the reduction will reduce our future Delaware franchise tax.

***Update on COVID-19 Impact***

The COVID-19 pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to businesses and capital markets around the world. The extent to which the coronavirus impacts us will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

At present, we have experienced delays from COVID-19 on our business and operations. Although enrolment and treatment of patients in our Phase 2A trial has been completed, we have not been able to visit the clinical sites to close out the study and write the final report. In order to prioritize patient health and that of the investigators at clinical trial sites, enrollment of new patients in our planned clinical trials will be dependent on many factors, including the progression of the pandemic and its impact on patients and the investigators at clinical trial sites. Furthermore, our ability to initiate our planned clinical trials will require collaboration with and permission from each of the clinical trial sites. Over the coming weeks and months, we will continue to carefully monitor the situation with respect to each of our planned clinical trials and follow guidance from local and federal health authorities.

**Risks Associated with our Business and Related to this Offering**

We are a clinical stage biopharmaceutical company with limited operating history. We do not have any drug candidates approved for sale and have not yet generated any revenue from drug sales. We expect to continue to incur significant expenses, operating losses and negative cash flows from operations for the foreseeable future. Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the "Risk Factors" section of this prospectus. These risks include, but are not limited to the following:

- We have a history of losses and we may never become profitable;
- We have limited cash resources and will require additional financing;
- The ongoing COVID-19 pandemic may disrupt our operations and affect our ability to successfully conduct clinical studies and raise capital;
- We currently do not have, and may never develop, any FDA-approved, licensed or commercialized products;
- We depend entirely on the successful development of our product candidates, which have not yet demonstrated efficacy for their target indications in clinical trials. We may never be able to demonstrate efficacy for our product candidates, thus preventing us from licensing, obtaining marketing approval by any regulatory agency, and/or commercializing our product(s);
- We have little corporate history of conducting clinical trials. Our planned clinical trials or those of our collaborators may reveal significant adverse events, toxicities or other side effects not seen in our preclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates;
- We depend on rights to certain pharmaceutical compounds that are or will be licensed to us. We do not own the intellectual property rights to these pharmaceutical compounds and any loss of our rights to them could prevent us from selling our products;
- We cannot ensure protection of our licensed intellectual property rights;
- Our product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts;
- We have identified material weaknesses in our internal control over financial reporting related to our control environment, which in turn results in a material weakness in our disclosure controls. If we do not remediate the material weaknesses in our internal control over financial reporting, or if we fail to establish and maintain effective internal control, we may not be able to accurately report our financial results, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our stock;
- If you purchase shares of common stock in this offering, you will suffer substantial and immediate dilution of your investment; and
- Our common stock price is expected to be volatile.

**Corporate Information**

Our principal executive offices are located at 7380 Coca Cola Drive, Suite 106, Hanover, Maryland 21076. Our telephone number is (443) 776-3133. Our website is www.processapharmaceuticals.com. The information found on, or otherwise accessible through, our website is not incorporated into, and does not form a part of, this prospectus or any other report or document we file with or furnish to the U.S. Securities and Exchange Commission (the "SEC"). We have included our website address in this prospectus solely as an inactive textual reference. Investors should not rely on any such information in deciding whether to purchase our common stock.

| The Offering | |
|---|---|
| **Common Stock Offered by Us** | 2,150,000 shares of common stock (or 2,472,500 shares if the underwriters exercise their option to purchase additional shares in full). |
| **Common Stock to be Outstanding After this Offering*** | 7,665,447 shares (or 7,987,947 shares if the underwriters exercise their option to purchase additional shares in full).<br><br>We have assumed a public offering price of $8.45, which represents the last reported sales price of our common stock as reported on the OTCQB on September 15, 2020. |
| **Use of Proceeds** | We intend to use the net proceeds from this offering over the next 18-24 months to conduct clinical trials and for working capital and other general corporate purposes. See the section titled "Use of Proceeds" for more information. |
| **Risk Factors** | You should read the "Risk Factors" section of this prospectus beginning on page 10 and other information included in this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock. |
| **Proposed Nasdaq Capital Market Symbol** | Our common stock is currently quoted on the OTCQB Market under the symbol "PCSA." We have applied to list our common stock on the Nasdaq Capital Market under the symbol "PCSA" and our common stock has been approved for listing contingent on the completion of this offering. There can be no assurance that this offering will be completed, or as to the terms of this offering. |

* The number of shares of our common stock to be outstanding after this offering is based on 5,515,447 shares of common stock outstanding as of August 31, 2020 and excludes the following:

- 121,557 shares of our common stock issuable upon the exercise of outstanding stock options issued under the Processa Pharmaceuticals, Inc. 2019 Omnibus Incentive Plan, referred to herein as the Omnibus Plan, having a weighted-average exercise price of $17.24 per share, of which 37,009 options have vested, having a weighted-average exercise price of $17.49 per share. An additional 34,652 options will vest upon the successful completion of this offering;

- 324,360 shares of our common stock granted on August 5, 2020 to employees and directors as restricted stock awards under the Omnibus Plan of which restricted stock awards for 214,078 shares of common stock vest upon the successful completion of this offering, with the remaining 110,282 shares of common stock vesting over two years;

- 54,083 shares of common stock reserved for issuance pursuant to future awards under the Omnibus Plan;

- 47,772 shares of our common stock issuable upon the exercise of outstanding non-qualified stock options granted to our Chief Financial Officer on September 1, 2018, having an exercise price of $19.88 per share, of which 25,172 shares have vested;

- 533,959 shares of common stock issuable upon exercise of the outstanding and exercisable stock purchase warrants having a weighted average exercise price of $18.35 per share;

- 113,013 shares of common stock issuable upon the conversion of $805,000 principal amount of outstanding 2019 Senior Convertible Notes and related accrued interest, based on a conversion price of $7.61 per share, which, pursuant to the 2019 Senior Note Agreement, is a 10% discount on an assumed public offering price of $8.45 per share, which represents the last reported sales price of our common stock as reported on the OTCQB on September 15, 2020.

- 176,366 shares of common stock to be issued to stockholders who purchased common stock units in our 2018 Private Placement Transactions, based on an assumed public offering price of $8.45 per share, which represents the last reported sales price of our common stock as reported on the OTCQB on September 15, 2020, as a result of full ratchet anti-dilution provisions;

- 92,574 shares of common stock issuable upon the assumed conversion of the $700,000 principal amount outstanding under the LOC Agreement with DKBK expected to occur simultaneously with the closing of this offering, based on a conversion price of $7.61 per share, which, pursuant to the LOC Agreement, is a 10% discount on an assumed public offering price of $8.45 per share, which represents the last reported sales price of our common stock as reported on the OTCQB on September 15, 2020;

- 295,858 shares of common stock to satisfy the in-license obligation due to Aposense on closing of the offering and up-listing of our common stock to a national exchange, based on an assumed public offering price of $8.45 per share, which represents the last reported sales price of our common stock as reported on the OTCQB on September 15, 2020;

- 236,686 shares of common stock issued to Yuhan in connection with the Yuhan License Agreement, based on an assumed offering price of $8.45 per share price, which represents the last reported sales price of our common stock as reported on the OTCQB on September 15, 2020, subject to adjustment based on the offering price in this offering (but not less than 181,818 shares); and

- 500,000 shares of common stock to be issued to Elion in connection with the Elion License Agreement on closing of the offering and up-listing of our common stock to a national exchange, based on an assumed public offering price of $8.45 per share, which represents the last reported sales price of our common stock as reported on the OTCQB on September 15, 2020.

* Unless otherwise indicated, all information in this prospectus:

- assumes no exercise by the underwriters of their option to purchase additional shares of common stock in this offering; and

- gives effect to the Reverse Split.

## SUMMARY HISTORICAL CONSOLIDATED FINANCIAL DATA

The following tables summarize our historical consolidated financial data for the periods and as of the dates indicated.

We have derived the following summary historical consolidated financial data for the years ended December 31, 2019 and 2018 from our audited consolidated financial statements appearing elsewhere in this prospectus. The summary historical consolidated financial data as of June 30, 2020 and for the six months ended June 30, 2020 and 2019 have been derived from our unaudited condensed consolidated financial statements appearing elsewhere in this prospectus and have been prepared on the same basis as our audited consolidated financial statements. Our historical results are not necessarily indicative of the results that may be expected in the future.

You should read the following summary consolidated financial data in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Risk Factors" and our consolidated financial statements and the related notes included elsewhere in this prospectus.

| | Six Months Ended June 30, | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2019 | 2018 |
| Operating expenses | | | | |
| Research and development | $ 928,855 | $ 1,211,655 | $ 2,320,573 | $ 3,085,317 |
| General and administrative | 859,255 | 807,837 | 1,614,909 | 1,439,623 |
| Operating loss | (1,788,110) | (2,019,492) | (3,935,482) | (4,524,940) |
| Other income (expense) | | | | |
| Interest income | 846 | 9,383 | 11,548 | 18,297 |
| Interest expense | (36,450) | (10,702) | (36,658) | (161,205) |
| Net operating loss before income tax benefit | (1,823,714) | (2,020,811) | (3,960,592) | (4,667,848) |
| Income tax benefit | 215,964 | 300,901 | 602,716 | 902,801 |
| Net loss and comprehensive loss | $ (1,607,750) | $ (1,719,910) | $ (3,357,876) | $ (3,765,047) |
| Net loss per share attributable to common stockholders - basic and diluted | $ (0.29) | $ (0.31) | $ (0.70) | $ (0.71) |
| Weighted average common stock outstanding - basic and diluted | 5,515,447 | 5,525,009 | 5,525,635 | 5,332,141 |

| | As of June 30, 2020 | | |
|---|---|---|---|
| | Actual | Pro Forma [1] | Pro Forma, As Adjusted [2] |
| **Balance Sheet Data:** | | | |
| Cash and cash equivalents | $ 452,654 | $ 552,654 | |
| Total Assets | 10,011,456 | 10,111,456 | |
| Working Capital (Deficit) [3] | (1,321,086) | (717,063) | |
| 2019 Senior convertible debt [4] | 859,102 | 859,102 | |
| Line of Credit Payable | 504,023 | - | |
| Total Liabilities [5] | 3,418,436 | 2,914,413 | |
| Total Stockholders' Equity | 6,593,020 | 7,197,043 | |

(1) The pro forma consolidated balance sheet data gives effect to the following adjustments, referred to herein as the "Pro Forma Adjustments," certain of which are based on an assumed public offering price of $8.45 per share, which represents the last reported sales price of our common stock as reported on the OTCQB on September 15, 2020: (i) the issuance of 176,366 shares of common stock to stockholders who purchased common stock units in our 2018 Private Placement Transactions as a result of full ratchet anti-dilution provisions; (ii) the assumed conversion of the $700,000 principal amount outstanding under the LOC Agreement with DKBK expected to occur simultaneously with the closing of this offering into 92,574 shares of common stock; (iii) the issuance of 295,858 shares of common stock to Aposense; (iv) the issuance of 236,686 shares of common stock to Yuhan; and (v) the issuance of 500,000 shares of common stock and payment of $100,000 to Elion. The number of shares of common stock outstanding after giving effect to the Pro Forma Adjustments would be 6,816,931.

(2) Assumes the Pro Forma Adjustments and further gives effect to the issuance of 2,150,000 shares of common stock in this offering and the receipt of $ in net proceeds. The number of outstanding shares on a pro forma as adjusted basis would be .

(3) We define working capital as current assets less current liabilities.

(4) Includes accrued interest totaling $54,459 and a discount of $357.

(5) Our total liabilities at June 30, 2020 include a net deferred tax liability related to our acquisition of the license agreement for PCS499 from CoNCERT Pharmaceuticals, Inc. totaling $1,315,666.

## RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, the section of this prospectus entitled "Management's Discussion and Analysis of Financial Condition and Results of Operation" and our consolidated financial statements and related notes, before investing in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or that we currently deem immaterial may also adversely affect our business operations. If any of the following risks occur, our business, operating results and prospects could be materially harmed. In that event, the price of our common stock could decline, and you could lose part or all of your investment.*

### Risks Related to Our Financial Position and Need for Capital

***We have a history of losses and we may never become profitable.***

We are a clinical stage biopharmaceutical company with a limited operating history. Processa itself as an organization has never had a drug approved by the FDA or any regulatory agency. The likelihood of success of our business plan must be considered in light of the challenges, substantial expenses, difficulties, complications and delays frequently encountered in connection with developing and expanding early-stage businesses and the regulatory and competitive environment in which we operate. Biopharmaceutical product development is a highly speculative undertaking, involves a substantial degree of risk, and is a capital-intensive business. If we cannot successfully execute our plan to develop our pipeline of drug(s), our business may not succeed.

Since inception, we have incurred significant operating losses. Our net losses were $3.4 million for the year ended December 31, 2019 and $1.6 million for the six months ended June 30, 2020. As of June 30, 2020, we had an accumulated deficit of $12.6 million. To date, we have financed our operations with the proceeds raised from accredited investors in private transactions. We have devoted substantially all of our financial resources and efforts to research and development. We will incur additional losses as we continue our research and development activities, seek regulatory approvals for our product candidates, engage in clinical trials and expand our product portfolio. These losses will cause, among other things, our stockholders' equity and working capital to decrease. Any future earnings and cash flow from operations of our business are dependent on our ability to further develop our products and on revenues and profitability from sales of products or successful joint venture relationships.

There can be no assurance that we will be able to generate sufficient product revenue to become profitable at all or on a sustained basis. Even if we generate revenues, we expect to have quarter-to-quarter fluctuations in revenues and expenses, some of which could be significant, due to research, development, clinical trial, and marketing and manufacturing expenses and activities. We also expect to incur substantial expenses without corresponding revenues, unless and until we are able to obtain regulatory approval and successfully license or commercialize our product candidates. If our product candidates fail in clinical trials or do not gain regulatory approval, or if our products do not achieve market acceptance, we may never become profitable.

We may never be able to obtain regulatory approval for the marketing of our product candidates in any indication in the United States or internationally. As we commercialize and market products, we will need to incur expenses for product marketing and brand awareness and conduct significant research, development, testing and regulatory compliance activities that, together with general and administrative expenses, could result in substantial operating losses for the foreseeable future. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our stock price may decline, and you may lose all or a substantial part of your investment in us.

***We have limited cash resources and will require additional financing.***

We will require substantial additional capital in the future to further our development and license our current and any additional products. We have historically relied upon private investments to fund our operations. Delays in obtaining additional funding could adversely affect our ability to move forward with additional studies or in licensing activities.

Since inception, we have not generated any revenue, have incurred net losses, have used net cash in our operations and have funded our business and operations primarily through proceeds from the private placement of equity securities and senior secured convertible notes. We expect to continue to require significant future financing to fund our operating activities and to use cash in operating activities for the foreseeable future as we continue our research and development activities to develop products that can be commercialized to generate revenue. Our ability to obtain additional financing will be subject to many factors, including market conditions, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates, restrict our operations or obtain funds by entering into agreements on unattractive terms, which would likely have a material adverse effect on our business, stock price and our relationships with third parties with whom we have business relationships, at least until additional funding is obtained. If we do not have sufficient funds to continue operations, we could be required to seek bankruptcy protection or other alternatives that would likely result in our stockholders losing some or all of their investment in us.

We have not had any revenue since our inception, and we do not currently have any revenue under contract or any immediate sales prospects. As part of our effort to conserve cash, beginning on August 1, 2019 we have also delayed some of our cash outflows, primarily through the deferred payment of salaries ($210,800 has been included as accrued expenses at June 30, 2020) until such time as we have raised sufficient funding.

We may seek additional capital through a combination of private and public equity offerings, debt financings and strategic collaborations. If we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly issued securities may have rights, preferences or privileges senior to those of existing stockholders. Debt, receivables and royalty financings may be coupled with an equity component, such as warrants to purchase stock, which could also result in dilution of our existing stockholders' ownership. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business and may result in liens being placed on our assets and intellectual property. If we were to default on such indebtedness, we could lose such assets and intellectual property. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us.

***Substantial doubt exists about our ability to continue as a going concern.***

Substantial doubt exists about our ability to continue as a going concern as of the date hereof and our auditors included a going concern paragraph in their Report of Independent Registered Public Accounting Firm accompanying our audited financial statements for the year ended December 31, 2019. Our December 31, 2019 consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of recorded assets, or the amounts and classification of liabilities that might be different should we be unable to continue as a going concern based on the outcome of these uncertainties described above.

***The ongoing COVID-19 pandemic may disrupt our operations and affect our ability to successfully conduct clinical studies and raise capital.***

In March 2020, the World Health Organization declared COVID-19 a pandemic. The COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains, and created significant volatility and disruption in the financial and capital markets. We are unable to accurately predict the full impact that the ongoing COVID-19 pandemic will have on our results from operations, financial condition, and scientific and clinical activities due to numerous factors that are not within our control, including the duration and severity of the outbreak, stay-at-home orders, business closures, travel restrictions, supply chain disruptions and employee illness or quarantines, which could result in disruptions to our operations and adversely impact our results from operations and financial condition. In addition, the COVID-19 pandemic has resulted in ongoing volatility in the financial and capital markets. If our access to capital is restricted or associated borrowing costs increase as a result of developments in financial markets relating to the COVID-19 pandemic, our operations and financial condition could be adversely impacted. In addition, we have experienced delays in completing the closeout of our Phase 2A clinical trial for PCS499 and any future delays would delay our drug development process.

***Raising additional capital may cause dilution to our existing stockholders, including purchasers of common stock in this offering, restrict our operations or require us to relinquish rights to our technology or product candidates.***

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of private and public equity financings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt, receivables and royalty financings may be coupled with an equity component, such as warrants to purchase stock, which could also result in dilution of our existing stockholders' ownership. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business and may result in liens being placed on our assets and intellectual property. If we were to default on such indebtedness, we could lose such assets and intellectual property. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us.

***We have a significant amount of intangible assets related to our acquisition of PCS499 recorded on our balance sheet which may lead to potentially significant impairment charges in the future.***

We review long-lived assets, including intangible assets, for impairment whenever events or changes in estimates and circumstances indicate that the related carrying amounts may not be recoverable based on the existence of certain triggering events. Intangible assets are also subject to an impairment assessment at least annually. The amount of identifiable intangible assets in our consolidated balance sheet is related to our acquisition of PCS499 and our right of use assets. At June 30, 2020, intangible assets recorded on our consolidated balance sheet was $9.4 million.

***We have incurred indebtedness under the CARES Act, which will be subject to review, may not be forgivable in whole or in part and may eventually have to be repaid.***

We received funds under the Paycheck Protection Program in May 2020 in the amount of $162,459, serviced by the Bank of America. The application for these funds requires us to, in good faith, certify that the current economic uncertainty made the loan request necessary to support our ongoing operations. This certification further requires us to take into account our current business activity and our ability to access other sources of liquidity sufficient to support ongoing operations in a manner that is not significantly detrimental to the business. The receipt of these funds, and the forgiveness of the loan attendant to these funds, is dependent on us having initially qualified for the loan and qualifying for the forgiveness of such loan based on our future adherence to the forgiveness criteria.

Under the terms of the CARES Act and the corresponding promissory note, the use of the proceeds of the loan is restricted to payroll costs (as defined in the CARES Act), covered rent, covered utility payments and certain other expenditures that, while permitted, would not result in forgiveness of a corresponding portion of the loan. Following recent amendments to the Paycheck Protection Program, after an eight- or twenty-four-week period starting with the disbursement of the loan proceeds, we may apply for forgiveness of some or all of the loan, with the amount which may be forgiven equal to the sum of eligible payroll costs, mortgage interest (not applicable to us), covered rent, and covered utility payments, in each case incurred by us during the eight- or twenty-four-week period following the date of first disbursement. Certain reductions in our payroll costs or full-time equivalent employees (when compared against the applicable measurement period) may reduce the amount of the Loan eligible for forgiveness. The Payroll Protection Program has been amended twice with the latest series of amendments significantly altering the timeline associated with the Payroll Protection Program spending and loan forgiveness. While we believe we have acted in good faith and has complied with all requirements of the Payroll Protection Program, if Treasury or SBA determined that our loan application was not made in good faith or that the we did not otherwise meet the eligibility requirements of the Payroll Protection Program, we may not receive forgiveness of the loan (in whole or in part) and we could be required to return the loan or a portion thereof. Further, there is no guarantee that we will receive forgiveness for any amount and forgiveness will be subject to review by our bank of information and documentation that we submit, as required by SBA and the lender.

**Risks Relating to Clinical Development and Commercialization of Our Product Candidates**

***We currently do not have, and may never develop, any FDA-approved, licensed or commercialized products.***

We have not yet sought to obtain any regulatory approvals for any product candidates in the United States or in any foreign market. For us to develop any products that might be licensed or commercialized, we will have to invest further time and capital in research and product development, regulatory compliance and market development. Therefore, we and our licensor(s), prospective business partners and other collaborators may never develop any products that can be licensed or commercialized. All of our development efforts will require substantial additional funding, none of which may result in any revenue.

***Our licenses are subject to termination by the licensor in certain circumstances.***

Our rights to practice the inventions claimed in the licensed patents and patent applications are subject to our licensors abiding by the terms of those licenses and not terminating them. Our licenses may be terminated by the licensor if we are in material breach of certain terms or conditions of the license agreement or in certain other circumstances. Our license agreements each include provisions that allow the licensor to terminate the license if (i) we breach any payment obligation or other material provision under the agreement and fail to cure the breach within a fixed time following written notice of termination, (ii) we or any of our affiliates, licensees or sublicensees directly or indirectly challenge the validity, enforceability, or extension of any of the licensed patents, or (iii) we declare bankruptcy or dissolve. The majority of license agreements require us to satisfy due diligence milestones that relate to the development of new products containing the licensed drug or the agreement may be terminated by such counterparty. In addition, the grant of the Aposense license and the Elion license are contingent on our ability to successfully complete this offering and up-list to Nasdaq or they will not take effect. Our rights under theses licenses are subject to our continued compliance with the terms of the license, including the payment of royalties due under the license. Termination of any of these licenses could prevent us from marketing some or all of our products. Because of the complexity of our products and the patents we have licensed, determining the scope of the license and related royalty obligations can be difficult and can lead to disputes between us and the licensor. An unfavorable resolution of such a dispute could lead to an increase in the royalties payable pursuant to the license. If a licensor believed we were not paying the royalties due under the license or were otherwise not in compliance with the terms of the license, the licensor might attempt to revoke the license. If such an attempt were successful, we might be barred from producing and selling some or all of our products.

***We depend entirely on the successful development of our product candidates, which have not yet demonstrated efficacy for their target indications in clinical trials. We may never be able to demonstrate efficacy for our product candidates, thus preventing us from licensing, obtaining marketing approval by any regulatory agency, and/or commercializing our product(s).***

Our product candidates are either in the early stages of clinical development or late stages of preclinical development. Significant additional research and development activity and clinical testing are required before we will have a chance to achieve a viable product for licensing or commercialization from such candidates. Our research and development efforts remain subject to all the risks associated with the development of new biopharmaceutical products and treatments. Development of the underlying technology may be affected by unanticipated technical or other problems, among other research and development issues, and the possible insufficiency of funds needed in order to complete development of these product candidates. Safety, regulatory and efficacy issues, clinical hurdles or other challenges may result in delays and cause us to incur additional expenses that would increase our losses. If we and our collaborators cannot complete, or if we experience significant delays in developing, our potential therapeutics or products for use in potential commercial applications, particularly after incurring significant expenditures, our business may fail, and investors may lose the entirety of their investment.

When we submit an IND or foreign equivalent to the FDA or international regulatory authorities seeking approval to initiate clinical trials in the United States and other countries, we may not be successful in obtaining acceptance from the FDA or comparable foreign regulatory authorities to start our clinical trials. If we do not obtain such acceptance, the time in which we expect to commence clinical programs for any product candidate will be extended and such extension will increase our expenses and increase our need for additional capital. Moreover, there is no guarantee that our clinical trials will be successful or that we will continue clinical development in support of an approval from the FDA or comparable foreign regulatory authorities for any indication. We note that most drug candidates never reach the clinical development stage and even those that do commence clinical development have only a small chance of successfully completing clinical development and gaining regulatory approval. Therefore, our business currently depends entirely on the successful development, regulatory approval, and licensing or commercialization of our product candidates, which may never occur.

***We must successfully complete clinical trials for our product candidates before we can apply for marketing approval.***

Even if we complete our clinical trials, it does not assure marketing approval. Our clinical trials may be unsuccessful, which would materially harm our business. Even if our initial clinical trials are successful, we are required to conduct additional clinical trials to establish our product candidates' safety and efficacy, before submitting an NDA. Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in early phases of pre-clinical and clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates. The research, testing, manufacturing, labeling, packaging, storage, approval, sale, marketing, advertising and promotion, pricing, export, import and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United

States and other countries, which regulations differ from country to country.

We are not permitted to market our product candidates as prescription pharmaceutical products in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries.

***We have little corporate history of conducting clinical trials. Our planned clinical trials or those of our collaborators may reveal significant adverse events, toxicities or other side effects not seen in our preclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.***

Our operations to date have been limited to financing and staffing, conducting research and developing our core technologies, identifying and optimizing our lead product clinical candidates, performing due diligence on other potential drug in-licensing opportunities, receiving FDA orphan designation on PCS499 in Necrobiosis Lipoidica (NL), improving the manufacturing of PCS499 final product, receiving FDA IND clearance on one indication, conducting a healthy human volunteer trial and presently completing a Phase 2A clinical trial in patients with NL. Although we have recruited a team that has experience with clinical trials in the United States and outside the United States, as a company, we have only conducted two clinical trials in any jurisdiction and have not had previous experience commercializing product candidates through the FDA or similar submissions to initiate clinical trials or obtain marketing authorization to foreign regulatory authorities. We cannot be certain that other planned clinical trials will begin or be completed on time, if at all; that our development program and studies would be acceptable to the FDA or other regulatory authorities; or that, if regulatory approval is obtained, our product candidates can be successfully commercialized. Clinical trials and commercializing our product candidates will require significant additional financial and management resources, and reliance on third-party clinical investigators, contract research organizations ("CROs"), consultants and collaborators. Relying on third-party clinical investigators, CROs or collaborators may result in delays that are outside of our control.

Furthermore, we may not have the financial resources to continue development of, or to enter into collaborations for, a product candidate if we experience any problems or other unforeseen events that delay or prevent regulatory approval of, or our ability to commercialize, product candidates.

Through our IND, we are currently evaluating the safety tolerability of PCS499 in patients with NL. We have developed dosing based on our past experience with the drug in a healthy human volunteer study, the experience of CoNCERT Pharmaceuticals in healthy human volunteers and patients with diabetic nephropathy studies, and the preclinical toxicology data and studies involving diabetic nephropathy patients. However, we do not know if the dosing will be safe and tolerated in patients with NL. Preliminary data from the Phase 2A appears to demonstrate that PCS499 at 1,800 mg/day was generally well tolerated. However, since the number of patients in this study was small, the risks associated with giving PCS499 still exists. Given NL patients are mainly women and multiple pathophysiological changes have occurred in their body from the NL, the NL patients could be more sensitive to the drug, thus decreasing their ability to tolerate PCS499. If this occurs, there may not be any way to differentiate PCS499 from PTX thus making development and commercialization of PCS499 in NL not worth pursuing.

Some preclinical studies of our product candidates have been completed, but we do not know the predictive value of these studies for our targeted population of patients, and we cannot guarantee that any positive results in preclinical studies will translate successfully to our targeted population of patients. It is not uncommon to observe results in human clinical trials that are unexpected based on preclinical testing, and many product candidates fail in clinical trials despite promising preclinical results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products. Human patients in clinical trials may suffer significant adverse events or other side effects not observed in our preclinical studies, including, but not limited to, immunogenic responses, organ toxicities such as liver, heart or kidney or other tolerability issues or possibly even death. The observed potency and kinetics of our planned product candidates in preclinical studies may not be observed in human clinical trials. If clinical trials of our planned product candidates fail to demonstrate efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our planned product candidates which may result in complete loss of expenditures which we devote to those products.

We may have difficulty recruiting patients to the clinical trial, patients may drop out of our trial, or we may be required to abandon the trial or our development efforts of that product candidate altogether. We, the FDA, an Institutional Review Board ("IRB"), or other applicable regulatory authorities may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage studies have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition, and prospects.

Further, if any of our product candidates obtains marketing approval, toxicities associated with our product candidates may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional warnings being added to the labeling, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early stage clinical testing. However, any such event, were it to occur, would cause substantial harm to our business and financial condition and would result in the diversion of our management's attention.

***Even if we receive regulatory approval for any of our product candidates, we may not be able to successfully license or commercialize the product and the revenue that we generate from its sales, if any, may be limited.***

If approved for marketing, the commercial success of our product candidates will depend upon each product's acceptance by the medical community (including physicians, patients and health care payors) and the potential competitive products available to the patients upon commercialization. The degree of market acceptance for any of our product candidates will depend on a number of factors, including:

- demonstration of clinical safety and efficacy;
- relative convenience, dosing burden and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe our product candidates, and the target patient population to try new therapies;

- efficacy of our product candidates compared to competing products;
- the introduction of any new products that may in the future become available targeting indications for which our product candidates may be approved;
- new procedures or therapies that may reduce the incidences of any of the indications in which our product candidates may show utility;
- pricing and cost-effectiveness;
- the inclusion or omission of our product candidates in treatment guidelines;
- the effectiveness of our own or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in approved labeling from regulatory authorities;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors or to receive the necessary pricing approvals from government bodies regulating the pricing and usage of therapeutics; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement or government pricing approvals.

If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our product candidates successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render our product candidates not commercially viable.

***We are completely dependent on third parties to manufacture our product candidates, and our commercialization of our product candidates could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices.***

In 2018, we incurred costs to establish a new site to contract manufacture the tablets of PCS499 needed for our clinical trial since the original CoNCERT tablet manufacturing site could no longer be used. Since PCS499 is a deuterated molecule requiring special facilities and chemicals for manufacturing, the manufacturing costs for PCS499 could result in the cost of goods being too high for the commercial price to be obtainable or too high to even manufacture the amount of drug needed to run the clinical studies prior to approval.

We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture the active pharmaceutical ingredient, or API, in our product candidates for use in our clinical trials or for commercial product. In addition, we do not have the capability to formulate any of our product candidates into a finished drug product for commercial distribution. As a result, we will be obligated to rely on contract manufacturers, if and when any of our product candidates are approved for commercialization. We have not entered into an agreement with any contract manufacturers for commercial supply and may not be able to engage a contract manufacturer for commercial supply of any of our product candidates on favorable terms to us, or at all.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or comparable foreign regulatory authorities pursuant to inspections that will be conducted after we submit an NDA or biologics license application to the FDA or their equivalents to other relevant regulatory authorities. We will not control the manufacturing process of, and will be completely dependent on, our contract manufacturing partners for compliance with cGMPs to manufacture both active drug substances and finished drug products. These cGMP regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to our product candidates. If our contract manufacturers do not successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Our contract manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. We will not have control over our contract manufacturers' compliance with these regulations and standards. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market any of our product candidates, delays, suspensions or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In addition, we will not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect our ability to develop, obtain regulatory approval for or market any of our product candidates.

If, for any reason, these third parties are unable or unwilling to perform, we may not be able to terminate our agreements with them, and we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our API or finished products or should cease doing business with us, we could experience significant interruptions in the supply of any of our product candidates or may not be able to create a supply of our product candidates at all. Were we to encounter manufacturing issues, our ability to produce a sufficient supply of any of our product candidates might be negatively affected. Our inability to coordinate the efforts of our third-party manufacturing partners, or the lack of capacity available at our third-party manufacturing partners, could impair our ability to supply any of our product candidates at required levels. Because of the significant regulatory requirements that we would need to satisfy in order to qualify a new bulk or finished product manufacturer, if we face these or other difficulties with our current manufacturing partners, we could experience significant interruptions in the supply of any of our product candidates if we decided to transfer the manufacture of any of our product candidates to one or more alternative manufacturers in an effort to deal with the difficulties.

Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture our potential products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to a future contract manufacturer caused by problems at suppliers could delay shipment of any of our product candidates, increase our cost of goods sold and result in lost sales.

We cannot guarantee that our future manufacturing and supply partners will be able to reduce the costs of commercial scale manufacturing of any of our product candidates over time. If the commercial-scale manufacturing costs of any of our product candidates are higher than expected, these costs may significantly impact our operating results. In order to reduce costs, we may need to develop and implement process improvements. However, in order to do so, we will need, from time to time, to notify or make submissions with regulatory authorities, and the improvements may be subject to approval by such regulatory authorities. We cannot be sure that we will receive these necessary approvals or that these approvals will be granted in a timely fashion. We also cannot guarantee that we will be able to enhance and optimize output in our commercial manufacturing process. If we cannot enhance and optimize output, we may not be able to reduce our costs over time.

***Even if we obtain marketing approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense.***

Even if we obtain regulatory approval for any of our product candidates for an indication, the FDA or foreign equivalent may still impose significant restrictions on their indicated uses or marketing or the conditions of approval or impose ongoing requirements for potentially costly and time-consuming post-approval studies, including Phase 4 clinical trials, and post-market surveillance to monitor safety and efficacy. Our product candidates will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post-market information. These requirements include registration with the FDA, as well as continued compliance with current Good Clinical Practices (cGCPs) for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents. Compliance with such regulations may result in significant costs and expenses.

***Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.***

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials, as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

***Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.***

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our product candidates. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

***We could face competition from other biotechnology and pharmaceutical companies, and our operating results would suffer if we fail to innovate and compete effectively.***

Our products are used for indications where we believe that there is an unmet medical need. If existing or newly approved drug products, whether approved by the FDA for the indication or not, are able to successfully treat the same patients, it may be more difficult to perform clinical studies, to develop our product and/or to commercialize our product, adversely affecting our business. Since the biopharmaceutical industry is characterized by intense competition and rapid innovation, our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results than our product candidates. Our competitors may include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as a larger research and development staff and experienced marketing and manufacturing organizations, established relationships with CROs and other collaborators, as well as established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates, or may develop proprietary technologies or secure patent protection and, in turn, exclude us from technologies that we may need for the development of our technologies and potential products.

Even if we obtain regulatory approval of any of our product candidates, we may not be the first to market and that may negatively affect the price or demand for our product candidates. Additionally, we may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances. Furthermore, for drugs that receive orphan drug designation at the FDA, a competitor could obtain orphan product approval from the FDA with respect to such competitor's drug product. If such competitor drug product is determined to be the same product as one of our product candidates, we may be prevented from obtaining approval from the FDA for such product candidate for the same indication for seven years, except in limited circumstances, and we may be subject to similar restrictions under non-U.S. regulations.

***We expect to rely on third parties to conduct clinical trials for our product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize any of our product candidates and our business would be substantially harmed.***

We expect to enter into agreements with third-party CROs to conduct and manage our clinical programs including contracting with clinical sites to perform our clinical studies. We plan to rely heavily on these parties for execution of clinical studies for our product candidates and will control only certain aspects of their activities. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs and clinical sites will not relieve us of our regulatory responsibilities. We and our CROs will be required to comply with cGCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA and its foreign equivalents enforce these cGCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA or other regulatory authorities will determine that any of our clinical trials comply with cGCPs. In addition, our clinical trials must be conducted with products produced under cGMP regulations and will require a large number of test subjects. Our failure or the failure of our CROs or clinical sites to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties.

Although we intend to design the clinical trials for our product candidates in consultation with CROs, we expect that the CROs will manage all of the clinical trials conducted at contracted clinical sites. As a result, many important aspects of our drug development programs would be outside of our direct control. In addition, the CROs and clinical sites may not perform all of their obligations under arrangements with us or in compliance with regulatory requirements. If the CROs or clinical sites do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of any of our product candidates for the subject indication may be delayed or our development program materially and irreversibly harmed. We cannot control the amount and timing of resources these CROs and clinical sites will devote to our program or any of our product candidates. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of our clinical trials, which could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party CROs or clinical sites terminate, we may not be able to enter into arrangements with alternative CROs or clinical sites. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any such clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for any of our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

***Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.***

Clinical testing of drug product candidates is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical studies and early clinical trials may not be predictive of the results of later-stage clinical trials. We cannot assure you that the FDA or comparable foreign regulatory authorities will view the results as we do or that any future trials of any of our product candidates will achieve positive results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Any future clinical trial results for our product candidates may not be successful.

In addition, a number of factors could contribute to a lack of favorable safety and efficacy results for any of our product candidates. For example, such trials could result in increased variability due to varying site characteristics, such as local standards of care, differences in evaluation period and surgical technique, and due to varying patient characteristics including demographic factors and health status.

***Even though we may apply for orphan drug designation for a product candidate, we may not be able to obtain orphan drug marketing exclusivity.***

There is no guarantee that the FDA, EMA or their foreign equivalents will grant any future application for orphan drug designation for any of our product candidates, which would make us ineligible for the additional exclusivity and other benefits of orphan drug designation. Even where orphan drug designation or equivalent status is granted, there is no guarantee of orphan drug marketing exclusivity.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug available in the Unites States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of regulatory review and approval process. In addition to the potential period of exclusivity, orphan designation makes a company eligible for grant funding of up to $400,000 per year for four years to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as (i) the drug's orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant's product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. If a drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity. While the FDA granted orphan-drug designation to PCS499 for the treatment of NL on June 18, 2018, there can be no assurance that we will receive orphan drug designation for any additional product candidates in the indications for which we think they might qualify, if we elect to seek such applications.

***Although we may pursue expedited regulatory approval pathways for a product candidate, it may not qualify for expedited development or, if it does qualify for expedited development, it may not actually lead to a faster development, regulatory review or approval process.***

Although we believe there may be an opportunity to accelerate the development of certain of our product candidates through one or more of the FDA's expedited programs, such as fast track, breakthrough therapy, accelerated approval or priority review, we cannot be assured that any of our product candidates will qualify for such programs.

For example, a drug may be eligible for designation as a breakthrough therapy if the drug is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Although breakthrough designation or access to any other expedited program may expedite the development or approval process, it does not change the standards for approval. If we apply for an expedited program for our product candidates, the FDA may determine that our proposed target indication or other aspects of our clinical development plans do not qualify for such expedited program. Even if we are successful in obtaining access to an expedited program, we may not experience faster development timelines or achieve faster review or approval compared to conventional FDA procedures. Access to an expedited program may also be withdrawn by the FDA if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory approval for such product candidate.

***Third-party coverage and reimbursement, health care cost containment initiatives and treatment guidelines may constrain our future revenues.***

Our ability to successfully market our product candidates will depend in part on the level of reimbursement that government health administration authorities, private health coverage insurers and other organizations provide for the cost of our products and related treatments. Countries in which any of our product candidates may be sold through reimbursement schemes under national health insurance programs frequently require that manufacturers and sellers of pharmaceutical products obtain governmental approval of initial prices and any subsequent price increases. In certain countries, including the United States, government-funded and private medical care plans can exert significant indirect pressure on prices. We may not be able to sell our product candidates profitably if adequate prices are not approved or coverage and reimbursement is unavailable or limited in scope.

***Legal, regulatory and legislative changes with respect to reimbursement, pricing and contracting may adversely affect our business and future prospects.***

Federal and state governments may adopt policies affecting drug pricing and contracting practices outside of the context of federal programs such as Medicare and Medicaid, which may adversely affect our business. For example, several states have adopted laws that require drug manufacturers to provide advance notice of certain price increase and to report information relating to those price increases. On May 11, 2018, the Department of Health and Human Services requested comments on a "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," which outlines a wide range of proposals and policy considerations intended to improve competition; lower patient out-of-pocket costs; enhance negotiation; and provide incentives for lower manufacturer list prices. Some of the proposals would require Congressional approval, while others could be adopted administratively. There can be no assurances that future changes to Medicare and/or Medicaid prescription drug reimbursement policies, drug pricing and contracting practices, or government drug price regulation programs such as the Medicaid Drug Rebate Program or 340B Drug Pricing Program will not have an adverse impact on our business and future prospects.

***We may face product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.***

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. This risk exists even if a product is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our product candidates could result in injury to a patient or even death. We cannot offer any assurance that we will not face product liability suits in the future, or that our insurance coverage will be sufficient to cover our liability under any such cases.

In addition, a liability claim may be brought against us even if our product candidates merely appear to have caused an injury. Product liability claims may be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates, among others. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- the inability to commercialize our product candidates;
- decreased demand for our product candidates;
- impairment of our business reputations;
- product recall or withdrawal from the market or labeling, marketing or promotional restrictions;
- substantial costs of any related litigation or similar disputes;
- distractions of management's attention and other resources from our primary business;
- substantial monetary awards to patients or other claimants against us that may not be covered by insurance; or
- loss of revenue.

We have obtained product liability insurance coverage for our clinical trials. However, large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects and our insurance coverage may not be sufficient to cover all of our product liability related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability. We will need to increase our product liability coverage if any of our product candidates receive regulatory approval, which will be costly, and we may be unable to obtain this increased product liability insurance on commercially reasonable terms, or at all. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and could harm our business, financial condition, operating results and prospects.

***If any of our product candidates are approved for marketing and we are found to have improperly promoted off-label uses, or if physicians misuse our products or use our products off-label, we may become subject to prohibitions on the sale or marketing of our products, product liability claims and significant fines, penalties and sanctions, and our brand and reputation could be harmed.***

The FDA and other regulatory agencies strictly regulate the marketing and promotional claims that are made about drug products. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling and comparative safety or efficacy claims cannot be made without direct comparative clinical data. If we are found to have promoted off-label uses of any of our product candidates, we may become subject to significant liability, which would materially harm our business. Both federal and state governments have levied large civil and criminal fines against companies for alleged improper promotion and have enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred, and our brand and reputation could be damaged.

The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to FDA regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities constitute promotion of an off-label use, which could result in significant penalties, including criminal, civil or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations.

We cannot, however, prevent a physician from using our product candidates outside of those indications for use when in the physician's independent professional medical judgment he or she deems appropriate. Physicians may also misuse our product candidates or use improper techniques, potentially leading to adverse results, side effects or injury, which may lead to product liability claims. If our product candidates are misused or used with improper technique, we may become subject to costly litigation by physicians or their patients. Furthermore, the use of our product candidates for indications other than those cleared by the FDA may not effectively treat such conditions, which could harm our reputation among physicians and patients.

***We may choose not to continue developing or commercializing any of our product candidates at any time during development or after approval, which would reduce or eliminate our potential return on investment for those product candidates.***

At any time, we may decide to discontinue the development of any of our product candidates or not to continue commercializing one or more of our approved product candidates for a variety of reasons, including changes in our internal product, technology or indication focus, the appearance of new technologies that make our product obsolete, competition from a competing product or changes in or failure to comply with applicable regulatory requirements. If we terminate a program in which we have invested significant resources, we will not receive any return on our investment, and we will have missed the opportunity to have allocated those resources to potentially more productive uses.

**Risks Relating to Our Intellectual Property Rights**

***We depend on rights to certain pharmaceutical compounds that are or will be licensed to us. We do not own the intellectual property rights to these pharmaceutical compounds and any loss of our rights to them could prevent us from selling our products.***

Within our present pipeline and potentially future pipeline of drugs, our drugs are in-licensed from other biotech or pharmaceutical companies. We do not currently own any intellectual property rights, including the patents that underlie these licenses. Our rights to use the pharmaceutical compounds we license are subject to the negotiation of, continuation of and compliance with the terms of those licenses. Thus, these patents and patent applications are not written by us or our attorneys, and we did not have control over the drafting and prosecution. The former patent owners and our licensors might not have given the same attention to the drafting and prosecution of these patents and applications as we would have if we had been the owners of the patents and applications and had control over the drafting. Moreover, under certain of our licenses, patent prosecution activities remain under the control of the licensor. We cannot be certain that drafting of the licensed patents and patent applications, or patent prosecution, by the licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights.

Our current patent portfolio consists of the number of patents related to our drug candidates licensed from each third party licensor. In addition to the international patents and/or international and U.S. patent applications licensed from our third party licensors, we have licensed at least the following number of U.S. patents:

| | CoNCERT | Yuhan | Elion | Aposense | Akashi | Total |
|---|---|---|---|---|---|---|
| U.S. patents | 9 | 4 | 2 | 3 | 2 | 20 |

Significant additional research and development activity, pre-clinical testing, and/or clinical testing of our drug product candidates are required before we will have a chance to achieve a viable product for licensing or commercialization. Our business currently depends entirely on the successful development, regulatory approval, and licensing or commercialization of our product candidates, which may never occur.

Enforcement of our licensed patents or defense of any claims asserting invalidity of these patents is often subject to the control or cooperation of our licensors. Legal action could be initiated against the owners of the intellectual property that we license and an adverse outcome in such legal action could harm our business because it might prevent such companies or institutions from continuing to license intellectual property that we may need to operate our business. In addition, such licensors may resolve such litigation in a way that benefits them but adversely affects our ability to have freedom to operate to develop and commercialize our product candidates.

***We cannot ensure protection of our licensed intellectual property rights.***

Our commercial success will depend, in part, on the ability of our licensors to obtain and maintain patent protection for our licensed technologies, products and processes, successfully defend these licensed patents against third-party challenges and successfully enforce these patents against third party competitors. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws may diminish the value of our licensed intellectual property rights. Accordingly, we cannot predict the breadth of claims that may be allowable or enforceable in our patents. The existing patents and patent applications relating to our drug product candidates may be challenged, invalidated or circumvented by third parties and might not protect us against competitors with similar products or technologies.

The degree of future protection for our proprietary rights is uncertain. We may not be able to adequately protect our rights, gain or keep our competitive advantage, or provide any competitive advantage at all. For example, others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to any of our product candidates, or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications licensed or filed by us, or that our licensed intellectual property or intellectual property that we develop in the future will not be involved in interference, opposition or invalidity proceedings before United States or foreign patent offices.

In the future, we may rely on know-how and trade secrets to protect technology, especially in cases when we believe patent protection is not appropriate or obtainable. However, know-how and trade secrets are difficult to protect. While we intend to require employees, academic collaborators, consultants and other contractors to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary or licensed information. Typically, research collaborators and scientific advisors have rights to publish data and information in which we may also have rights. If we cannot maintain the confidentiality of our licensed or owned proprietary technology and other confidential information, our ability to protect valuable information licensed or owned by us may be imperiled. Enforcing a claim that a third-party entity illegally obtained and is using any of our licensed or owned know-how and trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts are sometimes less willing to protect trade secrets than patents. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If we fail to obtain or maintain patent or trade secret protection for our product candidates or our technologies, third parties could use our licensed or owned intellectual property, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and attain profitability.

We may also rely on the trademarks we may develop to distinguish our products from the products of our competitors. We cannot guarantee that any trademark applications filed by our licensors, us, or our business partners will be approved. Third parties may also oppose such trademark applications, or otherwise challenge our use of the trademarks. In the event that the trademarks we use are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. Further, we cannot provide assurance that competitors will not infringe the trademarks we use, or that we, our licensors, or business partners will have adequate resources to enforce these trademarks.

***Our product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts.***

Our success depends in part on avoiding infringement of the proprietary technologies of others. The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Identification of third-party patent rights that may be relevant to our licensed technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Additionally, because patent applications are maintained in secrecy until the application is published, we may be unaware of third-party patents that may be infringed by commercialization of any of our licensed product candidates or any future product candidate. There may be certain issued patents and patent applications claiming subject matter that we may be required to license in order to research, develop or commercialize any of our product candidates, and we do not know if such patents and patent applications would be available to license on commercially reasonable terms, or at all. Any claims of patent infringement asserted by third parties would be time-consuming and may divert the time and attention of our technical personnel and management.

Third parties may hold proprietary rights that could prevent any of our licensed product candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to any of our product candidates or our processes could subject us to potential liability for damages and require us to obtain a license and pay royalties to continue to manufacture or market any of our product candidates or any future product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign our product candidates or any future product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing any of our product candidates or a future product candidate, which could harm our business, financial condition and operating results.

A number of companies, including several major pharmaceutical companies, have conducted, or are conducting, research within the licensed fields in which we intend to operate, which has resulted, or may result, in the filing of many patent applications related to this research. If we were to challenge the validity of these or any issued United States patent in court, we would need to overcome a statutory presumption of validity that attaches to every issued United States patent. This means that, in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. If we were to challenge the validity of these or any issued United States patent in an administrative trial before the Patent Trial and Appeal Board in the United States Patent and Trademark Office, we would have to prove that the claims are unpatentable by a preponderance of the evidence. There is no assurance that a jury and/or court would find in our favor on questions of infringement, validity or enforceability.

**General Company-Related Risks**

***We will need to grow the size of our organization, and we may experience difficulties in managing this growth.***

We anticipate having a total of 15-20 full-time or part-time employees or consultants. As our development and commercialization plans and strategies develop, we may need to expand the size of our employee and consultant/contractor base. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

- manage all our development efforts effectively, especially our clinical trials;
- integrate additional management, administrative, scientific, operation and regulatory personnel;
- maintain sufficient administrative, accounting and management information systems and controls; and
- hire and train additional qualified personnel.

We may not be able to accomplish these tasks, and our failure to accomplish any of them could harm our financial results.

***We have identified material weaknesses in our internal control over financial reporting related to our control environment, which in turn results in a material weakness in our disclosure controls. If we do not remediate the material weaknesses in our internal control over financial reporting, or if we fail to establish and maintain effective internal control, we may not be able to accurately report our financial results, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our stock.***

We identified a material weakness in our internal control over financial reporting. Our assessment has indicated we have material weaknesses related to certain entity level controls; inadequate segregations of duties throughout the entire year; and our formal documentation of certain policies and procedures, their related controls, and the operation thereof. Such a material weakness in our internal controls results in a material weakness in our disclosure controls. We continue to remediate our material weakness and to improve our internal controls and are in the process of implementing more fully documented formal policies and procedures.

A "material weakness" is a deficiency, or a combination of deficiencies, in internal controls, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements would not be prevented or detected. We cannot assure you that additional material weaknesses in our internal controls will not be identified in the future. Any failure to maintain or implement required new or improved controls, or any difficulties we encounter in their implementation, could result in additional material weaknesses, or could result in material misstatements in our financial statements. These misstatements could result in restatements of our financial statements, cause us to fail to meet our reporting obligations or cause investors to lose confidence in our reported financial information. Our inability to implement an effective internal control system in the future to prevent and/or detect and correct material misstatements could have a material and adverse effect on our financial condition.

However, while we remain a smaller reporting company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 of the Sarbanes-Oxley Act within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404 of the Sarbanes-Oxley Act. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

We have already and are planning to implement additional measures to address the material weaknesses we have identified, including hiring additional accounting personnel or consultants with appropriate expertise. We intend to complete the implementation of our remediation plan in 2021. However, we cannot assure you that we will be successful in remediating the material weaknesses we identified or that our internal control over financial reporting, as modified, will enable us to identify or avoid material weaknesses in the future.

We cannot assure you that management will be successful in identifying and retaining appropriate personnel; that newly engaged staff or outside consultants will be successful in identifying material weaknesses in the future; or that appropriate personnel will be identified and retained prior to these deficiencies resulting in material and adverse effects on our business.

Any failure to remediate the material weaknesses we identified or develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Any failure to remediate the material weaknesses we identified or implement and maintain effective internal control over financial reporting, as well as disclosure controls and procedures, could also adversely affect the results of management reports and independent registered public accounting firm audits of our internal control over financial reporting that we will eventually be required to include in our periodic reports that will be filed with the SEC. Ineffective disclosure controls and procedures, and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the market price of our common stock.

***Our limited operating history may make it difficult to evaluate our business and our future viability.***

We are in the relatively early stages of operations and development and have only a limited operating history as the existing entity on which to base an evaluation of our business and prospects. Even if we successfully obtain additional funding, we are subject to the risks associated with early stage companies with a limited operating history, including: the need for additional financings; the uncertainty of research and development efforts resulting in successful commercial products, as well as the marketing and customer acceptance of such products; unexpected issues with the FDA, other federal or state regulatory authorities or ex-US regulatory authorities; regulatory setbacks and delays; competition from larger organizations; reliance on the proprietary technology of others; dependence on key personnel; uncertain patent protection; fluctuations in expenses; and dependence on corporate partners and collaborators. Any failure to successfully address these risks and uncertainties could seriously harm our business and prospects. We may not succeed given the technological, marketing, strategic and competitive challenges we will face. The likelihood of our success must be considered in light of the expenses, difficulties, complications, problems and delays frequently encountered in connection with the growth of a new business, the continuing development of new drug technology, and the competitive and regulatory environment in which we operate or may choose to operate in the future.

***If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, our ability to identify and develop new or next generation product candidates will be impaired, could result in loss of markets or market share and could make us less competitive.***

We are highly dependent upon the principal members of our small management team and staff, including David Young, Pharm.D., Ph.D, our Chief Executive Officer, and Sian Bigora, Pharm.D., our Chief Development Officer. The employment of Drs. Young and Bigora may be terminated at any time by either us or Dr. Young or Dr. Bigora. The loss of any current or future team member could impair our ability to design, identify, and develop new intellectual property and product candidates and new scientific or product ideas. Additionally, if we lose the services of any of these persons, we would likely be forced to expend significant time and money in the pursuit of replacements, which may result in a delay in the development of our product candidates and the implementation of our business plan and plan of operations and diversion of our management's attention. We can give no assurance that we could find satisfactory replacements for our current and future key scientific and management employees on terms that would not be unduly expensive or burdensome to us.

Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we expect to have employment agreements with our key employees, these employment agreements may still allow these employees to leave our employment at any time, for or without cause. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical and scientific personnel.

***We are a "smaller reporting company," and the reduced disclosure requirements applicable to us as such may make our common stock less attractive to our stockholders and investors.***

We are a "smaller reporting company" under the federal securities laws and, as such, are subject to scaled disclosure requirements afforded to such companies. For example, as a smaller reporting company, we are subject to reduced executive compensation disclosure requirements. Our stockholders and investors may find our common stock less attractive as a result of our status as a "smaller reporting company" and our reliance on the reduced disclosure requirements afforded to these companies. If some of our stockholders or investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the market price of our common stock may be more volatile.

***We are exposed to cyber-attacks and data breaches, including the risks and costs associated with protecting our systems and maintaining integrity and security of our business information, as well as personal data of our guests, employees and business partners.***

We are subject to cyber-attacks. These cyber-attacks can vary in scope and intent from attacks with the objective of compromising our systems, networks and communications for economic gain to attacks with the objective of disrupting, disabling or otherwise compromising our operations. The attacks can encompass a wide range of methods and intent, including phishing attacks, illegitimate requests for payment, theft of intellectual property, theft of confidential or non-public information, installation of malware, installation of ransomware and theft of personal or business information. The breadth and scope of these attacks, as well as the techniques and sophistication used to conduct these attacks, have grown over time. We experienced a cybersecurity breach in January 2018 that resulted in a fraud loss of $144,200 where the probability of recovery of the loss is remote.

A successful cyber-attack may target us directly, or it may be the result of a third party's inadequate care. In either scenario, we may suffer damage to our systems and data that could interrupt our operations, adversely impact our reputation and brand and expose us to increased risks of governmental investigation, litigation and other liability, any of which could adversely affect our business. Furthermore, responding to such an attack and mitigating the risk of future attacks could result in additional operating and capital costs in systems technology, personnel, monitoring and other investments.

In addition, we are also subject to various risks associated with the collection, handling, storage and transmission of sensitive information. In the course of doing business, we collect employee, customer and other third-party data, including personally identifiable information and individual credit data, for various business purposes. These laws continue to develop and may be inconsistent from jurisdiction to jurisdiction. If we fail to comply with the various applicable data collection and privacy laws, we could be exposed to fines, penalties, restrictions, litigation or other expenses, and our business could be adversely impacted.

Any breach, theft, loss, or fraudulent use of employee, third-party or company data, could adversely impact our reputation and expose us to risks of data loss, business disruption, governmental investigation, litigation and other liability, any of which could adversely affect our business. Significant capital investments and other expenditures could be required to remedy the problem and prevent future breaches, including costs associated with additional security technologies, personnel, experts and credit monitoring services for those whose data has been breached. Further, if we or our vendors experience significant data security breaches or fail to detect and appropriately respond to significant data security breaches, we could be exposed to government enforcement actions and private litigation.

**Risks Related to Ownership of Our Common Stock and This Offering**

***If you purchase shares of common stock in this offering, you will suffer substantial and immediate dilution of your investment.***

You will suffer immediate and substantial dilution in the net tangible book value of the common stock you purchase in this offering. The public offering price of our common stock will be substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our net tangible book value per share after this offering. See the "Dilution" section of this prospectus for a more detailed description of the dilution to investors participating in the offering.

***You may experience future dilution as a result of future equity offerings, license transactions or acquisitions.***

In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share in this offering. We may sell shares or other securities in any future offering at a price per share that is less than the price per share paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into our common stock, in future transactions or acquisitions may be higher or lower than the price per share paid by investors in this offering.

In addition, we may engage in one or more potential license transactions or acquisitions in the future, which could involve issuing our common stock as some or all of the consideration payable by us to complete such transactions. If we issue common stock or securities linked to our common stock, the newly issued securities may have a dilutive effect on the interests of the holders of our common stock. Additionally, future sales of newly issued shares used to effect a transaction could depress the market price of our common stock.

We may also issue equity securities that provide rights, preferences and privileges senior to those of our common stock. If we raise additional funds by issuing debt securities, these debt securities would have rights senior to those of our common stock and the terms of the debt securities issued could impose significant restrictions on our operations, including liens on our assets. If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our technologies or candidate products, or to grant licenses on terms that are not favorable to us.

***Our common stock price is expected to be volatile.***

The offering price of our common stock could be subject to significant fluctuations. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- relatively low trading volume, which can result in significant volatility in the market price of our common stock based on a relatively smaller number of trades and dollar amount of transactions;
- changes in estimates or recommendations by securities analysts, if any, who cover our common stock;
- the timing and results of our current and any future preclinical or clinical trials of our product candidates;
- the entry into or termination of key agreements, including, among others, key collaboration and license agreements;
- the results and timing of regulatory reviews relating to the approval of our product candidates;
- the initiation of, material developments in, or conclusion of, litigation to enforce or defend any of our intellectual property rights;
- failure of any of our product candidates, if approved, to achieve commercial success;
- general and industry-specific economic conditions that may affect our research and development expenditures;
- the results of clinical trials conducted by others on products that would compete with our product candidates;
- issues in manufacturing our product candidates or any approved products;

- the introduction of technological innovations or new commercial products by our competitors;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- future sales of our common stock by us, our insiders or our other stockholders;
- a negative outcome in any litigation or potential legal proceeding.
- additions and departures of key personnel;
- negative publicity or announcements regarding regulatory developments relating to our products;
- actual or anticipated fluctuations in our financial condition and operating results, including our cash and cash equivalents balance, operating expenses, cash burn rate or revenue levels;
- our filing for protection under federal bankruptcy laws; or
- the other factors described in this "Risk Factors" section.

The stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock, especially in light of the COVID-19 pandemic. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

***After this offering, our executive officers, directors and principal stockholders and their affiliates, if they choose to act together, will have the ability to exercise significant influence over all matters submitted to stockholders for approval, which will limit your ability to influence corporate matters and could delay or prevent a change in corporate control.***

Upon the closing of this offering, our executive officers and directors, combined with our stockholders who owned more than 5% of our outstanding common stock before this offering and their respective affiliates, will, in the aggregate, beneficially own shares representing approximately % of our outstanding capital stock, assuming no exercise of the underwriters' option to acquire additional common stock in this offering and assuming we issue the number of shares of common stock as set forth on the cover page of this prospectus. As a result, if these stockholders were to choose to act together, they would be able to influence our management and affairs and potentially control the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our assets. These stockholders acquired their shares of common stock (including shares of common stock issuable upon the conversion of preferred stock) for less than the price of the shares of common stock being acquired in this offering, and these stockholders may have interests, with respect to their common stock, that are different from those of investors in this offering and the concentration of voting power among these stockholders may have an adverse effect on the price of our common stock. This concentration of ownership control may adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change in control;
- entrenching our management and the Board of Directors;
- impeding a merger, consolidation, takeover or other business combination involving us that other stockholders may desire;
- and/or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

See the "Principal Stockholders" section of this prospectus for more information regarding the ownership of our outstanding common stock by our executive officers, directors, principal stockholders and their affiliates.

***Sales of substantial amounts of our common stock in the public markets could cause the market price of our common stock to decline.***

Substantial amounts of our common stock may be sold under Rule 144 into the public market which may adversely affect prevailing market prices for the common stock and could impair our ability to raise capital in the future through the sale of equity securities. Rule 144 permits a person who presently is not and who has not been an affiliate of ours for at least three months immediately preceding the sale and who has beneficially owned the shares of common stock for at least six months to sell such shares without restriction other than the requirement that there be current public information as set forth in Rule 144. Shares held by directors, executive officers, and other affiliates will also be subject to volume limitations under Rule 144 under the Securities Act. See "Shares Eligible for Future Sale." Further, we have granted registration rights to certain of our stockholders. See "Shares Eligible for Future Sale," which also discusses registration rights we have granted to certain of our stockholders.

***We do not currently intend to pay dividends to our stockholders in the foreseeable future, and consequently, your ability to achieve a return on your investment will depend on appreciation in our value.***

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. There is no guarantee that our valuation will appreciate in value or even maintain the valuation at which our stockholders have purchased their shares.

***We may issue preferred stock which may have greater rights than our common stock.***

Our Fourth Amended and Restated Certificate of Incorporation allow our Board of Directors to issue up to 1,000,000 shares of preferred stock. Currently, no shares of preferred stock are issued and outstanding. However, we can issue shares of our preferred stock in one or more series and can set the terms of the preferred stock without seeking any further approval from the holders of our common stock. Any preferred stock that we issue may rank ahead of our common stock in terms of dividend priority or liquidation premiums and may have greater voting rights than our common stock. In addition, such preferred stock may contain provisions allowing it to be converted into shares of common stock, which could dilute the value of our common stock to the current stockholders and could adversely affect the market price, if any, of our common stock.

***If there should be dissolution of our company, you may not recoup all or any portion of your investment.***

In the event of a liquidation, dissolution or winding-up of our operations, whether voluntary or involuntary, the proceeds and/or assets remaining after giving effect to such transaction, and the payment of all of our debts and liabilities and distributions required to be made to holders of any outstanding common stock will then be distributed to our stockholders on a pro rata basis. We may incur substantial amounts of additional debt and other obligations such as convertible notes and loans and preferred stock that will rank senior to our common stock, and the terms of our common stock do not limit the amount of such debt or other obligations that we may incur. There can be no assurance that we will have available assets to pay any amount to the holders of common stock, upon such a liquidation, dissolution or winding-up. In this event, you could lose some or all of your investment.

***If securities or industry analysts do not publish research or reports about our business, or if they publish negative evaluations of our stock or negative reports about our business, our stock price and trading volume could decline.***

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. We may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, there can be no assurance that analysts will cover us or provide favorable coverage. If one or more of the analysts who covers us downgrades our stock or changes his or her opinion of our stock, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline.

***We have broad discretion in the use of the net proceeds from this offering and may not use them effectively, which could affect our results of operations and cause our stock price to decline.***

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the "Use of Proceeds" section of this prospectus and you will not have the opportunity to assess whether the net proceeds are being used appropriately as part of your investment decision. Our management could spend the net proceeds from this offering in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

***Provisions in our corporate documents and Delaware law could have the effect of delaying, deferring, or preventing a change in control of us, even if that change may be considered beneficial by some of our stockholders.***

The existence of some provisions of our certificate of incorporation or our bylaws or Delaware law could have the effect of delaying, deferring, or preventing a change in control of us that a stockholder may consider favorable. These provisions include:

- providing that the number of members of our Board is limited to a range fixed by our bylaws;
- establishing advance notice requirements for nominations of candidates for election to our Board of Directors or for proposing matters that can be acted on by stockholders at stockholder meetings; and
- authorizing the issuance of "blank check" preferred stock, which could be issued by our Board of Directors to issue securities with voting rights and thwart a takeover attempt.

As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the General Corporation Law of the State of Delaware. Section 203 prevents some stockholders holding more than 15% of our voting stock from engaging in certain business combinations unless the business combination or the transaction that resulted in the stockholder becoming an interested stockholder was approved in advance by our Board of Directors, results in the stockholder holding more than 85% of our voting stock (subject to certain restrictions), or is approved at an annual or special meeting of stockholders by the holders of at least 66 2/3% of our voting stock not held by the stockholder engaging in the transaction. Any provision of our certificate of incorporation or our bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and affect the price that some investors are willing to pay for our common stock.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical facts contained in this prospectus are forward-looking statements. In some cases, you can identify forward-looking statements by words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would," or the negative of these words or other comparable terminology. We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in "Risk Factors" and elsewhere in this prospectus. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our use of the net proceeds from this offering;
- our liquidity and working capital requirements, including cash requirements over the next 12 months;
- our ability to obtain funding for our operations;
- the impact of the COVID-19 pandemic on our business, operations or ability to obtain funding;
- our ability to obtain and maintain regulatory approval of PCS499 and/or our other product candidates;
- our ability to contract with third-party suppliers, manufacturers and other service providers and their ability to perform adequately;
- the potential market size, opportunity and growth potential for PCS499 and/or our other product candidates, if approved;
- our ability to build our own sales and marketing capabilities, or seek collaborative partners, to commercialize PCS499 and/or our other product candidates, if approved;
- the initiation, timing, progress and results of our pre-clinical studies and clinical trials, and our research and development programs;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- our ability to recruit and enroll suitable patients in our clinical trials;
- the timing or likelihood of the accomplishment of various scientific, clinical, regulatory filings and approvals and other product development objectives;
- the pricing and reimbursement of our product candidates, if approved;
- the rate and degree of market acceptance of PCS499 and/or our other product candidates by physicians, patients, third-party payors and others in the medical community, if approved;

- the implementation of our business model, strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- developments relating to our competitors and our industry;
- the accuracy of our estimates regarding expenses, capital requirements and needs for additional financing; and
- our financial performance.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable as of the date of this prospectus, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to new information, actual results or to changes in our expectations, except as required by law.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance, and events and circumstances may be materially different from what we expect.

## USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately $16.2 million from the sale of the shares of our common stock in this offering, or approximately $18.7 million, if the underwriters exercise their option to purchase additional shares of common stock in full, based on an assumed public offering price of $8.45 per share, which represents the last reported sales price of our common stock as reported on the OTCQB on September 15, 2020, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase (decrease) in the assumed public offering price of $8.45 per share, which represents the last reported sales price of our common stock as reported on the OTCQB on September 15, 2020, would increase (decrease) the net proceeds to us from this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, by approximately $2.0 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. We may also increase or decrease the number of shares we are offering. Similarly, each increase (decrease) of 1,000,000 in the number of shares we are offering would increase (decrease) the net proceeds to us from this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, by approximately $7.8 million, assuming no change in the assumed initial public offering price.

We intend to use the net proceeds from this offering over the next two years to conduct clinical trials and for working capital and other general corporate purposes.

We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements through the end of 2022. If we have based our estimates on assumptions that are incorrect, or we increase our anticipated clinical trials, then we could use our available capital resources sooner than we currently expect. We may satisfy our future cash needs through the sale of equity securities, debt financings, working capital lines of credit, corporate collaborations or license agreements, grant funding, interest income earned on invested cash balances or a combination of one or more of these sources.

Opportunities may come to our attention to expand our current business through acquisitions or in-licenses of complementary companies, medicines or technologies. While we have no current agreements, commitments or understandings for any specific acquisitions or in-licenses at this time, we may use a portion of the net proceeds for these purposes.

Pending their use as described above, we plan to invest the net proceeds in short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or guaranteed obligations of the U.S. government.

## MARKET FOR COMMON EQUITY AND DIVIDEND POLICY

### Market Information

We have applied to list our common stock on the Nasdaq Capital Market, or Nasdaq, under the symbol "PCSA" and our common stock has been approved for listing contingent on the completion of this offering. There is no assurance that this offering will be completed, or as to the terms of this offering. Our common stock is currently quoted on the OTCQB under the symbol "PCSA." Quotations on the OTCQB reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions. On December 23, 2019, we effected a one-for-7 reverse split of our common stock, or the Reverse Split. Unless otherwise specified or the context otherwise indicates, the information contained in this prospectus has been adjusted to give effect to the Reverse Split. On September 15, 2020, the closing sale price of our common stock as reported on the OTCQB was $8.45 per share. The closing sale price of our common stock as reported on the OTCQB may not be indicative of the market price of our common stock on the Nasdaq Capital Market.

### Holders of our Common Stock

As of August 31, 2020, we had 5,515,447 shares of common stock issued and outstanding and 204 holders of record of our common stock.

### Transfer Agent

Our transfer agent is Equiniti Trust Company, 3200 Cherry Creek Dr. South Suite 430 Denver, CO 80209; telephone (303) 282-4800.

### Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and future earnings, if any, for use in the operation of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any future determination to declare and pay dividends will be made at the discretion of our Board of Directors and will depend on various factors, including applicable laws, our results of operations, our financial condition, our capital requirements, general business conditions, our future prospects and other factors that our Board of directors may deem relevant. Our ability to pay cash dividends on our capital stock in the future may also be limited by the terms of any preferred securities we may issue or agreements governing any additional indebtedness we may incur. Investors should not purchase our common stock with the expectation of receiving cash dividends.

## CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of June 30, 2020 as follows:

- on an actual basis.
- on a pro forma basis after giving effect to the Pro Forma Adjustments based on an assumed public offering price of $8.45 per share, the last reported sales price of our common stock as reported on the OTCQB on September 15, 2020.
- on a pro forma basis, as adjusted to give further effect to the issuance by us of 2,150,000 shares of our common stock in this offering.

Our capitalization following the completion of this offering will be adjusted based on the actual public offering price and other terms of the offering determined at pricing. You should read this information together with our audited financial statements and related notes appearing elsewhere in this prospectus and the information set forth under the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section.

| | As of June 30, 2020 | | |
|---|---|---|---|
| | **Actual** | **Pro forma** | **Pro forma, as adjusted** |
| Cash and cash equivalents | $ 452,654 | $ 552,654 | $ |
| 2019 Senior Convertible Notes and accrued interest | 859,102 | 859,102 | |
| Line of credit payable and accrued interest | 504,023 | - | |
| Preferred stock, $0.0001 par value: 1,000,000 shares authorized, no shares issued or outstanding | - | - | |
| Common stock $0.0001 par value: 30,000,000 shares authorized, 5,514,447 shares issued and outstanding, actual; 6,816,931 shares issued and outstanding, pro forma and shares issued and outstanding pro forma, as adjusted[1] | 552 | 683 | |
| Additional paid-in capital | 19,182,228 | 28,611,120 | |
| Accumulated equity | (12,589,760) | (21,414,760) | |
| Total stockholders' equity | 6,593,020 | 7,197,043 | |
| Total capitalization | $ 7,956,145 | $ 8,056,145 | $ |

[1] The number of shares of our common stock to be outstanding after this offering gives effect to the Pro Forma Adjustments and excludes the following as of June 30, 2020:

- 121,557 shares of our common stock issuable upon the exercise of outstanding stock options issued under the Omnibus Plan, having a weighted-average exercise price of $17.24 per share, of which 33,564 options have vested, having a weighted-average exercise price of $17.50 per share. An additional 34,652 options will vest upon the successful completion of this offering;
- 324,360 shares of our common stock granted on August 5, 2020 to employees and directors as restricted stock awards under the Omnibus Plan of which restricted stock awards for 214,078 shares of common stock vest upon the successful completion of this offering, with the remaining 110,282 shares of common stock vesting over two years;
- 54,083 shares of common stock reserved for issuance pursuant to future awards under the Omnibus Plan;
- 47,772 shares of our common stock issuable upon the exercise of outstanding non-qualified stock options granted to our Chief Financial Officer on September 1, 2018, having an exercise price of $19.88 per share, of which 23,289 shares have vested;
- 533,959 shares of common stock issuable upon exercise of the outstanding and exercisable stock purchase warrants having a weighted average exercise price of $18.35 per share; and
- 113,013 shares of common stock issuable upon the conversion of $805,000 principal amount of outstanding 2019 Senior Convertible Notes and related accrued interest, based on a conversion price of $7.61 per share, which, pursuant to the 2019 Senior Note Agreement, is a 10% discount on an assumed public offering price of $8.45 per share, which represents the last reported sales price of our common stock as reported on the OTCQB on September 15, 2020.

## DILUTION

If you invest in our common stock in this offering, your interest will immediately be diluted to the extent of the difference between the public offering price per share of our common stock in this offering and the as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book value is the amount of our total tangible assets less our total liabilities and deferred taxes. Our historical net tangible book value per share is our historical net tangible book value divided by 5,514,447, the number of shares of common stock outstanding as of June 30, 2020. Our historical net tangible book value as of June 30, 2020, was $(1,336,104), or $(0.24) per share of common stock.

Our pro forma net tangible book value per share as of June 30, 2020 gives effect to the Pro Forma Adjustments based on an assumed public offering price of $8.45 per share, and is calculated based on an aggregate of 6,816,931 shares of our common stock outstanding.

Our pro forma as adjusted net tangible book value per share gives further effect to the issuance by us of 2,150,000 shares of our common stock in this offering and receipt of the net proceeds therefrom, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, based on an assumed public offering price of $8.45 per share, and is calculated based on an aggregate of 8,966,931 shares of our common stock outstanding.

The following table illustrates this per share dilution to investors participating in this offering:

| | | |
|---|---|---|
| Assumed public offering price per share | | $ 8.45 |
| Historical net tangible book value per share as of June 30, 2020, before giving effect to the offering | $ (0.24) | |
| Pro forma change in net tangible book value per share as of June 30, 2020 | 0.13 | |
| Pro forma net tangible book value as of June 30, 2020, before giving effect to the offering | (0.11) | |
| Increase in net tangible book value per share from new investors participating in this offering | 1.84 | |
| Pro forma, as adjusted net tangible book value per share after this offering | | 1.73 |
| Dilution in net tangible book value per share to new investors participating in this offering | | 6.72 |

The information discussed above is illustrative only, and the dilution information following this offering will be adjusted based on the actual public offering price and other terms of this offering determined at pricing. A $1.00 increase in the assumed public offering price of $8.45 per share, which represents the last reported sales price of our common stock on the OTCQB on September 15, 2020, would increase the pro forma, as adjusted net tangible book value by $0.24 per share and the dilution to investors participating in this offering by $0.76 per share, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated expenses payable by us. Similarly, a $1.00 decrease in the assumed public offering price of $8.45 per share, which represents the last reported sales price of our common stock on the OTCQB on September 15, 2020, would decrease the pro forma, as adjusted net tangible book value by ($0.25) per share and the dilution to investors participating in this offering by ($0.75) per share, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated expenses payable by us.

We may also increase or decrease the number of shares we are offering. An increase of 1,000,000 shares offered by us would increase the pro forma, as adjusted net tangible book value by $0.61 per share and decrease the dilution to investors participating in this offering by $(0.61) per share, assuming the assumed public offering price of $8.45 per share remains the same and after deducting the estimated underwriting discounts and commissions and estimated expenses payable by us. Similarly, a decrease of 1,000,000 shares offered by us would decrease the pro forma, as adjusted net tangible book value by ($0.76) per share and increase the dilution to investors participating in this offering by $0.76 per share, assuming the assumed public offering price of $8.45 per share remains the same and after deducting the estimated underwriting discounts and commissions and estimated expenses payable by us.

If the underwriters exercise their option to purchase additional shares of common stock in full, the net tangible book value as of June 30, 2020, will increase to $18.0 million, or $1.94 per share, representing an increase to existing stockholders of $0.21 per share, and decrease the dilution to investors participating in this offering by $(0.21) per share.

The number of shares of our common stock to be outstanding after this offering is based on an aggregate of 5,515,447 shares of common stock outstanding as of June 30, 2020, as adjusted for the Pro Forma Adjustments and the issuance of 2,150,000 shares in this offering and excludes the following as of June 30, 2020:

- 121,557 shares of our common stock issuable upon the exercise of outstanding stock options issued under the Omnibus Plan, having a weighted-average exercise price of $17.24 per share, of which 33,564 options have vested, having a weighted-average exercise price of $17.50 per share. An additional 34,652 options will vest upon the successful completion of this offering;

- 324,360 shares of our common stock granted on August 5, 2020 to employees and directors as restricted stock awards under the Omnibus Plan of which restricted stock awards for 214,078 shares of common stock vest upon the successful completion of this offering, with the remaining 110,282 shares of common stock vesting over two years;

- 54,083 shares of common stock reserved for issuance pursuant to future awards under the Omnibus Plan;

- 47,772 shares of our common stock issuable upon the exercise of outstanding non-qualified stock options granted to our Chief Financial Officer on September 1, 2018, having an exercise price of $19.88 per share, of which 23,289 shares have vested; and

- 533,959 shares of common stock issuable upon exercise of the outstanding and exercisable stock purchase warrants having a weighted average exercise price of $18.35 per share.

- 113,013 shares of common stock issuable upon the conversion of $805,000 principal amount of outstanding 2019 Senior Convertible Notes and related accrued interest, based on a conversion price of $7.61 per share, which, pursuant to the 2019 Senior Note Agreement, is a 10% discount on an assumed public offering price of $8.45 per share, which represents the last reported sales price of our common stock as reported on the OTCQB on September 15, 2020.

To the extent that any options are exercised, new options or other securities are issued under our equity incentive plans, or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of such securities could result in further dilution to our stockholders.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes and other financial information included elsewhere in this prospectus. Some of the information contained in this discussion and analysis contains forward-looking statements that involve risks and uncertainties. You should review the section titled "Risk Factors" in this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described below.*

**Overview**

We are a clinical stage biopharmaceutical company focused on the development of drug products that are intended to improve the survival and/or quality of life for patients who have a highly unmet medical need condition. Within this group of pharmaceutical products, we currently are developing one product for multiple indications (i.e., the use of a drug to treat a particular disease) and will begin developing our newly acquired drugs (PCS12852, PCS6422, PCS11T and PCS100) once adequate funding has been obtained. We continue searching for additional products for our portfolio that meet our criteria.

Our drug portfolio approach is to develop drugs with potentially high return on investment and lower risk of development failure. Our drugs are focused on treating patients who do not have adequate treatment options for their conditions and have some clinical evidence supporting the efficacy of the drug, whether it be evidence with the drug itself or a drug with similar pharmacological properties. Given the prior success of our development team, the regulatory science approach that we employ not only allows us to develop drugs focused on FDA approval, but also allows us to select drugs for our portfolio which may have a greater chance for approval in a population of patients who need treatment options.

Part of our business strategy is:

(i) to identify drugs that have potential efficacy in patients with an unmet medical need, as demonstrated by some clinical evidence that the targeted pharmacology of the drug provides clinical efficacy in the targeted patient population, including published case studies or clinical experience;

(ii) to identify drug products that have been developed or approved for other indications but can be repurposed to treat those patients who have an unmet medical need; and

(iii) to identify drugs that can be quickly developed such that within 2-4 years critical value added clinical milestones can be achieved (for example, a pivotal study can be completed in 2 to 4 years or enough clinical data can be obtained to demonstrate the value of the asset to a future licensing partner) while advancing the drug closer to the submission of an NDA to the FDA, or to license the drug to a potential strategic partner just prior to a more expensive and time consuming pivotal study.

In order to add significant value to our in-licensed drugs within 2 to 4 years, the drugs must be in the clinical development stage and not in discovery stage, and during those 2 to 4 years we must be able to obtain clinical data to support the added value. The additional clinical data could range from a clinical proof-of-concept data to further demonstrate that the proposed pharmacology occurs clinically in the targeted patient population in a pivotal well-designed randomized controlled trial.

Our portfolio specifically includes drugs that (i) already have clinical proof-of-concept data demonstrating the desired pharmacological activity in humans or, minimally, clinical evidence in the form of case studies or clinical experience demonstrating the drug or a similar drug pharmacologically can successfully treat patients with the targeted indication, (ii) target indications for which the FDA believes that a single positive pivotal study demonstrating efficacy provides enough evidence that the clinical benefits of the drug and its approval outweighs the risks associated with the drug or the present standard of care (e.g., some orphan indications, many serious life-threatening conditions, some serious quality of life conditions), and/or (iii) target indications where the prevalence of the condition and the likelihood of patients enrolling in a study meet the desired time-frame to demonstrate that the drug can, at some level, treat or potentially treat patients with the condition.

To advance our mission, we have assembled an experienced and talented management and product development team. Our team is experienced in developing drug products through all principal regulatory tiers from IND enabling studies to NDA submission. Our combined scientific, development and regulatory experience has resulted in more than 30 drug approvals by the FDA, over 100 meetings with the FDA and involvement with more than 50 drug development programs, including drug products targeted to patients who have an unmet medical need. Although we believe that the skills and experience of our team in drug development and commercialization is an important indicator of our future success, the past successes of our team in developing and commercializing pharmaceutical products does not guarantee that they will successfully develop and commercialize drugs for us. In addition, the growth in revenues of companies at which our executive officers and directors served in was due to many factors and does not guarantee that they will successfully operate or manage us or that we will experience similar growth in revenues, even if they continue to serve as executive officers and/or directors.

Our ability to generate meaningful revenue from any products depends on our ability to out-license the drugs in the U.S. and/or ex-U.S. before or after we obtain FDA NDA approval. Even if our products are authorized and approved by the FDA, it should be noted that the products must still meet the challenges of successful marketing, distribution and consumer acceptance.

**Going Concern and Management's Plan**

Our consolidated financial statements are prepared using U.S. GAAP and are based on the assumption that we will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. We face certain risks and uncertainties regarding product development and commercialization, limited working capital, recurring losses and negative cash flow from operations, future profitability, ability to obtain future capital, protection of patents, technologies and property rights, competition, rapid technological change, navigating the domestic and major foreign markets' regulatory and clinical environment, recruiting and retaining key personnel, dependence on third party manufacturing organizations, third party collaboration and licensing agreements, lack of sales and marketing activities and having no customers or pharmaceutical products to sell or distribute. These risks and other factors raise substantial doubt about our ability to continue as a going concern.

We have relied primarily on private placements with a small group of accredited investors to finance our business and operations. As described in more detail below, we recently entered into two line of credit agreements with related parties providing a revolving commitment of an aggregate of up to $1.4 million. We have not had any revenue since our inception, and we do not currently have any revenue under contract or any immediate sales prospects. For the six months ended June 30, 2020 and year ended December 31, 2019, we incurred a net loss from continuing operations of approximately $1.6 million and $3.4 million, respectively; and used approximately $897,000 and $2.8 million in net cash from operating activities, respectively. We expect our operating costs to be substantial as we incur costs related to the clinical trials for our product candidates and that we will operate at a loss for the foreseeable future. At June 30, 2020, we had cash and cash equivalents totaling $452,654.

On September 20, 2019, we entered into two separate Line of Credit Agreements ("LOC Agreements") to borrow up to $700,000 with current stockholders and related parties DKBK Enterprises, LLC ("DKBK") and CorLyst, LLC ("CorLyst") ($1.4 million total). Under the LOC Agreements, all funds borrowed bear an 8% annual interest rate. The lenders have the right to convert all or any portion of the debt and interest into shares of our common stock. Our Chief Executive Officer (CEO) is also the CEO and Managing Member of both lenders. DKBK directly holds 16,166 shares of our common stock and CorLyst beneficially owns 1,095,649 shares. In April and June 2020, we drew $500,000 under the LOC Agreement with DKBK. On July 21, 2020, we drew an additional $200,000, bringing the total amount drawn under the LOC Agreement with DKBK to $700,000.

In December 2019 we closed our bridge financing and issued $805,000 of the 2019 Senior Notes to accredited investors. In order to preserve cash, in August 2019 we began delaying some cash outflows, primarily through the deferred payment of certain salaries ($210,800 has been included in accrued expenses at June 30, 2020) until such time as we have raised sufficient funding.

In May 2020, we entered into a promissory note in favor of the Bank of America under the Small Business Administration Paycheck Protection Program of the Coronavirus Aid, Relief and Economic Security Act of 2020 ("the CARES Act"), for a $162,459 loan (the "PPP Loan"). We have used the loan proceeds for payroll costs in accordance with the relevant terms and conditions of the CARES Act.

Substantial doubt existed about our ability to continue as a going concern as of the date of our annual report for the year ended December 31, 2019 and our auditors included a going concern paragraph in their Report of Independent Registered Public Accounting Firm accompanying our audited financial statements for the year ended December 31, 2019. The accompanying consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of recorded assets, or the amounts and classification of liabilities that might be different should we be unable to continue as a going concern based on the outcome of these uncertainties described above.

It is our current expectation, assuming the receipt of the net proceeds from this offering and based on current cash flow projections, that the going concern paragraph would be removed in our auditors' report for the year ending December 31, 2020.

**Components of Results of Operations**

On October 4, 2017, we acquired all the net assets of Promet Therapeutics, LLC ("Promet) a private Delaware limited liability company, including the rights to the CoNCERT Agreement in exchange for 4,535,121 shares of our common stock. Immediately following the transaction, the former equity holders of Promet owned approximately 84% and held approximately 6% of the shares for the benefit of CoNCERT in relation to the CoNCERT contribution of the license to Processa as part of the transaction, and our stockholders immediately prior to the transaction owned approximately 10% of our common stock. Promet distributed all 4,236,421 shares of the common stock it held to its partners.

We accounted for the net asset acquisition transaction as a "reverse acquisition" merger under the acquisition method for GAAP, where Promet was considered the accounting acquirer; and for tax purposes, as a tax-free contribution under Internal Revenue Code Section 351. Accordingly, Promet's historical results of operations replaced our historical results of operations for all periods prior to the merger. Prior to the acquisition, we had nominal net liabilities and operations. We were considered a non-operating public shell corporation.

***Revenues***

We did not have any revenue in the periods presented below, nor do we currently have any revenue under contract or any immediate sales prospects.

***Operating Expenses***

*Research and Development Expenses.*

Our research and development costs are expensed as incurred. Research and development expenses include (i) amortization of the exclusive license intangible asset and software used in research and development activities, (ii) internal research and development staff related payroll, taxes, stock-based compensation and employee benefits, and (iii) program and testing related expenses, including external consulting and professional fees related to the product testing and our development activities. Non-refundable advance payments for goods and services to be used in future research and development activities are recorded as prepaid expenses and expensed when the research and development activities are performed.

*General and Administrative Expenses.*

General and administrative expenses primarily consist of payroll, stock-based compensation and employee benefits for general and administrative staff, professional fees for legal, accounting and tax services and other general and administrative costs such as rent, utilities and taxes.

*Interest Expense and Interest Income.*

Interest expense incurred consists primarily of interest expense related to our 2017 and 2019 Senior Notes. Interest income represents interest earned on funds in our bank accounts and certificates of deposit.

*Income Tax Benefit.*

We recognize an income tax benefit as a result of our recording and amortizing the deferred tax liability created in connection with our acquisition of CoNCERT's license and "Know-How" in exchange for Processa stock that had been issued in the Internal Revenue Code Section 351 transaction on March 19, 2018. The Section 351 transaction treated the acquisition of the Know-How for stock as a tax-free exchange. As a result, under ASC 740-10-25-51 *Income Taxes*, Processa recorded a deferred tax liability of $3,037,147 for the acquired temporary difference between the financial reporting basis of $11,038,929 and the tax basis of $1,782. Each year, the deferred tax liability is decreased for the non-deductibility of the amortization of the intangible asset for the current period. Additionally, the liability is being offset for the deferred tax assets resulting from our net taxable operating losses.

***Comparison of the three and six months ended June 30, 2020 and 2019***

The following table summarizes our net loss during the periods indicated:

| | Three Months Ended June 30, | | | Six Months Ended June 30, | | |
|---|---|---|---|---|---|---|
| | 2020 | 2019 | Change | 2020 | 2019 | Change |
| **Operating Expenses** | | | | | | |
| Research and development expenses | $ 427,109 | $ 726,904 | $ (299,795) | $ 928,855 | $ 1,211,655 | $ (282,800) |
| General and administrative expenses | 374,878 | 410,072 | (35,194) | 859,255 | 807,837 | 51,418 |
| **Operating Loss** | (801,987) | (1,136,976) | | (1,788,110) | (2,019,492) | |
| **Other Income (Expense)** | | | | | | |
| Interest expense | (19,280) | (6,102) | (13,178) | (36,450) | (10,702) | (25,748) |
| Interest income | 18 | 3,398 | (3,380) | 846 | 9,383 | (8,537) |
| **Net Operating Loss Before Income Tax Benefit** | (821,249) | (1,139,680) | | (1,823,714) | (2,020,811) | |
| **Income Tax Benefit** | 87,835 | 170,602 | (82,767) | 215,964 | 300,901 | (84,937) |
| **Net Loss** | $ (733,414) | $ (969,078) | | $ (1,607,750) | $ (1,719,910) | |

*Revenues*.

We had no revenue during the three and six months ended June 30, 2020 and 2019. We do not currently have any revenue under contract or any immediate sales prospects.

*Research and Development Expenses.*

Our research and development costs are expensed as incurred. Research and development expenses include (i) licensing of compounds for product testing and development, (ii) program and testing related expenses, (iii) amortization of the exclusive PCS499 license intangible asset used in research and development activities, and (iv) internal research and development staff related payroll, taxes and employee benefits, external consulting and professional fees related to the product testing and our development activities. Non-refundable advance payments for goods and services to be used in future research and development activities are recorded as prepaid expenses and expensed when the research and development activities are performed.

During the three months ended June 30, 2020 and 2019, we incurred total research and development expenses of $427,109 and $726,904, respectively, for the continued development and testing of our lead product, PCS499. Research and development expenses were approximately $929,000 and $1.2 million for the six months ended June 30, 2020 and 2019, respectively. Costs for the three and six months ended June 30, 2020 and 2019 were as follows:

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| Amortization of intangible assets | $ 198,832 | $ 198,832 | $ 397,664 | $ 397,664 |
| Research and development salaries and benefits | 114,579 | 160,992 | 254,851 | 319,848 |
| Preclinical, clinical trial and other costs | 113,698 | 367,080 | 276,340 | 494,143 |
| Total | $ 427,109 | $ 726,904 | $ 928,855 | $ 1,211,655 |

Overall, during the three months ended June 30, 2020, our research and development costs decreased by $299,795. The decrease was due to a decrease in preclinical, clinical trial and other costs of $253,382 during the three months ended June 30, 2020 when compared to the same period in 2019. This decrease was attributable to decreased costs related to our Phase 2A clinical trial, as we have completed the patient portion of the study. We also had a decrease in research and development salaries and benefits of $46,413 for the three months ended June 30, 2020 when compared to the same period in 2019 related to the departure of two research and development team members in the first quarter of 2020.

During the six months ended June 30, 2020, our research and development costs decreased by $282,800 as compared to the six months ended June 30, 2019. The decrease in research and development expenses was due to a decrease in preclinical, clinical trial and other costs of $217,803 and in research and development salaries and benefits of $64,997 during the six months ended June 30, 2020 when compared to the same period in 2019 for the same reasons as stated above.

We anticipate our research and development costs to increase significantly in the future as we continue pre-clinical studies and conduct future clinical trials related to our current drug portfolio. We incurred $181,751 of costs related to our Phase 2A trial during the six months ended June 30, 2020 and expect to spend an additional $242,000 for the remainder of the trial. We believe, based on our estimates, the total cost of our current Phase 2A trial in NL to be approximately $1.5 million. We had a clinical trial funding investor pay for $900,000 of the clinical trial costs and we are covering the remaining $600,000 with funds received from the sale of our 2019 Senior Notes and our LOC Agreements, as necessary.

The funding necessary to bring a drug candidate to market is, however, subject to numerous uncertainties. Once a drug candidate is identified, the further development of that drug candidate can be halted or abandoned at any time due to a number of factors. These factors include, but are not limited to, funding constraints, safety or a change in market demand. For each of our drug candidate programs, we periodically assess the scientific progress and merits of the programs to determine if continued research and development is economically viable. Certain of our programs may be terminated due to the lack of scientific progress and lack of prospects for ultimate commercialization. We anticipate our research and development costs to increase in the future as we finalize our Phase 2A clinical trial activities and beginning designing and conducting a Phase 2B trial to evaluate the ability of PCS499 to completely close ulcers in patients with NL and initiate any research activities related to other drug candidates in our portfolio (PCS12852, PCS6422, PCS11T and PCS100). We expect to begin recruiting patients for our Phase 2B trial for NL in early 2021.

Our clinical trial accruals are based on estimates of patient enrollment and related costs at clinical investigator sites, as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf.

We estimate preclinical and clinical trial expenses based on the services performed, pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials on our behalf. In accruing service fees, we estimate the time-period over which services will be performed and the level of patient enrollment and activity expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related series are recorded as prepaid expenses until the services are rendered.

*General and Administrative Expenses.*

Our general and administrative expenses for the three months ended June 30, 2020 decreased by $35,194 to $374,878 from $410,072 for the three months ended June 30, 2019. We experienced reductions in professional fees for legal, accounting, advisory and consulting costs of approximately $40,000, as well as decreases in other administrative costs such as office expenses, travel, and taxes and licenses of approximately $25,000. These decreases were offset by an increase in insurance and telephone expenses of $3,800 and increased payroll and related costs of approximately $26,000 (primarily due to an increase in stock-based compensation of approximately $23,000). Reimbursements from CorLyst of $25,894 for rent and other costs during the six months ended June 30, 2020 were comparable to the same period in 2019.

For the six months ended June 30, 2020, general and administrative expenses increased by $51,418 to $859,255 from $807,837 for the six months ended June 30, 2019. The majority of the increase was due to a $109,000 increase in taxes and licenses, primarily due to our Delaware franchise tax as a result of our 1-for-7 reverse stock split in December 2019. Delaware used the assumed par value method to compute their franchise tax. The reverse stock split increased the assumed par value per share which was assessed on the number of authorized shares to compute the franchise tax. On June 25, 2020, we amended our certificate of incorporation to reduce the number of authorized shares in part to decrease our future Delaware franchise tax.

We also experienced increases of approximately $44,000 in payroll and related costs (due to an increase in stock-based compensation of approximately $47,000) and approximately $12,000 in administrative costs for items such as insurance and telephone expenses. The overall increase was offset by decreases in professional fees for legal, accounting, advisory and consulting costs of approximately $95,000, as well as reductions of approximately $20,000 in office expenses, travel, continuing education, utilities and repairs and maintenance. Reimbursements from CorLyst of $50,642 for rent and other costs during the six months ended June 30, 2020 were $1,800 less than the same period in 2019.

We expect the general and administrative expenses to increase in the future as we add staff to support our growing research and development activities and the administration required to operate as a public company.

*Interest Expense and Interest Income.*

Interest expense was $19,280 and $6,102 for the three months ended June 30, 2020 and 2019, respectively, and $36,450 and $10,702 for the six months ended June 30, 2020 and 2019, respectively, related to our $805,000 and $2.58 million of 8% Senior Notes sold in 2019 and 2017, respectively, and to the 2020 borrowings on the LOC Agreement with DKBK. Included in interest expense is the amortization of debt issuance costs totaling $2,140 and $0 for the six months ended June 30, 2020 and 2019, respectively.

Interest income was $18 and $3,398 for the three months ended June 30, 2020 and 2019, respectively, and $846 and $9,383 for the six months ended June 30, 2020 and 2019, respectively. Interest income represents interest earned on money market funds.

*Income Tax Benefit.*

We recognized an income tax benefit of $87,835 and $170,602 for the three months ended June 30, 2020 and 2019, respectively, and $215,964 and $300,901 for the six months ended June 30, 2020 and 2019, respectively, as a result of our recording and amortizing the deferred tax liability created in connection with our acquisition of CoNCERT's license and "Know-How" in exchange for Processa stock that had been issued in the Internal Revenue Code Section 351 transaction on March 19, 2018. The Section 351 transaction treated the acquisition of the Know-How for stock as a tax-free exchange. As a result, under ASC 740-10-25-51 *Income Taxes*, we recorded a deferred tax liability of $3,037,147 for the acquired temporary difference between the financial reporting basis of $11,038,929 and the tax basis of $1,782. The deferred tax liability will be reduced for the effect of the non-deductibility of the amortization of the intangible asset and may be offset by the deferred tax assets resulting from net operating tax losses. This offset results in the recognition of a deferred tax benefit shown in the condensed consolidated statements of operations.

***Comparison of the years ended December 31, 2019 and 2018***

The following table summarizes our operations and net loss during the periods indicated:

| | Year ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| **Operating Expenses** | | |
| Research and development expenses | $ 2,320,573 | $ 3,085,317 |
| General and administrative expenses | 1,614,909 | 1,439,623 |
| **Operating Loss** | (3,935,482) | (4,524,940) |
| **Other Income (Expense)** | | |
| Interest expense | (36,658) | (161,205) |
| Interest income | 11,548 | 18,297 |
| **Net Operating Loss Before Income Tax Benefit** | (3,960,592) | (4,667,848) |
| **Income Tax Benefit** | 602,716 | 902,801 |
| **Net Loss** | $ (3,357,876) | $ (3,765,047) |

*Revenues*

We had no revenue during the years ended December 31, 2019 and 2018, and we do not currently have any revenue under contract or any immediate sales prospects.

*Research and Development Expenses.*

During the years ended December 31, 2019 and 2018, we incurred total research and development expenses of $2,320,573, and $3,085,317, respectively, for the continued development and testing of our lead product, PCS499. As a result of exercising the CoNCERT license and option agreement for PCS499 in March 2018, and the purchase of a software license during the second quarter of 2018, we recognized $795,328 and $621,647 of amortization expense during the years ended December 31, 2019 and 2018, respectively. Costs for the years ended December 31, 2019 and 2018 were as follows:

| | Year ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Amortization of intangible assets | $ 795,328 | $ 621,647 |
| Research and development salaries and benefits | 742,254 | 650,702 |
| Preclinical, clinical trial and other costs | 782,991 | 1,812,968 |
| Total | $ 2,320,573 | $ 3,085,317 |

Our research and development salaries and benefits increased by $91,552 for the year ended December 31, 2019 when compared to the same period in 2018 related to an increase in stock-based compensation of $113,239, which was offset by a decrease in salaries and related benefits of $21,687. The decrease in salaries and related benefits related to one of our research and development team members having a reduced level of involvement in 2019. We also recognized lower research and development expenses for preclinical, clinical trial and other costs of $1,029,977 during the year ended December 31, 2019 when compared to the same period in 2018. During the year ended December 31, 2019, our focus was on enrolling patients in our trial, along with other trial costs, including providing doses of PCS499 to participants in our Phase 2A clinical trial in NL. In contrast, during the same period in 2018, we experienced significantly higher costs related to a Phase 1 trial for PCS499 and costs related to having to establish a new site to contract manufacture the tablets of PCS499 needed for our clinical trial since the original CoNCERT tablet manufacturing site could no longer be used.

We incurred $554,935 in costs related to our Phase 2A trial during the year ended December 31, 2019 and expect to spend an additional approximately $487,000 through 2020 to complete our current trial. We believe, based on our estimates, the cost of our current Phase 2A trial to be approximately $1.5 million. PoC Capital paid for $900,000 of the clinical trial costs, and we will cover the remaining $600,000 with funds received from the sale of our 2019 Senior Notes and our LOC Agreements, as necessary. During the year ended December 31, 2018, we made payments to our CRO related to our Phase 2A trial of approximately $239,000. We have accounted for these payments as either a prepaid expense or a research and development expense depending on whether the related service has been provided. During the year ended December 31, 2019, PoC Capital made payments directly to our CRO totaling $689,168 for amounts invoiced. PoC Capital also repaid us $210,832 for clinical trial expenses we previously paid to our CRO, $180,119 of which is included in Prepaid and Other on our consolidated balance sheet at December 31, 2019.

*General and Administrative Expenses.*

Our general and administrative expenses for the year ended December 31, 2019 increased by $175,286 to $1,614,909 from $1,439,623 for the year ended December 31, 2018. The increase related mostly to increased payroll and related costs of approximately $413,000 (including an increase in stock-based compensation of $323,176) as we built our finance team and hired our CFO and Director of Finance and Accounting in the second half of 2018 to support our growth and public company reporting and compliance requirements. We also experienced increases of approximately $47,000 in other administrative costs such as insurance, office, rent, repairs and maintenance, and travel expenses. Our tax expense also increased by approximately $84,000 in 2019 compared to 2018 due to our Delaware franchise taxes.

The above increases were offset by a cybersecurity fraud loss of approximately $144,000, for which we did not have insurance coverage, which occurred during the year ended December 31, 2018. We also had a reduction in professional fees of approximately $222,000, as we established in-house capabilities, and in other administrative expenses of approximately $7,300. Reimbursable expenses from CorLyst of $103,047 for rent and other costs during the year ended December 31, 2019 were approximately $4,400 less than those the same periods in 2018.

*Interest Expense and Interest Income.*

Interest expense was $36,658 and $161,205 for the years ended December 31, 2019 and 2018, respectively, related to our 2019 and 2017 Senior Notes. Included in interest expense is the amortization of debt issuance costs totaling $1,783 and $67,069 for the years ended December 31, 2019 and 2018, respectively. In May 2018, $2.35 million of the 2017 Senior Notes were converted into shares of our common stock and stock purchase warrants.

Interest income was $11,548 and $18,297 for the years ended December 31, 2019 and 2018, respectively. Interest income represents interest earned on funds in our bank accounts and certificates of deposit.

*Income Tax Benefit.*

We recognized an income tax benefit of $602,716 and $902,801 for the years ended December 31, 2019 and 2018, respectively. Our taxable net operating loss for 2019 was $1,043,567 less than that of 2018 as we focus on the Phase 2A clinical trial study and decrease administrative costs such as professional fees.

**Financial Condition**

At June 30, 2020, we had $452,654 in cash. We used net cash in our operating activities of $897,029 and $1,414,903 during the six months ended June 30, 2020 and 2019, respectively. The decrease in cash used in operating activities during the first six months of 2020 compared to the comparable period in 2019 was related to a decreased amount of direct cash costs incurred, such as salaries and clinical trial costs.

Our total assets decreased by approximately $872,000 to $10 million at June 30, 2020 compared to $10.9 million at December 31, 2019. This decrease is a result of the operating costs we incurred during the six months ended June 30, 2020.

At June 30, 2020, our total liabilities, not including the impact of deferred income taxes, increased approximately $764,000 to $2,102,770 when compared to $1,338,954 at December 31, 2019. This increase is due to increases in accrued expenses related to accrued salary liability, accrued interest related to the 2019 Senior Notes and other borrowings, funds drawn under the LOC Agreement with DKBK and the promissory note we entered into with the Bank of America under the Paycheck Protection Program.

In connection with exercising the option agreement with CoNCERT, we recognized a $3,037,147 deferred income tax liability since the intangible assets purchased had only a nominal tax basis. Our deferred tax liability has been and is expected to be reduced each period by the effect of the combination of the tax non-deductibility of the amortization of the intangible asset and an amount up to the income tax effect of our net loss.

**Liquidity and Capital Resources**

To date, we have funded our business and operations primarily through the private placement of equity securities and senior secured convertible notes. At June 30, 2020, we had $452,654 in cash compared to $691,536 at December 31, 2019. We have taken the following actions to address our liquidity:

- Starting in August 2019, we began deferring the salaries of certain employees. At June 30, 2020 we have deferred a total of $210,800 (which has been included in accrued expenses on the condensed consolidated balance sheet) until such time as we have raised sufficient funding.

- On September 20, 2019, we entered into two separate LOC Agreements with current stockholders and related parties DKBK and CorLyst, which provide a revolving commitment of up to $700,000 each ($1.4 million total). Under the LOC Agreements, all funds borrowed will bear an 8% annual interest rate. The Lenders have the right to convert all or any portion of the debt and interest into shares of our common stock. Our CEO is also the CEO and Managing Member of both Lenders. DKBK directly holds 16,166 shares of our common stock, and CorLyst beneficially owns 1,095,649 shares. In April and June 2020, we drew $500,000 under the LOC Agreement with DKBK. On July 21, 2020, we drew an additional $200,000, bringing the total amount drawn under the LOC Agreement with DKBK to $700,000. We have not drawn any funds under the LOC Agreement with CorLyst.

- In December 2019, we closed a bridge financing raising $805,000 through the issuance of 2019 Senior Notes to accredited investors.

- In May 2020, we received $162,459 from a loan with Bank of America under the Paycheck Protection Program.

- Through this offering, we intend to undertake an underwritten capital raise and, upon completion of this offering, list our common stock to the Nasdaq Capital Market.

Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, and the extent to which we may enter into additional agreements with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future capital requirements will depend on many factors, including:

- the timing and extent of spending on our research and development efforts, including with respect to PCS499 and our other product candidates;
- the scope, rate of progress, results and cost of our clinical trials, preclinical testing and other related activities;
- the time and costs involved in obtaining regulatory and marketing approvals in multiple jurisdictions for our product candidates that successfully complete clinical trials;
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the emergence of competing technologies or other adverse market developments;
- the introduction of new product candidates and the number and characteristics of product candidates that we pursue; and
- the potential acquisition and in-licensing of other technologies, products or assets.

Based on our current plan and assuming we consummate this offering, we believe the net proceeds together with our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through 2022. The funds will allow us to complete the closeout of our current Phase 2A trial in NL, conduct the Phase 2B clinical trial approved by the FDA and develop our other drug candidates. We may incur costs that we do not currently anticipate in order to develop our drug candidates, requiring us to need additional capital sooner than currently expected. We may satisfy our future cash needs through the sale of equity securities, debt financings, working capital lines of credit, corporate collaborations or license agreements, grant funding, interest income earned on invested cash balances or a combination of one or more of these sources.

**Cash Flows**

The following table sets forth our sources and uses of cash and cash equivalents for the six months ended June 30, 2020 and 2019:

| | Six months ended June 30, | |
|---|---|---|
| | 2020 | 2019 |
| Net cash (used in) provided by: | | |
| Operating activities | $ (897,029) | $ (1,414,903) |
| Investing activities | - | - |
| Financing activities | 658,147 | 395,927 |
| Net decrease in cash | $ (238,882) | $ (1,018,976) |

*Net cash used in operating activities*

We used net cash in our operating activities of $897,029 and $1,414,903 during the six months ended June 30, 2020 and 2019, respectively. The decrease in cash used in operating activities during the first six months of 2020 compared to the comparable period in 2019 was related to a decreased amount of direct cash costs incurred, such as salaries and clinical trial costs. Additionally, prepaid expenses decreased by approximately $218,000, $145,000 of which related to costs for our Phase 2A clinical trial.

Since we are in the process of developing our products, we anticipate our research and development efforts and on-going general and administrative costs will continue to generate negative cash flows from operating activities for the foreseeable future and that these amounts will increase in the future. We do not currently sell or distribute pharmaceutical products or have any sales or marketing capabilities.

*Net cash used in investing activities*

We had no cash sources or uses for investing activities during the six months ended June 30, 2020 or 2019.

*Net cash (used in) provided by financing activities*

Net cash provided by financing activities during the six months ended June 30, 2020 of $658,147 was from borrowings totaling $500,000 under our LOC Agreement with DKBK and $162,459 we received from the Bank of America pursuant to a promissory note under the Paycheck Protection Program, less transaction costs of $4,312 related to our anticipated 2020 offering. During the six months ended June 30, 2019, net cash provided by financing activities of $395,927 were funds received from our clinical trial funding investor in partial satisfaction of his stock subscription receivable that he paid directly to our CRO.

We expect that we will continue to seek additional capital through a combination of private and public equity offerings, debt financings, and strategic collaborations to fund future operations. However, no assurance can be given that we will be successful in raising adequate funds needed. Absent additional financing, substantial doubt exists about our ability to continue as a going concern, as noted under “Going Concern” above.

**Off-balance Sheet Arrangements**

We do not have any off-balance sheet arrangements as defined by Item 303(a)(4) of Regulation S-K.

**Critical Accounting Policies and Use of Estimates**

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following accounting policies and estimates are most critical to aid in understanding and evaluating our financial results reported in our consolidated financial statements.

*Valuation of Intangible Assets*

Our intangible assets consist of the capitalized costs of $20,500 for a software license and $11,038,929 associated with the exercise of the option to acquire the exclusive license from CoNCERT related to patent rights and know-how to develop and commercialize compounds and products for PCS499 and each metabolite thereof and the related income tax effects. The capitalized costs for the license rights to PCS499, in addition to the fair value of the common stock issued, also includes $1,782 in transaction costs and $3,037,147 associated with the initial recognition of an offsetting deferred tax liability related to the acquired temporary difference for an asset purchased that is not a business combination and has a nominal tax basis in accordance with ASC 740-10-25-51 *Income Taxes.* In accordance with ASC Topic 730, *Research and Development*, we capitalized the costs of acquiring the exclusive license rights to PCS499 as the exclusive license rights represent intangible assets to be used in research and development activities that have future alternative uses.

We used a market approach to estimate the fair value of the common stock issued to CoNCERT in this transaction. Our estimate was based on the final negotiated number of shares of stock issued and the volume weighted average price of our common stock quoted on the OTC Pink Marketplace over a 45-day period preceding the mid-February 2018 finalized negotiation of the modification to the option and license agreement with CoNCERT. We believe the fair values used to record intangible assets acquired in this transaction are based upon reasonable estimates and assumptions given the facts and circumstances as of the related valuation dates.

We determined our intangible assets to have finite useful lives and review them for impairment when facts or circumstances suggest that the carrying value of these assets may not be recoverable.

*Clinical Trial Accruals / Research and Development*

As part of the process of preparing our consolidated financial statements, we are required to estimate expenses resulting from our obligations under contracts with vendors, CROs and consultants and under clinical site agreements related to conducting our clinical trials. The financial terms of these contracts vary and may result in payment flows that do not match the period over which materials or services are provided under such contracts.

Our clinical trial accruals are based on estimates of patient enrollment and related costs at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. During a clinical trial, we will adjust the clinical expense recognition if actual results differ from estimates. We make estimates of accrued expenses as of each balance sheet date based on the facts and circumstances known at that time. Our clinical trial accruals are partially dependent on the accurate reporting by the CRO and other third-party vendors. Although we do not expect estimates to differ materially from actual amounts, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that may be too high or too low for any reporting period.

Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered. We expense research and development costs as they are incurred.

*Stock-Based Compensation*

We account for the cost of employee services received in exchange for the award of equity instruments based on the fair value of the award, determined on the date of grant. Significant assumptions utilized in determining the fair value of our stock options include the volatility rate, estimated term of the options, risk-free interest rate and forfeiture rate. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. We estimate forfeitures at the time of grant and make revisions, if necessary, at each reporting period if actual forfeitures differ from those estimates.

Non-employee stock-based compensation awards generally are immediately vested and have no future performance requirements by the non-employee and the total stock-based compensation charge is recorded in the period of the measurement date.

We estimate the fair value of stock option grants using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. The Black-Scholes option-pricing model requires the use of subjective assumptions that include the expected stock price volatility and the fair value of the underlying common stock on the date of grant. See Note 10 – Stock-Based Compensation for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted during the years ended December 31, 2019 and 2018.

All stock-based compensation costs are recorded in general and administrative or research and development costs in the consolidated statements of operations based upon the underlying individual's role.

*Income Taxes*

As a result of our reverse acquisition, there was an ownership change as defined by Internal Revenue Code Section 382. Prior to the closing of the transaction, Promet was treated as a partnership for federal income tax purposes and thus was not subject to income taxes at the entity level and no provision or liability for income taxes has been included in the consolidated financial statements through October 4, 2017. In addition, Promet determined that it was not required to record a liability related to uncertain tax positions as a result of the requirements of ASC 740-10-25 *Income Taxes.* The net deferred tax assets of Heatwurx were principally federal and state net operating loss carry forwards, which are significantly limited following an ownership change as defined by Internal Revenue Code Section 382.

We account for income taxes in accordance with ASC 740 *Income Taxes,* which provides for deferred taxes using an asset and liability approach. We recognized deferred tax assets and liabilities for the expected future tax consequences of events that have been in our consolidated financial statements and income tax returns. Deferred tax assets and liabilities are determined based on the difference between our consolidated financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the years in which the differences are expected to reverse. Valuation allowances are recorded to reduce deferred tax assets when it is more-likely-than-not that a tax benefit will not be realized.

We account for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, we recognize the tax benefit from an uncertain tax position only if it is more-likely-than-not that the tax position will be sustained upon examination by the taxing authorities, based on the technical merits of the position. Estimated interest and penalties related to uncertain tax positions are included as a component of interest expense and general and administrative expense, respectively. We had no unrecognized tax benefits or uncertain tax positions for any periods presented.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 ("TCJA") was signed into law. In December 2017, the SEC issued Staff Accounting Bulletin 118 ("SAB 118") to provide clarification in implementing the TCJA when registrants do not have the necessary information available to complete the accounting for an element of the TCJA in the period of its enactment. SAB 118 provides for tax amounts to be classified as provisional and subject to remeasurement for up to one year from the enactment date for such elements when the accounting effect is not complete but can be reasonably estimated. We consider our estimates of the tax effects of the TCJA on the components of our tax provision to be reasonable and no provisional estimates subject to remeasurement will be necessary to complete the accounting.

We file U.S. federal income and California and Maryland state tax returns. There are currently no income tax examinations underway for these jurisdictions. However, tax years from and including 2016 remain open for examination by federal and state income tax authorities.

During the years ended December 31, 2019 and 2018, we incurred net operating losses of $3,960,592 and $4,667,848, respectively. We did not record any income tax benefit for the $1,205,811 ($331,809 tax effected) and $1,356,840 ($373,368 tax effected) of general and administrative expenses treated as deferred start-up expenditures for tax purposes for the years ended December 31, 2019 and 2018, respectively. We did not record any income tax benefit for the $283,189 of federal orphan drug tax credits for the year ended December 31, 2019. Additionally, we did not record any income tax benefit in 2017 for the $259,049 ($71,284 tax effected) of tax losses incurred in 2017 which resulted in tax loss carryforwards. The benefit was recognized in 2018 in the calculation of the valuation allowance. The 2017 net operating loss carry forwards are available for application against future taxable income for 20 years expiring in 2037. Tax losses incurred after December 31, 2017 have an indefinite carry forward period. However, the tax loss incurred after December 31, 2017 and carried forward can only offset 80 percent of future taxable income in any one year (other than in 2020), with any excess losses being carried forward indefinitely. We have recorded the benefit of our 2019 and 2018 net operating losses in our consolidated financial statements as a reduction in the deferred tax liability created by the future financial statement amortization of the intangible asset from the acquired Know-How. The benefit associated with the net operating loss carry forward will more-likely-than-not go unrealized unless future operations are successful except for their offset against the deferred tax liability created by the acquired CoNCERT license and "Know-How."

**Recently Issued Accounting Pronouncements**

See Note 3 of our consolidated financial statements for new accounting pronouncements or changes to the recent accounting pronouncements during the year ended December 31, 2019.

**Quantitative and Qualitative Disclosures about Market Risk**

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate risks and inflation risks. Periodically, we maintain deposits in accredited financial institutions in excess of federally insured limits. We deposit our cash in financial institutions that we believe have high credit quality and have not experienced any losses on such accounts and do not believe we are exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

***Interest Rate Risk***

Our cash consists of cash in readily available checking accounts and short-term money market fund investments. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant.

***Effects of Inflation***

Inflation generally affects us by increasing our cost of labor and research and development contract costs. We do not believe inflation has had a material effect on our results of operations during the periods presented.

## BUSINESS

## DESCRIPTION OF BUSINESS

### Overview

*Our mission is to develop drug products that improve the survival and/or quality of life for patients with highly unmet medical needs.*

We are a clinical-stage biopharmaceutical company focused on the development of drug products that are intended to provide treatment for and improve the survival and/or quality of life of patients who have a highly unmet medical need condition or who have no alternative treatment. Our most advanced product candidate, PCS499, is an oral tablet that is a deuterated analog of one of the major metabolites of pentoxifylline (PTX or Trental®). We have completed the patient portion of our Phase 2A trial for PCS499 and are in the process of closing the trial, and we plan to begin recruiting for a Phase 2B trial in 2021. We also have four newly licensed drugs (PCS12852, PCS6422, PCS11T and PCS100) and will begin developing these products once adequate funding has been obtained.

### Our Strategy

Our vision is to develop drugs with potentially high return on investment and lower risk of development failure. Our portfolio drugs are focused on treating patients who do not have adequate treatment options for their conditions and have some clinical evidence supporting the efficacy of the drug, whether it be evidence with the drug itself or a drug with similar pharmacological properties. Given the prior success of our development team, the regulatory science approach that we employ not only allows us to develop drugs focused on FDA approval, but also allows us to select drugs for our portfolio which may have a greater chance for approval in a population of patients who need treatment options. The key pillars of our strategy to achieve our vision include:

(i) identifying drugs that have potential efficacy in patients with an unmet medical need, as demonstrated by some clinical evidence that the targeted pharmacology of the drug provides clinical efficacy in the targeted patient population;

(ii) identifying drug products that have been developed or approved for other indications but can be repurposed to treat those patients who have an unmet medical need; and

(iii) identifying drugs that can be quickly developed such that within 2-4 years, critical value-added clinical milestones can be achieved while advancing the drug closer to commercialization.

### Our Team

Our drug development efforts are driven by our extensive knowledge in applying rigorous regulatory science to the FDA approval pathway. We have assembled a seasoned management team with extensive experience in developing therapies, including advancing product candidates from preclinical research through clinical development and ultimately regulatory approval and commercialization. Together, our management team has completed over 30 FDA approvals. Our team is led by our Chairman and CEO David Young, Pharm.D., Ph.D. who has extensive experience in research, regulatory approval and business development and who served at Questcor for eight years as independent director and Chief Scientific Officer, helping lead to the ultimate sale of Questcor in 2014.

### Our Pipeline

The table below summarizes our clinical product pipeline. We have completed the patient portion of our Phase 2A clinical trial for PCS499, however, the finalization of the trial data and its closeout has been delayed due to the ongoing COVID-19 pandemic.

| Program | Indications | Pre-Clinical | Phase I | Phase II | Phase III | Key Upcoming Milestones |
|---|---|---|---|---|---|---|
| PCS499 | Necrobiosis Lipoidica | | | | | Enroll first patient in a Phase 2B study in the first half of 2021; release clinical data in the second half of 2022 |
| PCS12852 | POGD (Postoperative Ileus) | | | | | Enroll first patient in a Phase 2A in the first half of 2021; release clinical data in the second half of 2022 |
| PCS6422 | Colorectal (colon, metastatic), Metastatic Breast | | | | | Enroll first patient in a Phase 1B in the first half of 2021; release clinical data in the second half of 2022 |
| PCS11T | Small Cell Lung and Pancreatic Cancer | | | | | Complete the IND-enabling studies; submit the Phase 1B IND in the second half of 2022. |
| PCS100 | Fibrotic Disease | | | | | FDA meeting in 2021; GLP Tox |

***PCS499***

Our lead product, PCS499, is an oral tablet that is a deuterated analog of one of the major metabolites of pentoxifylline (PTX or Trental®). PCS499 is classified by FDA as a new molecular entity. PCS499 and its metabolites act on multiple pharmacological targets that are important in a variety of conditions. We have identified Necrobiosis Lipoidica (NL) as our lead indication for PCS499. NL is a chronic, disfiguring condition affecting the skin and the tissue under the skin typically on the lower extremities with no currently approved FDA treatments. NL presents more commonly in women than in men and occurs more often in people with diabetes. Ulceration occurs in approximately 30% of NL patients, which can lead to more severe complications, such as deep tissue infections and osteonecrosis threatening the life of the limb. Approximately 22,000 - 55,000 people in the United States and more than 120,000 people outside the United States are affected with ulcerated NL.

The degeneration of tissue occurring at the NL lesion site may be caused by a number of pathophysiological changes, which has made it extremely difficult to develop effective treatments for this condition. Because PCS499 and its metabolites affect a number of biological pathways, several of which could contribute to the pathophysiology associated with NL, PCS499 may provide a novel treatment solution for NL, a condition for which there are currently no FDA-approved treatments.

On June 18, 2018, the FDA granted orphan-drug designation for PCS499 for the treatment of NL. On September 28, 2018, the IND for PCS499 in NL became effective, such that we could move forward with a Phase 2A multicenter, open-label prospective trial designed to determine the safety and tolerability of PCS499 in patients with NL. The study initially had a six-month treatment phase and a six-month optional extension phase. In December 2019, we informed patients and sites that the study would conclude after the treatment phase and there would no longer be an extension phase. The first enrolled NL patient in this Phase 2A clinical trial was dosed on January 29, 2019 and the study completed enrollment on August 23, 2019. The last patient visit took place in February 2020. Due to COVID-19 related restrictions at certain sites, study closeout and database lock have yet to be completed.

The main objective of the trial was to evaluate the safety and tolerability of PCS499 in patients with NL and to use the collected safety and efficacy data to design future clinical trials. Based on toxicology studies and healthy human volunteer studies, Processa and the FDA agreed that a PCS499 dose of 1.8 grams/day would be the highest dose administered to NL patients in this Phase 2A trial. As anticipated, the PCS499 dose of 1.8 grams/day, 50% greater than the maximum tolerated dose of PTX, appeared to be well tolerated with no serious adverse events reported. All adverse events reported in the study were mild in severity. As expected, gastrointestinal symptoms were the most noted adverse events and reported in four patients, all of which were mild in severity and resolved within 1-2 weeks of starting dosing.

Two of the twelve patients in the study presented with more severe ulcerated NL and had ulcers for more than two months prior to dosing. At baseline, the reference ulcer in one of the two patients measured 3.5 cm2 and had completely closed by Month 2 of treatment. The second patient had a baseline reference ulcer of 1.2 cm2 which completely closed by Month 9 during the patient's treatment extension period. In addition, while in the trial, both patients also developed small ulcers at other sites, possibly related to contact trauma, and these ulcers resolved within one month. However, the other ten patients, presenting with mild to moderate NL and no ulceration, had more limited improvement of the NL lesions during treatment. Historically, less than 20% of all the patients with NL naturally progress to complete healing over many years after presenting with NL. Although the natural healing of the more severe NL patients with ulcers has not been evaluated independently, medical experts who treat NL patients believe that the natural progression of an open ulcerated wound to complete closure would be significantly less than the 20% reported as the maximum percentage of patients who naturally heal over several years after NL presentation.

On March 25, 2020, we met with the FDA and discussed the clinical program, as well as the nonclinical and clinical pharmacology plans to ultimately support the submission of the PCS499 New Drug Application (NDA) in the U.S. for the treatment of ulcers in NL patients. With input from the FDA, we will be designing the next trial as a randomized, placebo-controlled trial to evaluate the ability of PCS499 to completely close ulcers in patients with NL. We initially planned to begin recruiting for the randomized, placebo-controlled trial in the fourth quarter of 2020, but we now expect to begin recruiting patients in 2021 due to the ongoing COVID-19 pandemic. This PCS499 NL study will be a randomized, placebo-controlled Phase 2B study to better understand the potential response of NL patients on drug and on placebo. After obtaining the results from this Phase 2B study, we expect to meet with FDA to discuss our Phase 2B drug and placebo response findings while further discussing the next steps to obtain approval.

***PCS12852***

On August 19, 2020, we entered into a License Agreement ("Yuhan License Agreement") with Yuhan Corporation ("Yuhan"), pursuant to which we acquired an exclusive license to develop, manufacture and commercialize PCS12852 (formerly known as YH12852) globally, excluding South Korea.

PCS12852 is a novel, potent and highly selective 5-hydroxytryptamine 4 (5-HT4) receptor agonist. Other 5-HT receptor agonists with less 5-HT4 selectivity have been shown to successfully treat gastrointestinal (GI) motility disorders such as chronic constipation, constipation-predominant irritable bowel syndrome, functional dyspepsia and gastroparesis. Less selective 5-HT4 agonists, such as cisapride, have been either removed from the market or not approved because of the cardiovascular side effects associated with the drugs binding to other receptors, especially 5-HT receptors other than 5-HT4.

We plan to meet with the FDA in early 2021 to further define the clinical development program required for the PCS12852 product and discuss a Phase 2A proof of concept randomized, placebo-controlled study for PCS12852 in a gastrointestinal (GI) motility dysfunction disorder (e.g., post-operative ileus also called gastrointestinal dysfunction (POGD), opioid induced constipation, chronic idiopathic constipation). The purpose of the Phase 2A trial would be to better define a dosage regimen of PCS128552 that could be potentially efficacious and safe in a larger pivotal study. The patients with these types of conditions have an abnormal pattern of GI motility in the absence of mechanical obstruction. For example, POGD is characterized by nausea, vomiting, abdominal distension and/or delated passage of flatus or stool, following surgery (most commonly with abdominal surgery). It is the most common cause of prolonged length of stay in hospital following GI surgery, leading to an increase in healthcare costs. The only FDA-approved drug to treat POGD is a mu-opioid receptor antagonist alvimopan (Entereg®), which is only available through a restricted program for short-term use due to the potential risk of myocardial infarction with long-term use.

Two clinical studies have been previously conducted by Yuhan with PCS12852. In the first-in-human clinical trial (Protocol YH12852-101), the initial safety and tolerability of PCS12852 were evaluated after single and multiple oral doses in healthy subjects. PCS12852 increased stool frequency with faster onset when compared to prucalopride, an FDA approved drug for the treatment of chronic idiopathic constipation. Compared to the group receiving prucalopride (an FDA approved drug for the treatment of chronic idiopathic constipation), the PCS12852 dose groups showed higher stool frequency for 24 hours following single dosing and had faster onset of spontaneous bowel movements (SBMs) with comparable or relatively higher Bristol Stool Form Scale score (lower stool consistency) for 24 hours following first dosing. In addition, based on an increase of ≥ 1 SBM/week from baseline during 7-day multiple dosing, the PCS12852 dose group had a higher percent of patients with an increase than the prucalopride group. All doses of PCS12852 were safe and well tolerated and no serious adverse events (SAE) occurred during the study. The most frequently reported adverse events (AEs) were headache, nausea and diarrhea which were temporal, manageable, and reversible within 24 hours. There were no clinically significant changes in platelet aggregation or ECG parameters including no sign of QTc prolongation in the study. The second study conducted was a Phase 1/2A clinical trial (Protocol YH12852-102) to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of PCS12852 immediate release (IR) formulation and delayed release (DR) formulation after multiple oral dosing. PCS12852 was safe and well tolerated after single and multiple administrations. The most frequent AEs for both the IR and DR formulations of PCS12852 were headache, nausea and diarrhea, but the incidences of these AEs were comparable with those of the prucalopride 2 mg group. These AEs, which were transient and mostly mild in severity, are also commonly observed with other 5-HT4 agonists. Both formulations of PCS12852 also showed pharmacologic activity as assessed using various pharmacodynamic parameters for stool assessment.

Yuhan had also conducted extensive toxicological studies for the product that demonstrated that the product is safe for use and can be moved quickly into Phase 2 studies.

***PCS6422***

On August 23, 2020, we entered into a License Agreement ("Elion License Agreement") with Elion Oncology, Inc. ("Elion"), pursuant to which we acquired an exclusive contingent license to develop, manufacture and commercialize PCS6422 globally.

Elion acquired the eniluracil (PCS6422) product from Fennec Pharmaceuticals (formerly known as Adherex Technologies) in 2016. PCS6422 is an oral, potent, selective, and irreversible inhibitor of dihydropyrimidine dehydrogenase (DPD), the enzyme that rapidly metabolizes 5-FU, a common chemotherapy drug, to inactive metabolites, such as α-fluoro-β-alanine (F-Bal). F-Bal is thought to cause the neurotoxicity and Hand–Foot Syndrome (HFS) associated with 5-FU, and greater formation of F-Bal appears to be associated with a decrease in the antitumor activity of 5-FU. HFS can affect daily living activities, quality of life, and requires dose interruptions/adjustments and even therapy discontinuation resulting in suboptimal tumor effects. We believe that the inhibition of DPD by PCS6422 may significantly improve exposure to 5-FU and reduce 5-FU side effects related to F-Bal. One dose of PCS6422 irreversibly blocks DPD activity for up to two weeks until DPD levels recover via de novo synthesis of the DPD enzyme. Thus, we believe inhibition of tumor DPD will result in higher 5-FU intra-tumoral concentration and potentially better tumor response along with the decrease in F-Bal.

Fluoropyrimidines (e.g., 5-FU) are still the cornerstone of treatment for many different types of cancers, either as monotherapy or in combination with other chemotherapy agents by an estimated two million patients annually. Xeloda®, an oral pro-drug of 5-FU, is approved as first-line therapy for metastatic colorectal and breast cancer. However, its use is limited by adverse effects such as the development of HFS in up to 60% of patients.

Elion evaluated the potential for the combination of PCS6422 with capecitabine (Xeloda®, and, together with PCS6422, known as ECAPE) as a treatment of advanced gastrointestinal (GI) tumors. Nonclinical efficacy data indicated that in colorectal cancer models, pretreatment with PCS6422 enhanced the antitumor activity of capecitabine. PCS6422 increased the antitumor potency of capecitabine while not increasing the toxicity. The antitumor efficacy of the combination of PCS6422 and capecitabine was tested in several xenograft animal models with human breast, pancreatic and colorectal cancer cells. These preclinical xenograft models demonstrate that PCS6422 potentiates the antitumor activity of capecitabine and significantly reduces the dose of capecitabine required to be efficacious.

Elion met with the FDA in 2019 and agreed upon the clinical development program required for the combination of PCS6422 and capecitabine as first-line therapy for metastatic colorectal cancer when treatment with fluoropyrimidine therapy alone is preferred. Subsequently, an IND has been granted safe to proceed by FDA on May 17, 2020, for the Phase 1B study. This Phase 1B study will evaluate the safety and tolerability of several dose combinations of PCS6422 and capecitabine in advanced GI tumor patients and should be initiated in the first half of 2021.

Other DPD enzyme inhibitors (e.g. Gimeracil used in Teysuno® approved only outside the US) act as competitive reversible inhibitors. These agents must be present when 5-FU or capecitabine are administered to inhibit 5-FU breakdown by DPD in order to improve the efficacy and safety profiles of 5-FU. Given the reversible nature of their effect on DPD, over time 5-FU metabolism to F-Bal will return, decreasing the amount of 5-FU in the cancer cells and decreasing the potential cytotoxicity on the cancer cells. There is also evidence that administering DPD inhibitors directly with 5-FU may also decrease the antitumor effect of the 5-FU. Because PCS6422 is an irreversible inactivator of DPD, it can be dosed the day before capecitabine administration and its effect on DPD can last longer than the reversible DPD inhibitors and beyond the time 5-FU exists in the cancer cell. We believe this can optimize the potential cytotoxic effect and minimize the metabolism of 5-FU.

Prior to Elion's involvement, two multicenter Phase 3 studies were conducted in patients with colorectal cancer (CRC) with PCS6422 administered in 10-fold excess to 5-FU. Unfortunately, we believe the dose of PCS6422 during these trials was not optimal, and that PCS6422 was not administered early enough to irreversibly affect the DPD enzyme, thus the regimen tended to produce less antitumor benefit than the control arm with the standard regimen of 5-FU/leucovorin (LV) without PCS6422. Later preclinical work suggested that when PCS6422 was present at the same time as and in excess to 5-FU, it diminished the antitumor activity of 5-FU, which we believe supports the proposal of exploring clinically dosing PCS6422 several hours before 5-FU to allow its clearance before the administration of 5-FU.

***PCS11T***

On May 24, 2020, we entered into an exclusive License Agreement with Aposense, Ltd., ("Aposense"), pursuant to which we were granted a contingent license in Aposense's patent rights and know-how to develop and commercialize their next generation irinotecan cancer drug, PCS11T (formerly known as ATT-11T). The grant of license is conditioned on the following being satisfied within 9 months of May 24, 2020 (or the agreement shall terminate): (i) our closing of an equity financing and successful up-listing to Nasdaq and (ii) Aposense obtaining the approval of the Israel Innovation Authority for the consummation of the transactions contemplated by the agreement, which approval was obtained on August 24, 2020.

PCS11T is a novel lipophilic anti-cancer pro-drug that is being developed for the treatment of the same solid tumors as prescribed for irinotecan. This pro-drug is a conjugate of a specific proprietary Aposense molecule connected to SN-38, the active metabolite of irinotecan. The proprietary molecule in PCS11T has been designed to allow PCS11T to bind to cell membranes to form an inactive pro-drug depot on the cell with SN-38 preferentially accumulating in the membrane of tumors cells and the tumor core. This unique characteristic may make the therapeutic window of PCS11T wider than other irinotecan products such that the antitumor effect of PCS11T could occur at a much lower dose with a milder adverse effect profile than irinotecan. Despite the widespread use of commercially marketed irinotecan products in the treatment of metastatic colorectal cancer and other cancers resulting in peak annual sales of approximately $1.1 billion, irinotecan has a narrow therapeutic window and includes an FDA "Black Box" warning for both neutropenia and severe diarrhea. There is, therefore, a substantial unmet need to overcome the limitations of the current commercially marketed irinotecan products, improving efficacy and reducing the severity of treatment emergent adverse events. We believe the potential wider therapeutic window of PCS11T will likely lead to more patients responding with less side effects when on PCS11T compared to other irinotecan products.

Pre-clinical studies conducted to date showed that PCS11T demonstrated tumor eradication at much lower doses than irinotecan across various tumor xenograft models. PCS11T does not affect acetyl choline esterase (AChE) activity in human and rat plasma in vitro, which would suggest that PCS11T will show an improved safety profile, compared to irinotecan, which is known for its cholinergic-related side effects.

We are currently planning to manufacture the product at a GMP facility, conduct the required toxicological studies required to file the IND and initiate the Phase 1B study in oncology patients with solid tumors in 2021/2022.

***PCS100***

On August 29, 2019, we entered into an exclusive license agreement with Akashi Therapeutics, Inc. ("Akashi") to develop and commercialize an anti-fibrotic, anti-inflammatory drug, PCS100 (formerly known as HT-100), which also promotes healthy muscle fiber regeneration. In previous clinical trials in Duchenne Muscular Dystrophy (DMD), PCS100 showed promising improvement in the muscle strength of non-ambulant pediatric patients. Although the FDA placed a full clinical hold on the DMD trial after a serious adverse event in a pediatric patient, the FDA has partially removed the clinical hold and defined how PCS100 can resume clinical trials in DMD. Once we have obtained adequate funding, we plan to develop PCS100 in rare adult fibrotic related diseases such as focal segmental glomerulosclerosis, idiopathic pulmonary fibrosis or Scleroderma. At the present time, we are evaluating the potential GMP manufacturing facilities and the potential indications for PCS100.

**Manufacturing and Clinical Supplies**

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third party contract manufacturing organizations, or CMOs, for the supply of current good manufacturing practice-grade, or cGMP-grade, clinical trial materials and commercial quantities of our product candidates and products, if approved. We require all of our CMOs to conduct manufacturing activities in compliance with cGMP. We have assembled a team of experienced employees and consultants to provide the necessary technical, quality and regulatory oversight of our CMOs.

We anticipate that these CMOs will have the capacity to support both clinical supply and commercial-scale production, but we do not have any formal agreements at this time with any of these CMOs to cover commercial production.

We also may elect to pursue additional CMOs for manufacturing supplies of drug substance and finished drug product in the future. We believe that our standardized manufacturing process can be transferred to a number of other CMOs for the production of clinical and commercial supplies of our product candidates in the ordinary course of business.

**Competition**

Many of our potential competitors may have significantly greater financial resources, a more established presence in the market, and more expertise in research and development, manufacturing, pre-clinical and clinical testing, obtaining regulatory approvals and reimbursement, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These potential competitors may also compete with us in recruiting and retaining top qualified scientific, sales, marketing and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

The key competitive factors affecting each of our products, if approved, are likely to include the efficacy, safety, convenience and price of the products relative to other approved products used on-label or off-label for each unmet medical need condition. Although preliminary clinical data exists to support the possibility of improved efficacy and safety profiles for our drugs, more in-depth randomized, controlled studies are required for our products to determine if our preliminary findings will support the approval in the designated unmet medical need indication.

For PCS499, there are currently no FDA-approved drugs for the treatment of patients with NL, and few drugs are used off-label for NL given the lack of efficacy and/or side effect concerns.

For PCS12852, the competitive factors will include establishing marketing penetration against other 5HT4 receptor agonists such as Entereg® and Motegrity®. The market penetration will depend on an improved safety profile potentially due to the very selective 5HT4 receptor binding by PCS12852 and similar or greater efficacy in the treatment of gastrointestinal motility dysfunction disorders.

For PCS6422, the competitive factors will be related to the efficacy and safety of the product when used in combination with existing cytotoxic drugs such as capecitabine and fluoropyrimidines compared to the efficacy and safety when these cytotoxic agents are administered without PCS6422 or with other reversible enzyme inhibitors. The market penetration will depend on how much improvement will occur in the efficacy and safety profiles when administered in combination with PCS6422. Currently, there are no other reversible or irreversible enzyme inhibitor products approved in the US, which may make PCS6422 the first DPD inhibitor available in the US.

For PCS11T, the competitive factors will include establishing marketing penetration against the existing irinotecan product (Camptosar®) and the newer liposomal irinotecan product (Onivyde®). The establishment of that market will be based upon improved efficacy and/or safety of PCS11T. For PCS100, the competitive factors will be contingent on the indication chosen for the product. For the adult fibrotic conditions currently being evaluated, very few treatment options are currently approved and are usually limited in efficacy and/or safety. For the DMD indication, the existing therapies are either limited for use in patients with specific genetic mutations or may show initial improvements in the treatment of DMD, but the improvement diminishes over time and, therefore, new treatments are still needed.

Our commercial opportunity for any of our product candidates could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, less expensive, more convenient or easier to administer, or have fewer or less severe side effects, than any products that we may develop. Our competitors also may obtain FDA, EMA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

**Intellectual Property**

Our success will depend in large part on our ability and that of our licensors to:

- obtain and maintain international and domestic patent and other legal protections for the proprietary technology, inventions and improvements we consider important to our business;
- prosecute and defend our future patents, once obtained;
- preserve confidentiality of our own and our licensed methods, processes and know-how; and
- operate without infringing the patents and proprietary rights of other parties.

Although we rely extensively on licensing patents from third parties, we intend to seek appropriate patent protection for product candidates in our research and development programs, where applicable, and their uses by filing patent applications in the United States and other selected countries. We intend for these patent applications to cover, where possible, claims for compositions of matter, medical uses, processes for preparation and formulations.

Our current patent portfolio consists of the number of patents related to our drug candidates licensed from each third party licensor. In addition to the international patents and/or international and U.S. patent applications licensed from our third party licensors, we have licensed at least the following number of U.S. patents:

| | CoNCERT | Yuhan | Elion | Aposense | Akashi | Total |
|---|---|---|---|---|---|---|
| U.S. patents | 9 | 4 | 2 | 3 | 2 | 20 |

We also rely on trade secrets, proprietary know-how and continuing innovation to develop and maintain our competitive position, especially when we do not believe that patent protection is appropriate or can be obtained. We seek protection of these trade secrets, proprietary know-how and any continuing innovation, in part, through confidentiality and proprietary information agreements. However, these agreements may not provide meaningful protection for, or adequate remedies to protect, our technology in the event of unauthorized use or disclosure of information. Furthermore, our trade secrets may otherwise become known to, or be independently developed by, our competitors.

**License Agreements**

The following descriptions of our license agreements are only summaries. You should also refer to the copies of such agreements which have been filed as part of this registration statement.

***License Agreement with CoNCERT Pharmaceuticals, Inc.***

On October 4, 2017, Promet entered into a license agreement with CoNCERT (the "CoNCERT Agreement"). On March 19, 2018, we, Promet, and CoNCERT entered into an Amended Option Licensing Agreement ("March Amendment") that, among other things, assigned the CoNCERT Agreement from Promet to us and we exercised the exclusive commercial license option for the PCS499 compound from CoNCERT.

The CoNCERT Agreement provides us with an exclusive (including as to CoNCERT) royalty-bearing license to CoNCERT's patent rights and know-how to develop, manufacture, use, sub-license and commercialize compounds (PCS499 and each metabolite thereof) and pharmaceutical products with such compounds worldwide. We are required to pay CoNCERT royalties, on a product by product basis, on worldwide net sales, as follows:

- 4% of the net sales of the portion less than or equal to $100 million;
- 5% of the net sales of the portion greater than $100 million and less than or equal to $500 million;
- 6% of the net sales of the portion greater than $500 million and less than or equal to $1.0 billion;
- 10% of the net sales of the portion greater than $1 billion if such sales are made by us or our affiliates; and with respect to net sales made by us or any of our affiliates, we will pay 10% of net sales and with respect to sales by our sublicensees, we will pay the greater of (i) 6% or (ii) 50% of all payment received by us with respect to such sublicensee.

We will also pay 15% of any sublicense revenue earned by us for a period equivalent to the royalty term (as defined in the CoNCERT Agreement) until the earliest of (a) our raising $8 million of gross proceeds and (b) CoNCERT being able to sell its shares of our common stock without restrictions pursuant to the terms of the amended Agreement. All other terms of the CoNCERT Agreement remained unchanged.

We will incur royalty obligations to CoNCERT on a country-by-country and product-by-product basis that expire on a country-by-country and product-by-product basis on the later of (i) expiration or invalidation of the last patent rights covering such product in such country or (ii) the tenth anniversary of the date of the first commercial sale to a non-sublicensee third party of such product in such country.

We are required to use commercially reasonable efforts, at our sole cost and expense, to develop and obtain regulatory approval for one product in the U.S. and at least one other major market and, subject to obtaining regulatory approval in the applicable major market, commercialize one product in the U.S. and at least one other major market. CoNCERT may terminate the agreement if, following written notice and a 60 day opportunity to demonstrate a plan to cure, it believes that we are not using commercially reasonable efforts to develop and obtain regulatory approval for one product in the U.S. and in at least one other major market for any consecutive nine month period.

The term of the CoNCERT Agreement continues in full force and effect until the expiration of the last royalty term. On a country-by-country and product-by-product basis, upon the expiration of the royalty term in such country with respect to such product, we shall have a fully paid-up, perpetual, irrevocable license to such intellectual property with respect to such product in such country. In the event of a material breach of the CoNCERT Agreement, either party may terminate the agreement provided such breach is not cured in the 90 days following written notice of the breach (which period is shortened to 15 days for a payment breach). In addition, either party may terminate the agreement upon an assignment for the benefit of creditors or the filing of an insolvency proceeding by or against the other party that is not dismissed within 90 days of such filing.

***License Agreement with Yuhan Corporation***

On August 19, 2020, we entered into a License Agreement (the "Yuhan License Agreement") with Yuhan, pursuant to which we acquired an exclusive license to develop, manufacture and commercialize PCS12852 globally, excluding South Korea.

As consideration for the Yuhan License Agreement, we issued to Yuhan 250,000 shares of common stock (based upon an $8.00 per share price), subject to adjustment based on the offering price in this offering (but not less than 181,818 shares). As additional consideration, we will pay Yuhan development and regulatory milestone payments (a portion of which are payable in shares of our common stock based on the volume weighted average trading price during the period prior to such achievement and a portion of which are payable in cash) upon the achievement of certain milestones, which primarily consist of dosing a patient in pivotal trials or having a drug indication approved by a regulatory authority in the United States or another country. The amount of such development and regulatory milestone payments increases if Yuhan does not invest at least $3.0 million in this offering. In addition, we must pay Yuhan one-time sales milestone payments based on the achievement during a calendar year of one or more thresholds for annual sales for products made and pay royalties based on annual licensing sales. We are also required to split any milestone payments received with Yuhan based on any sub-license agreement we may enter into.

We are required to use commercially reasonable efforts, at our sole cost and expense, in conjunction with a joint Processa-Yuhan Board to oversee such commercialization efforts, to research, develop and commercialize products in one or more countries, including meeting specific diligence milestones that consist of: (i) preparing a first draft of the product development plan within 90 days; (ii) requesting an FDA pre-IND meeting for a product within 6 months; (iii) dosing a first patient in a Phase 2A clinical trial with a product within 24 months; and (iv) dosing a first patient with a product in a Phase 2B clinical trial, Phase 3 clinical trial or other pivotal clinical trial with a product within 48 months. Either party may terminate the agreement in the event of a material breach of the agreement that has not been cured following written notice and a 60-day opportunity to cure such breach (which is shortened to 15 days for a payment breach).

***License Agreement with Elion Oncology, Inc.***

On August 23, 2020, we entered into the Elion License Agreement with Elion, pursuant to which we acquired an exclusive license to develop, manufacture and commercialize PCS6422 globally.

The grant of license is conditioned on the closing on this offering with at least $15 million in gross proceeds and the successful up-listing to Nasdaq by October 30, 2020. Following the satisfaction of the conditions, we must pay Elion $100,000 and issue Elion 500,000 shares of our common stock, subject to increase in the event the price per share is this offering is less than $8.34 per share. Such shares will be subject to a lock-up, with 50% of such shares released from such lock up after six months and the remaining 25% tranches to be released following 9 months and 12 months, respectively.

As additional consideration, we will pay Elion development and regulatory milestone payments (a portion of which are payable in shares of our common stock and a portion of which are payable in cash) upon the achievement of certain milestones, which include 100,000 shares of common stock due on the first two annual anniversaries of the effective date of the agreement, FDA or other regulatory approval and dosing a patient. In addition, we must pay Elion one-time sales milestone payments based on the achievement during a calendar year of one or more thresholds for annual sales for products made and pay royalties based on annual licensing sales. We are also required to split any milestone payments received with Elion based on any sub-license agreement we may enter into.

We are required to use commercially reasonable efforts, at our sole cost and expense to research, develop and commercialize products in one or more countries, including meeting specific diligence milestones that consist of: (i) dosing a first patient in a Phase 1B clinical trial with a product within 12 months; and (ii) dosing a first patient with a product in a Phase 2 or 3 clinical trial within 48 months. Either party may terminate the agreement in the event of a material breach of the agreement that has not been cured following written notice and a 90-day opportunity to cure such breach (which is shortened to 15 days for a payment breach).

***License Agreement with Aposense, Ltd.***

On May 24, 2020, we entered into an exclusive License Agreement with Aposense, Ltd., ("Aposense"), pursuant to which we were granted a contingent license in Aposense's patent rights and know-how to develop and commercialize their next generation irinotecan cancer drug, PCS11T (formerly known as ATT-11T).

The Aposense Agreement provides us with an exclusive worldwide license (excluding China), to research, develop and commercialize products comprising or containing PCS11T. The grant of license is conditioned on the following being satisfied within 9 months of May 24, 2020 (or the agreement shall terminate): (i) our closing of an equity financing and successful up-listing to Nasdaq and (ii) Aposense obtaining the approval of the Israel Innovation Authority for the consummation of the transactions contemplated by the Aposense Agreement, which approval was obtained on August 24, 2020.

Within five business days of satisfying the conditions, we must issue Aposense a number of shares of common stock determined by dividing $2.5 million by the price per share paid by such investors in this offering. Such shares will be subject to a lock-up, with 40% of such shares released from such lock up after six months and the remaining 30% tranches to be released upon completion of the next two subsequent quarters. As additional consideration, we will pay Aposense development and regulatory milestone payments (up to $3.0 million per milestone) upon the achievement of certain milestones, which primarily consist of having a drug indication approved by a regulatory authority in the United States or another country. In addition, we must pay Aposense one-time sales milestone payments based on the achievement during a calendar year of one or more thresholds for annual sales for products made and pay royalties based on annual licensing sales. We are also required to split any milestone payments we receive with Aposense based on any sub-license agreement we may enter into.

We are required to use commercially reasonable efforts, at our sole cost and expense, to research, develop and commercialize products in one or more countries, including meeting specific diligence milestones that consist of (i) submitting an IND for a drug indication within 30 months following the satisfaction of the license conditions above; (ii) dosing of a first patient with a product within 42 months following the satisfaction of the license conditions above; (iii) dosing of a first patient with a product in a pivotal clinical trial within 72 months following the satisfaction of the license conditions above and (iv) an NDA submission within 120 months following the satisfaction of the license conditions above. Either party may terminate the agreement in the event of a material breach of the license agreement that has not been cured following written notice and a 90-day opportunity to cure such breach (which is shortened to 15 days for a payment breach).

***License Agreement with Akashi Therapeutics, Inc.***

On August 29, 2019, we entered into an exclusive license agreement (the "Akashi Agreement") with Akashi Therapeutics, Inc. ("Akashi") to develop and commercialize an anti-fibrotic, anti-inflammatory drug, PCS100, which also promotes healthy muscle fiber regeneration. In previous clinical trials in Duchenne Muscular Dystrophy (DMD), PCS100 showed promising improvement in the muscle strength of non-ambulant pediatric patients. Although the FDA placed a clinical hold on the DMD trial after a full serious adverse event in a pediatric patient, the FDA has partially removed the clinical hold and defined how PCS100 can resume clinical trials in DMD. Once we have obtained adequate funding, we plan to develop PCS100 in rare adult fibrotic related diseases such as focal segmental glomerulosclerosis, idiopathic pulmonary fibrosis or Scleroderma.

The Akashi Agreement provides us with a worldwide license to research, develop, make and commercialize products comprising or containing PCS100. As partial consideration for the license, we paid $10,000 to Akashi upon full execution of the Akashi Agreement. This upfront payment was expensed as a research and development cost. As additional consideration, we will pay Akashi development and regulatory milestone payments (up to $3.0 million per milestone) upon the achievement of certain milestones, which primarily consist of having a drug indication approved by a regulatory authority in the United States or another country. In addition, we must pay Akashi one-time sales milestone payments based on the achievement during a calendar year of one or more thresholds for annual sales for products made and pay royalties based on annual licensing sales. We are also required to split any milestone payments we receive with Akashi based on any sub-license agreement we may enter into.

We are required to use commercially reasonable efforts, at our sole cost and expense, to research, develop and commercialize products in one or more countries, including meeting specific diligence milestones that consist of (i) requesting a meeting with the FDA for a first indication within 18 months of the date of the agreement, (ii) submitting an IND for a drug indication on or before June 30, 2022 and (iii) initiating a Phase 1 or 2 trial for a drug indication on or before December 30, 2022. Either party may terminate the agreement in the event of a material breach of the license agreement that has not been cured following written notice and a 60-day opportunity to cure such breach (which is shortened to 15 days for a payment breach).

**Government Regulation**

The FDA and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements upon companies involved in the clinical development, manufacture, marketing and distribution of drugs, such as those we are developing. These agencies and other federal, state and local entities regulate, among other things, the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion, distribution, post-approval monitoring and reporting, sampling and export and import of our product candidates.

***U.S. Government Regulation***

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of pre-clinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND application, which must become effective before human clinical trials may begin;

- approval by an independent IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices (GCP) requirements to establish the safety and efficacy of the proposed drug product for each indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to commercial marketing or sale of the drug in the United States; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy (REMS) or to conduct a post-approval study.

***Pre-clinical studies***

Before testing any biological product candidate, including our product candidates, in humans, the product candidate must undergo rigorous pre-clinical testing. The pre-clinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of pre-clinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the pre-clinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND.

An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. Some long-term pre-clinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time, the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

***Clinical trials***

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by, or under control of, the trial sponsor, in accordance with GCPs, which include the requirement that all research patients provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Information about most clinical trials must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website. Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in some cases for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the drug.

- Phase 2 clinical trials involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.

- Phase 3 clinical trials generally involve a larger number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow up. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of a biologics license application, or BLA.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. The FDA or the sponsor may suspend or terminate a clinical trial at any time, or the FDA may impose other sanctions on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk. Similarly, an IRB can refuse, suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Concurrently with clinical trials, companies usually complete additional pre-clinical studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

***Marketing Approval***

Assuming successful completion of the required clinical testing, the results of the pre-clinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision.

In addition, under the Pediatric Research Equity Act of 2003, as amended and reauthorized, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

The FDA also may require submission of a REMS plan to ensure that the benefits of the drug outweigh its risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical trials or pre-clinical studies in order for FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

***Orphan drug designation***

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product in the United States. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety, by providing a major contribution to patient care or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication that could be used "off-label" by physicians in the orphan indication, even though the competitor's product is not approved in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do of the same product, as defined by the FDA, for the same indication we are seeking, or if our product candidate is determined to be contained within the scope of the competitor's product for the same indication or disease. If one of our products designated as an orphan drug receives marketing approval for an indication broader than that which is designated, it may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union, or EU, has similar, but not identical, requirements and benefits.

***Expedited review and approval***

The FDA has various programs, including fast track designation, accelerated approval, priority review, and breakthrough therapy designation, which are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. The FDA may review sections of the NDA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

The FDA may give a priority review designation to drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Under the new PDUFA agreement, these six- and ten-month review periods are measured from the "filing" date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast track designation are also likely to be considered appropriate to receive a priority review.

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug may be subject to accelerated withdrawal procedures.

Moreover, under the provisions of the Food and Drug Administration Safety and Innovation Act, passed in July 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, fast track designation, priority review, and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process. We may explore some of these opportunities for our product candidates as appropriate.

***Post-approval requirements***

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product;
- complete withdrawal of the product from the market or product recalls;

- safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warning or other safety information about the product;

- fines, warning letters or holds on post-approval clinical trials;

- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals; product seizure or detention, or refusal to permit the import or export of products; or

- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

***Other Regulatory Matters***

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Manufacturing, sales, promotion and other activities following product approval are subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including Centers for Medicare and Medicaid Services (CMS), other divisions of the Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, and state and local governments.

For example, in the United States, sales, marketing and scientific and educational programs also must comply with state and federal fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws. These laws include the following:

- the federal Anti-Kickback Statute, which makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Moreover, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA), provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal civil and criminal false claims and civil monetary penalties laws, including the civil False Claims Act that can be enforced by private citizens through civil whistleblower or qui tam actions, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the Federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments and other transfers of value to physicians and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require biotechnology companies to report information on the pricing of certain drug products; and state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant civil, criminal and administrative penalties, including damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, injunctions, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts.

***U.S. Patent-Term Restoration and Marketing Exclusivity***

Depending upon the timing, duration and specifics of FDA approval of any future product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent-term restoration period is generally one-half the time between the effective date of an IND or the issue date of the patent, whichever is later, and the submission date of an NDA plus the time between the submission date of an NDA or the issue date of the patent, whichever is later, and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application (ANDA) or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

***European Union Drug Development***

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Although the European Union Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority (NCA) and one or more Ethics Committees (ECs). Under the current regime, all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

The EU clinical trials legislation currently is undergoing a transition process mainly aimed at harmonizing and streamlining clinical-trial authorization, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. Recently enacted Clinical Trials Regulation EU No 536/2014 ensures that the rules for conducting clinical trials in the EU will be identical. In the meantime, Clinical Trials Directive 2001/20/EC continues to govern all clinical trials performed in the EU.

***European Union Drug Review and Approval***

In the European Economic Area (EEA), which is comprised of the 26 Member States of the European Union (including Norway and excluding Croatia), Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization (MA). There are two types of marketing authorizations:

- The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use (CHMP) of the EMA, and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.

- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the European Union, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure, an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State (RMS). The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics (SmPC), and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SmPC, labeling or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Member States Concerned).

Under the above described procedures, before granting the MA, EMA or the competent authorities of the Member States of the European Union make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. Similar to the U.S. patent term-restoration, Supplementary Protection Certificates (SPCs) serve as an extension to a patent right in Europe for up to five years. SPCs apply to specific pharmaceutical products to offset the loss of patent protection due to the lengthy testing and clinical trials these products require prior to obtaining regulatory marketing approval.

***Coverage and Reimbursement***

Sales of our products will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance, and managed healthcare organizations. There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, for example, principal decisions about reimbursement for new products are typically made by CMS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

***Healthcare Reform***

The United States government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price-controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs. For example, the ACA was passed in March 2010 which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs.

The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the HHS Secretary as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price (AMP), to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. Effective April 1, 2020, Medicaid rebate liability will be expanded to include the territories of the United States as well. Additionally, for a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial, Congressional and executive branch challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

Additionally, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, at the federal level, the Trump administration released a "Blueprint" to lower prescription drug prices and reduce out-of-pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. Additionally, on January 31, 2019, HHS Office of Inspector General proposed modifications to federal Anti-Kickback Statute safe harbors which, among other things, may affect rebates paid by manufacturers to Medicare Part D plan sponsors, Medicaid managed care organizations, and those entities' pharmacy benefit managers, the purpose of which is to further reduce the cost of drug products to consumers. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Moreover, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan likely will be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private third-party payors often follow Medicare coverage policy and payment limitations in setting their own payment rates.

**Combination with Heatwurx**

On October 2, 2017, Heatwurx, Inc. ("Heatwurx") entered into a transaction pursuant to the Asset Purchase Agreement with Promet Therapeutics, LLC, a Delaware limited liability company ("Promet") pursuant to which, on October 4, 2017, Heatwurx acquired all the net assets of Promet, including the rights to the CoNCERT Agreement in exchange for issuing Promet (and CoNCERT) 4,535,121 shares of its common stock. Immediately following the transaction, Promet owned approximately 84% of our common stock and, as part of the Section 351 transaction, held approximately 6% of our common stock for the benefit of CoNCERT, until the CoNCERT transaction had been concluded whereupon CoNCERT took title to their shares. Following the closing, we changed our name from "Heatwurx Inc." to "Processa Pharmaceuticals Inc." and abandoned Heatwurx's prior business plan. We are now pursuing Promet's historical and proposed business.

We accounted for the net asset acquisition transaction as a reverse acquisition in accordance with U.S. GAAP, Financial Accounting Standards Board ("FASB"), Accounting Standards Codification ("ASC") 805-40-45, *Business Combinations – Reverse Acquisitions,* where Promet was considered the accounting acquirer. Accordingly, Promet's historical results of operations replaced our historical results of operations for all periods prior to the transaction. Prior to the acquisition, we had nominal net liabilities and operations. It was considered a non-operating public shell corporation.

**Business Segments**

We manage our business as one segment which includes all activities related to the discovery, development, and commercialization of drug products for the treatment of serious medical conditions. For financial information related to our one segment, see our Consolidated Financial Statements and related notes.

**Employees**

As of June 30, 2020, we had 11 employees (full and part time). None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union and we believe our relationships with our employees are good.

**Facilities**

Our principal executive office is located at 7380 Coca Cola Drive, Suite 106, Hanover, MD 21076. We currently lease approximately 6,500 square feet of office space at this location under a three-year lease agreement until September 2022. We believe our facilities are adequate for our current needs and that suitable additional substitute space would be available if needed.

**Legal Proceedings**

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings. Regardless of outcome, any litigation that we may become involved in can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

## MANAGEMENT

### Executive Officers and Directors

The following table provides information regarding our executive officers and directors as of June 30, 2020:

| Name | Age | Position |
|---|---|---|
| **Executive Officers:** | | |
| David Young, Pharm.D, Ph.D. | 67 | Chairman of the Board of Directors and Chief Executive Officer |
| Patrick Lin | 54 | Chief Business and Strategy Officer and Director |
| Sian Bigora, Pharm.D. | 59 | Chief Development Officer |
| James Stanker | 62 | Chief Financial Officer |
| Wendy Guy | 55 | Chief Administrative Officer |
| **Non-Employee Directors:** | | |
| Justin Yorke | 53 | Director |
| Virgil Thompson | 80 | Director |
| Geraldine Pannu | 51 | Director |

***Executive Officers***

*David Young, Pharm.D., Ph.D.* - Dr. Young has served as our Chairman and Chief Executive Officer since October 4, 2017 and has over 30 years of pharmaceutical research, drug development, and corporate experience. He was a Founder and CEO of Promet Therapeutics, LLC ("Promet") since its formation in August 2015. He served as our interim CFO from October 4, 2017 to September 1, 2018. From 2006 to 2009, prior to joining the Questcor executive management team, Dr. Young served as an independent Director on the Questcor Board of Directors. As an independent director, Dr. Young, representing Questcor, worked with the FDA in developing a process to obtain approval for Acthar (the only commercial product owned by Questcor) in Infantile Spasms (IS), a deadly and debilitating very rare orphan indication. In 2009, Dr. Young joined the Questcor executive management team as Chief Scientific Officer (CSO) in order to obtain IS FDA approval and market exclusivity by completing the New Drug Application (NDA) process, working with FDA on modernizing the label, and leading all aspects of approval including the Advisory Committee Meeting that voted to approve the NDA for IS. During the eight years that Dr. Young was involved with Questcor as an independent director and as its CSO, Questcor transitioned to an orphan drug specialty pharmaceutical company, moving from an outdated Acthar label and near bankruptcy in 2007 to a modernized Acthar label that helped it to achieve sales greater than $750 million per year and the ultimate sale of the company for approximately $5.6 billion in 2014. While serving on Questcor's Board of Directors, Dr. Young was Executive Director & President, U.S. Operations of AGI Therapeutics plc. Dr. Young has also served as the Executive Vice President of the Strategic Drug Development Division of ICON plc, an international CRO, and was the Founder and CEO of GloboMax LLC, a CRO specializing in FDA drug development, purchased by ICON plc in 2003. Prior to forming GloboMax, Dr. Young was a Tenured Associate Professor at the School of Pharmacy, University of Maryland at Baltimore (UMAB), where he led a group of 30 faculty, scientists, postdocs, graduate students and technicians in evaluating the biological properties of drugs and drug delivery systems in animals and humans.

Dr. Young is an expert in small molecule and protein non-clinical and clinical drug development. He has served on FDA Advisory Committees, was Co-Principal Investigator on a FDA-funded Clinical Pharmacology contract, was responsible for the analytical and pharmacokinetic evaluation of all oral products manufactured in the UMAB-FDA contract which led to the Scale-up and Post-Approval Changes (SUPAC) and in-vitro in-vivo correlation (IVIVC) FDA Guidance, taught FDA reviewers as part of the UMAB-FDA contract for five years, has served on National Institutes of Health (NIH) grant review committees, and was Co-Principal Investigator on a National Cancer Institute contract to evaluate new oncology drugs. Dr. Young has met more than 100 times with the FDA on more than 50 drug products and has been a key team member on more than 30 NDA/supplemental NDA approvals. Dr. Young has more than 150 presentations-authored publications-book chapters, including formal presentations to the FDA, FDA Advisory Committees, and numerous invited presentations at both scientific and investment meetings. Dr. Young received his B.S. in Physiology from the University of California at Berkeley, his M.S. in Medical Physics from the University of Wisconsin at Madison, and his Pharm.D. - Ph.D. with emphasis in Pharmacokinetics and Pharmaceutical Sciences from the University of Southern California.

*Patrick Lin* - Mr. Lin has served as our Chief Business & Strategy Officer since October 4, 2017 and has over 20 years of financing and investing experience in the Biopharm Sector. He was Co-Founder and Chairman of the Board of Promet Therapeutics, LLC. He is Founder and, for more than 15 years, Managing Partner of Primarius Capital, a family office that manages public and private investments focused on small capitalization companies. For 10 years prior to forming Primarius Capital, Mr. Lin worked at several Wall Street banking and brokerage firms including Robertson Stephens & Co., E*Offering, and Goldman Sachs & Co. Mr. Lin was Co-Founding Partner of E*Offering. Mr. Lin received an MBA from Kellogg Graduate School of Management, a Master of Engineering Management, and a Bachelor of Science in Business Administration from the University of Southern California. We believe Mr. Lin is qualified to serve on our Board because of his extensive investment experience with publicly traded biotechnology companies.

*Sian Bigora, Pharm.D.* - Dr. Bigora has served as our Chief Development Officer since October 4, 2017 and has over 20 years of pharmaceutical research, regulatory strategy and drug development experience working closely with Dr. Young. She was Co-Founder, Director, and Chief Development Officer at Promet Therapeutics, LLC. Prior to Promet, Dr. Bigora was Vice President of Regulatory Affairs at Questcor Pharmaceuticals (acquired by Mallinckrodt Pharmaceuticals in 2014) from 2009-2015, including leading efforts on modernizing the Acthar Gel label and in obtaining FDA approval in Infantile Spasms, events of material importance to Questcor's subsequent success. During her time at Questcor, she assisted in building an expert regulatory group to address both commercial and development needs for complex products such as Acthar. Dr. Bigora's role at Questcor included heading up the development of a safety pharmacovigilance group and a clinical quality group. Prior to her position at Questcor, Dr. Bigora was Vice President of Clinical and Regulatory Affairs, U.S. Operations of AGI Therapeutics, plc. In this role, she was responsible for the development and implementation of Global Phase 3 studies and interactions with regulatory authorities. Previously, she operated her own consulting company, serving as the regulatory and drug development expert team member for multiple small and mid-sized pharmaceutical companies. Dr. Bigora held multiple positions in regulatory affairs, operations and project management ending as VP of Regulatory Affairs at the Strategic Drug Development Division of ICON, plc, an international CRO, and at GloboMax LLC, a CRO specializing in FDA drug development, purchased by ICON plc in 2003. Prior to GloboMax, she worked in the Pharmacokinetics and Biopharmaceutics Laboratory at the School of Pharmacy, University of Maryland on the FDA funded Clinical Pharmacology contract and UMAB-FDA contract as a clinical scientist and instructor for FDA reviewers. Dr. Bigora received a Pharm.D. from the School of Pharmacy at the University of Maryland at Baltimore. She also completed a Fellowship in Pharmacokinetics and Pediatric Infectious Diseases at the University of Maryland at Baltimore.

*James Stanker* - Mr. Stanker has served as our Chief Financial Officer since September 5, 2018. Mr. Stanker has over 30 years of financial and executive leadership experience in the areas of accounting principles and audit standards, regulatory reporting, and fiscal management and strategy. He has served in a financial leadership role as an audit partner at Grant Thornton from February 2000 until his retirement in August 2016. His responsibilities included managing the audit quality in the Atlantic Coast Market Territory. From 2009 to 2012, he served as the Global Head of Audit Quality for Grant Thornton International. Prior to joining Grant Thornton, Mr. Stanker served as the Chief Financial Officer for a Nasdaq listed company and for a privately-held life science company. Mr. Stanker is a Certified Public Accountant. He has a Bachelor's degree in Aeronautics from San Jose State University and a Master's in Business Administration from California State University, East Bay. He currently serves on the Board of Directors and is Chairman of the Audit Committee of GSE Systems, Inc. Mr. Stanker is also a visiting professor in the George B. Delaplaine School of Business at Hood College.

*Wendy Guy* - Ms. Guy has served as our Chief Administrative Officer since October 4, 2017 and has more than 20 years of experience in business operations. She has worked closely with Dr. Young over the last 18 years in corporate management and operations, human resources, and finance. She was Co-Founder, Director, and Chief Administrative Officer of Promet Therapeutics, LLC. Prior to Promet, Ms. Guy was employed at Questcor Pharmaceuticals (acquired by Mallinckrodt Pharmaceuticals in 2014) as Senior Manager, Business Operation in charge of the Maryland Office for Questcor. During the five years she spent at Questcor, she built a dynamic administrative and contracts team, grew the Maryland Office from two employees to just under 100, and expanded the facility from 1,200 sq. ft. to 15,000 sq. ft. Prior to her position at Questcor, Ms. Guy was Senior Manager, U.S. Operations of AGI Therapeutics, plc. In this role, she was responsible for the day to day business and administrative operations of the company. Previously, she held multiple senior level positions with the Strategic Drug Development Division of ICON, GloboMax, and Mercer Management Consulting. Ms. Guy received an A.A. from Mount Wachusett Community College.

***Non-Employee Directors***

*Justin W. Yorke* - Mr. Yorke has served as a Director since October 2017. Mr. Yorke has over 25 years of experience as an institutional equity fund manager and senior financial analyst for investment funds and investment banks and was appointed as a Director in August 2017. For more than the past 10 years, he has been a manager of the San Gabriel Fund, JMW Fund and the Richland Fund whose primary activity is investing in public and private companies in the United States. Mr. Yorke served as non-executive Chairman of Jed Oil and a Director/CEO at JMG Exploration. Mr. Yorke was a Fund Manager and Senior Financial Analyst, based in Hong Kong, for Darier Henstch, S.A., a private Swiss bank, where he managed their $400 million Asian investment portfolio. Mr. Yorke was an Assistant Director and Senior Financial Analyst with Peregrine Asset Management, which was a unit of Peregrine Securities, a regional Asian investment bank. Mr. Yorke was a Vice President and Senior Financial Analyst with Unifund Global Ltd., a private Swiss Bank, as a manager of its $150 million Asian investment portfolio. Mr. Yorke has a B.A. from University of California, Los Angeles. We believe Mr. Yorke is qualified to serve on our Board because of his extensive investment experience.

*Virgil Thompson* **-** Mr. Thompson has served as a Director since October 2017 and previously served on the Board of Directors at Promet Therapeutics, LLC. He served as a Director of Mallinckrodt Pharmaceuticals (formerly Questcor Pharmaceuticals), and Director of GenZ Corporation, both companies he resigned from in 2017. From July 2009 to July 2015, he served as Chief Executive Officer and Director of Spinnaker Biosciences, Inc., and now serves as Chairman of the Board. Mr. Thompson also served as Chairman of the Board of Aradigm Corporation, as well as of Questcor Pharmaceuticals, Inc. until Questcor was acquired by Mallinckrodt in August 2014. Mr. Thompson served as the Chief Executive Officer and as a Director of Angstrom Pharmaceuticals, Inc. from 2002 until 2007. From 2000 until 2002, Mr. Thompson was Chief Executive Officer and a Director of Chimeric Therapies, Inc. From 1999 until 2000, Mr. Thompson was President, Chief Operating Officer and, from 1994, a Director of Bio-Technology General Corporation (subsequently Savient Pharmaceuticals, Inc.). Mr. Thompson obtained a bachelor's degree in Pharmacy from the University of Kansas and a J.D. degree from the George Washington University Law School. We believe Mr. Thompson is qualified to serve on our Board because of his extensive industry and Board experience with publicly traded biotechnology companies.

*Geraldine Liu Pannu* - Ms. Pannu has served as a Director since February 13, 2020. Ms. Pannu has over 25 years of experience in investment and financial management, fund operations, consulting and marketing. Since January 2020, she has been the Founding and Managing Partner of GLTJ Pioneer Capital, a firm that specializes in land acquisition, entitlement and vertical development of multifamily, student and senior housing in the San Francisco Bay Area. From March 2007 to December 2016, Ms. Pannu was the COO and Managing Partner for ChinaRock Capital Management, a leading hedge and venture capital fund company. She previously worked at McKinsey & Co, Monitor Company as management consultant. She had successfully raised capital for several hedge, venture capital and real estate funds. She also helped start-up companies to expand and diversify business categories, client verticals and grow revenue. Ms. Pannu was born in Shanghai and grew up in Hong Kong. She received her Bachelor of Business Administration degree from the Chinese University of Hong Kong and an MBA from Harvard Business School. She is fluent in English, Mandarin, Cantonese and Shanghainese. We believe Ms. Pannu is qualified to serve on our Board because of her extensive investment experience.

***Board Composition***

We currently have five directors on our Board. Our Board of Directors may consider a broad range of factors relating to the qualifications and background of nominees, which may include diversity, which is not only limited to race, gender or national origin. We have no formal policy regarding Board diversity. Our Board of Directors' priority in selecting Board members is identification of persons who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among Board members, knowledge of our business, understanding of the competitive landscape and professional and personal experiences and expertise relevant to our growth strategy. Our directors hold office until their successors have been elected and qualified or until the earlier of their death, resignation or removal.

***Director Independence***

The Nasdaq Marketplace Rules require a majority of a listed company's Board of Directors to be comprised of independent directors within one year of listing. In addition, the Nasdaq Marketplace Rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act.

Under Rule 5605(a)(2) of the Nasdaq Marketplace Rules, a director will only qualify as an "independent director" if, in the opinion of our Board of Directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3 of the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the Board of Directors, or any other Board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries.

Our Board of Directors has reviewed the composition of our Board of Directors and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our Board of Directors has determined that each of Justin Yorke, Virgil Thompson and Geraldine Pannu is an "independent director" as defined under Rule 5605(a)(2) of the Nasdaq Marketplace Rules. Our Board of Directors also determined that the directors who serve on our audit committee, our compensation committee, and our nominating and corporate governance committee satisfy the independence standards for such committees established by the SEC and the Nasdaq Marketplace Rules, as applicable. In making such determinations, our Board of Directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances our Board of Directors deemed relevant in determining independence, including the beneficial ownership of our capital stock by each non-employee director. There are no family relationships among any of our directors or executive officers.

***Committees of the Board of Directors***

Each of the below committees will have a written charter approved by our Board of Directors, effective upon completion of this offering. Each of the committees report to our Board of Directors as such committee deems appropriate and as our Board of Directors may request. Upon completion of this offering, copies of each charter will be posted on the investor relations section of our website. Members serve on these committees until their resignation or until otherwise determined by our Board of Directors. In addition, from time to time, special committees may be established under the direction of our Board of Directors when necessary to address specific issues.

***Audit Committee***

Our audit committee is comprised of Justin Yorke, Virgil Thompson and Geraldine Pannu with Justin Yorke serving as chairman of the committee. Our Board of Directors has determined that each member of the audit committee meets the independence requirements of Rule 10A-3 under the Exchange Act and the applicable Nasdaq Listing Rules and has sufficient knowledge in financial and auditing matters to serve on the audit committee. Our Board of Directors has determined that Justin Yorke is an "audit committee financial expert" within the meaning of the SEC regulations and the applicable Nasdaq Listing Rules. The audit committee's responsibilities include:

- selecting a firm to serve as the independent registered public accounting firm to audit our financial statements;
- ensuring the independence of the independent registered public accounting firm;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and that firm, our interim and year-end operating results;
- establishing procedures for employees to anonymously submit concerns about questionable accounting or audit matters;
- considering the effectiveness of our internal controls and internal audit function;
- reviewing material related-party transactions or those that require disclosure; and
- approving or, as permitted, pre-approving all audit and non-audit services to be performed by the independent registered public accounting firm.

***Compensation Committee***

Our compensation committee is comprised of Justin Yorke, Virgil Thompson and Geraldine Pannu with Geraldine Pannu serving as chairman of the committee. Each member of this committee is a non-employee director, as defined by Rule 16b-3 promulgated under the Exchange Act, and an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended (the "Code"). Our Board of Directors has determined that each member of the compensation committee is "independent" as defined in the Nasdaq Listing Rules. The composition of our compensation committee meets the requirements for independence under the Nasdaq Listing Rules, including the applicable transition rules. The compensation committee's responsibilities include:

- reviewing and approving, or recommending that our Board of Directors approve, the compensation of our executive officers;
- reviewing and recommending to our Board of Directors the compensation of our directors;
- reviewing and recommending to our Board of Directors the terms of any compensatory agreements with our executive officers;
- administering our stock and equity incentive plans;
- reviewing and approving or making recommendations to our Board of Directors with respect to, incentive compensation and equity plans; and
- reviewing all overall compensation policies and practices.

***Nominating and Governance Committee***

Our nominating and governance committee is comprised of Justin Yorke, Virgil Thompson and Geraldine Pannu with Virgil Thompson as the chairman of the committee. Our Board of Directors has determined that each member of the nominating and corporate governance committee is "independent" as defined in the applicable Nasdaq Listing Rules. The nominating and corporate governance committee's responsibilities include:

- identifying and recommending candidates for membership on our Board of Directors;
- recommending directors to serve on Board committees;
- reviewing and recommending our corporate governance guidelines and policies;
- reviewing proposed waivers of the code of conduct for directors and executive officers;
- evaluating, and overseeing the process of evaluating, the performance of our Board of Directors and individual directors; and
- assisting our Board of Directors on corporate governance matters.

***Leadership Structure and Risk Oversight***

Our Board of Directors is currently chaired by David Young, Pharm.D, Ph.D., who also serves as our Chief Executive Officer. Our Board of Directors does not have a policy regarding the separation of the roles of Chief Executive Officer and Chairman of the Board of Directors, as our Board of Directors believes it is in our best interest to make that determination based on our position and direction and the membership of the Board of Directors. Our Board of Directors has determined that having an employee director serve as Chairman is in the best interest of our stockholders at this time because of the efficiencies achieved in having the role of Chief Executive Officer and Chairman combined, and because the detailed knowledge of our day-to-day operations and business that the Chief Executive Officer possesses greatly enhances the decision-making processes of our Board of Directors as a whole. We have a governance structure in place, including independent directors, designed to ensure the powers and duties of the dual role are handled responsibly. We do not have a lead independent director.

Our Board of Directors oversees the management of risks inherent in the operation of our business and the implementation of our business strategies. Our Board of Directors performs this oversight role by using several different levels of review. In connection with its reviews of our operations and corporate functions, our Board of Directors addresses the primary risks associated with those operations and corporate functions. In addition, our Board of Directors reviews the risks associated with our business strategies periodically throughout the year as part of its consideration of undertaking any such business strategies.

Each of our Board committees also oversees the management of our risks that fall within the committee's areas of responsibility. In performing this function, each committee has full access to management, as well as the ability to engage advisors. Our Chief Executive Officer reports to the audit committee and is responsible for identifying, evaluating and implementing risk management controls and methodologies to address any identified risks. In connection with its risk management role, our audit committee meets privately with representatives from our independent registered public accounting firm and our Chief Executive Officer. The audit committee oversees the operation of our risk management program, including the identification of the primary risks associated with our business and periodic updates to such risks, and reports to our Board of Directors regarding these activities.

***Compensation Committee Interlocks and Insider Participation***

None of the members of our compensation committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the Board of Directors or compensation committee of any entity that has one or more executive officers serving on our Board of Directors or compensation committee.

***Code of Business Conduct and Ethics***

We maintain a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Our code of business conduct and ethics will be available on our website at *www.processapharmaceuticals.com*. We intend to disclose any amendments to the code, or any waivers of its requirements, on our website or in a Current Report on Form 8-K.

## EXECUTIVE AND DIRECTOR COMPENSATION

***Summary Compensation Table***

The following table and footnotes show information regarding the total compensation paid or accrued during the years ended December 31, 2019 and 2018 to our Chairman and Chief Executive Officer and executive officers (our "named executive officers").

| Name and Principal Position | Year | Salary ($) | Option Awards ($) [2] | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|---|
| **David Young** | 2019 | - | 163,202 | - | 163,202 |
| **Chairman and Chief Executive Officer** | 2018 | - | - | - | - |
| **Patrick Lin** | 2019 | 52,500 | 163,202 | - | 215,702 |
| **Chief Business and Strategy Officer** | 2018 | 44,479 | - | - | 44,479 |
| **Sian Bigora** | 2019 | 52,500 | 163,202 | - | 215,702 |
| **Chief Development Officer** | 2018 | 50,750 | - | - | 50,750 |
| **Wendy Guy** | 2019 | 87,500 | 163,202 | - | 250,702 |
| **Chief Administrative Officer** | 2018 | 87,500 | - | - | 87,500 |
| **James Stanker** | 2019 | 87,500 | 163,202 | - | 250,702 |
| **Chief Financial Officer [1]** | 2018 | 29,167 | 700,440 | 10,800[3] | 740,407 |

(1) Mr. Stanker started with the Company September 1, 2018.

(2) Reflects the aggregate grant date fair value of equity awards to each named executive officer, calculated in accordance with FASB ASC Topic 718. Refer to "Note 10 – Stock-Based Compensation" in our December 31, 2019 audited consolidated financial statements included elsewhere in this prospectus for a discussion of the assumptions used in calculating the award amount.

(3) Reflects consulting fees paid prior to Mr. Stanker joining the Company as CFO.

***Employment Agreements***

We do not currently have any executive employment agreements with any of our named executive officers in connection with their employment with us other than our employment agreement with James Stanker.

Pursuant to the Company's employment agreement with James Stanker, Mr. Stanker receives a base salary of $87,500. Mr. Stanker's options shall vest in full upon a Change in Control (as defined in the employment agreement) and if terminated without Cause or for Good Reason (also defined in the employment agreement) in connection therewith, he shall also receive six months of base salary as a severance payment. Mr. Stanker is entitled to participate in all employee benefits available to employees of the Company. The employment agreement also includes confidentiality provisions.

***Processa Pharmaceuticals, Inc. 2019 Omnibus Incentive Plan***

We maintain an Omnibus Plan that provides us with the authority to issue up to 500,000 shares of our common stock to eligible participants. The two complementary goals of the Omnibus Plan are to attract and retain outstanding individuals to serve as our officers, directors, employees, and consultants and to increase stockholder value by providing participants incentives to increase stockholder value by offering the opportunity to acquire shares of our common stock, receive monetary payments based on the value of our common stock and receive other incentive compensation on the potentially favorable terms that the Plan provides. The following is a summary of the material provisions of the Omnibus Plan:

*Administration.* The Omnibus Plan is administered by our Board of Directors, the compensation committee of the Board of Directors, any other committee of the Board, any subcommittee of the compensation committee or one or more of our officers to whom the Board or compensation committee has delegated authority, which are collectively referred to as the "Administrator." The Administrator has the authority to interpret the Omnibus Plan or award agreements entered into with respect to the Omnibus Plan; make, change, and rescind rules and regulations relating to the Omnibus Plan; make changes to, or reconcile any inconsistency in, the Omnibus Plan or any award or agreement covering an award; and take any other action needed to administer the Omnibus Plan.

*Eligibility; Participant Award Limits.* The Administrator may designate any of the following as a participant under the Omnibus Plan: any officer or employee, or individuals engaged to become an officer or employee, of our company or our affiliates; consultants of our company or our affiliates; and our directors, including our non-employee directors.

*Types of Awards.* The Omnibus Plan permits the Administrator to grant stock options, stock appreciation rights, performance units, shares of common stock, restricted stock, restricted stock units, cash incentive awards, dividend equivalent units, or any other type of award permitted under the Omnibus Plan. The Administrator may grant any type of award to any participant it selects, but only our employees or our subsidiaries' employees may receive grants of incentive stock options within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended (the "Code"). Awards may be granted alone or in addition to, in tandem with, or (subject to the repricing prohibition described below) in substitution for any other award (or any other award granted under another plan of our company or any affiliate, including the plan of an acquired entity).

*Shares Reserved under the Omnibus Plan.* An aggregate of 500,000 shares of our common stock, adjusted for the one for seven reverse stock split completed on December 23, 2019, were initially available for issuance under the Omnibus Plan. We may issue all reserved shares pursuant to the exercise of incentive stock options. The number of shares reserved for issuance under the Omnibus Plan will be reduced on the date of the grant of any award by the maximum number of shares, if any, that may become payable with respect to which such award is granted. However, an award that may be settled solely in cash will not deplete the Omnibus Plan's share reserve at the time the award is granted. If (a) an award lapses, expires, is canceled, or terminates without issuance of shares or is settled in cash, (b) the Administrator determines that the shares granted under an award will not be issuable because the conditions for issuance will not be satisfied, (c) shares are forfeited under an award, or (d) shares are issued under any award and we reacquire them pursuant to our reserved rights upon the issuance of the shares, then those shares are added back to the reserve and may again be used for new awards under the Omnibus Plan. Shares that are tendered or withheld in payment of the exercise price of a stock option or as a result of the net settlement of an outstanding stock appreciation right, shares we purchase using proceeds from stock option exercises and shares tendered or withheld to satisfy any federal, state, or local tax withholding obligations may not be made available for re-issuance under the Omnibus Plan.

*Transferability.* Awards are not transferable other than by will or the laws of descent and distribution, unless the Administrator allows a participant to (i) designate in writing a beneficiary to exercise the award or receive payment under the award after the participant's death, (ii) transfer an award to a former spouse as required by a domestic relations order incident to a divorce, or (iii) otherwise transfer an award without receiving any consideration.

*Adjustments.* If (i) we are involved in a merger or other transaction in which our shares of common stock are changed or exchanged; (ii) we subdivide or combine shares of common stock or declare a dividend payable in shares of common stock, other securities, or other property (other than stock purchase rights issued pursuant to a stockholder rights agreement); (iii) we effect a cash dividend that exceeds 10% of the fair market value of a share of common stock or any other dividend or distribution in the form of cash or a repurchase of shares of common stock that our Board determines is special or extraordinary, or that is in connection with a recapitalization or reorganization; or (iv) any other event occurs that in the Administrator's judgment requires an adjustment to prevent dilution or enlargement of the benefits intended to be made available under the Omnibus Plan, then the Administrator will, in a manner it deems equitable, adjust any or all of (A) the number and type of shares subject to the Omnibus Plan and which may, after the event, be made the subject of awards; (B) the number and type of shares of common stock subject to outstanding awards; (C) the grant, purchase, or exercise price with respect to any award; and (D) the performance goals of an award.

In any such case, the Administrator may also provide for a cash payment to the holder of an outstanding award in exchange for the cancellation of all or a portion of the award, subject to the terms of the Omnibus Plan.

The Administrator may, in connection with any merger, consolidation, acquisition of property or stock, or reorganization, authorize the issuance or assumption of awards upon terms and conditions we deem appropriate without affecting the number of shares of common stock otherwise reserved or available under the Omnibus Plan.

*Change of Control.* To the extent a participant has an employment, retention, change of control, severance, or similar agreement with us or any of our affiliates that discusses the effect of a change of control (as defined in the Omnibus Plan) on the participant's awards, such agreement will control. Otherwise, unless otherwise provided in an award agreement or by the Administrator prior to the change of control, in the event of a change of control, if the purchaser, successor or surviving entity (or parent thereof) (the "Successor") agrees, then some or all outstanding awards will be assumed or replaced with the same type of award with similar terms and conditions. If applicable, each award that is assumed must be appropriately adjusted, immediately after such change of control, to apply to the number and class of securities that would have been issuable to a participant upon the consummation of such change of control had the award been exercised, vested, or earned immediately prior to such change of control, and other appropriate adjustment to the terms and conditions of the award may be made.

If a participant is terminated from employment without cause (as defined in the Omnibus Plan) or the participant resigns employment for good reason (as defined in the Omnibus Plan) within 24 months following the change of control, then upon such termination, all of the participant's awards in effect on the date of such termination will vest in full or be deemed earned in full.

*Term of Omnibus Plan.* Unless earlier terminated by our Board of Directors, the Omnibus Plan will remain in effect until the date all shares reserved for issuance have been issued, except that no incentive stock options may be issued if the term of the Omnibus Plan extends beyond 10 years from the effective date without stockholder approval of such extension.

**Outstanding Equity Awards at Fiscal Year-End**

The following table lists the outstanding equity awards held by each of our named executive officers as of December 31, 2019:

| Name | Number of Securities Underlying Unexercised Options [1] Exercisable | Number of Securities Underlying Unexercised Options [1] Unexercisable | Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options | Option Exercise Price ($) | Option Expiration Date |
|---|---|---|---|---|---|
| David Young [2] | - | 7,859 | - | 16.80 | 6/20/2024 |
| | 1,733 | - | - | 16.80 | 6/20/2024 |
| | - | 1,733 | - | 16.80 | 6/20/2024 |
| | - | 5,198 | - | 16.80 | 6/20/2024 |
| Patrick Lin [2] | - | 7,859 | - | 16.80 | 6/20/2024 |
| | 1,733 | - | - | 16.80 | 6/20/2024 |
| | - | 1,733 | - | 16.80 | 6/20/2024 |
| | - | 5,198 | - | 16.80 | 6/20/2024 |
| Sian Bigora [2] | - | 7,859 | - | 16.80 | 6/20/2024 |
| | 1,733 | - | - | 16.80 | 6/20/2024 |
| | - | 1,733 | - | 16.80 | 6/20/2024 |
| | - | 5,198 | - | 16.80 | 6/20/2024 |
| Wendy Guy [2] | - | 7,859 | - | 16.80 | 6/20/2024 |
| | 1,733 | - | - | 16.80 | 6/20/2024 |
| | - | 1,733 | - | 16.80 | 6/20/2024 |
| | - | 5,198 | - | 16.80 | 6/20/2024 |
| James Stanker [2] | - | 7,859 | - | 16.80 | 6/20/2024 |
| | 1,733 | - | - | 16.80 | 6/20/2024 |
| | - | 1,733 | - | 16.80 | 6/20/2024 |
| | - | 5,198 | - | 16.80 | 6/20/2024 |
| | 14,125 | 31,075 | - | 19.88 | 8/31/2028 |
| | 2,571 | - | - | 19.88 | 8/31/2028 |

(1) The standard vesting schedule for all stock option grants is vesting over three years.

(2) Options for the purchase of 16,523 shares of our common stock were granted to each of Dr. David Young, Patrick Lin, Dr. Sian Bigora, Wendy Guy and James Stanker on June 20, 2019 contained either service or performance vesting conditions, have a contractual term of five years and an exercise price equal to the closing price of our common stock on the OTCQB on the date of grant of $16.80. Stock options for the purchase of 7,859 shares of common stock vest one-third on the first anniversary date of the grant, with the remaining options vesting ratably over the subsequent two years. Stock options for the purchase of 8,664 shares vest upon meeting the following performance criteria: (i) 1,733 shares vest when we in-license one new or additional drug; (ii) 1,733 shares vest when our current Phase 2A clinical trial for PCS499 is complete; and (iii) 5,198 shares vest when we up-list from the OTCQB to either the Nasdaq or NYSE markets. On August 29, 2019, we reached a license agreement with Akashi Therapeutics for PCS100 and as such, the performance condition related to the award for in-licensing one new or additional drug was met; accordingly stock options to purchase 1,733 shares have vested.

## DIRECTOR COMPENSATION

Effective February 10, 2020, each non-employee director receives an annual cash retainer of $20,000, payable quarterly. In addition, each new director will receive an initial stock option grant of approximately 5,000 shares of common stock and each non-employee director will receive an annual stock option grant to a number of shares of common stock equal to $20,000 total value. All such awards are made under our Omnibus Plan. The annual stock option awards may be pro-rated in the first year of service depending on when the non-employee director joins the Board. This compensation program was reviewed by the Board of Directors in February 2020. Our directors have decided to waive any cash compensation and directors fees until we complete our up-list to Nasdaq.

During 2019, our non-employee directors did not receive any cash compensation for their service on the Board. On June 20, 2019, both Mr. Yorke and Mr. Thompson were granted options for the purchase of 2,068 shares of our common stock. The options granted contained either service or performance vesting conditions, have a contractual term of five years and an exercise price equal to the closing price of our common stock on the OTCQB on the date of grant of $16.80. Of these options, each received options for the purchase of 1,085 shares of common stock that vest one-third on the first anniversary date of the grant, with the remaining options vesting ratably over the subsequent two years. Stock options for the purchase of 983 shares vest upon meeting the following performance criteria: (i) 197 shares vest when we in-license one new or additional drug; (ii) 197 shares vest when our current Phase 2A clinical trial for PCS499 is complete; and (iii) 589 shares vest when we up-list from the OTCQB to either the Nasdaq or NYSE markets.

Our directors are reimbursed for any reasonable out-of-pocket expenses incurred in connection with service as a director.

| Name | Fees Earned or Paid in Cash ($) | Option Awards ($) [1][2] | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|
| Justin Yorke | - | 20,423 | - | 20,423 |
| Virgil Thompson | - | 20,423 | - | 20,423 |

(1) The "Option Awards" column reflects the grant date fair value for all stock option awards granted under the Omnibus Plan during 2019. These amounts are determined in accordance with FASB Accounting Standards Codification 718 (ASC 718), without regard to any estimate of forfeiture for service vesting. Assumptions used in the calculation of the amounts are included in Note 10 to the Company's consolidated audited financial statements for the year ended December 31, 2019 in Item 8 of this Annual Report on Form 10-K.

(2) Options for the purchase of 2,068 shares of our common stock were granted to each of Justin Yorke and Virgil Thompson on June 20, 2019 contained either service or performance vesting conditions, have a contractual term of five years and an exercise price equal to the closing price of our common stock on the OTCQB on the date of grant of $16.80. Stock options for the purchase of 1,085 shares of common stock vest one-third on the first anniversary date of the grant, with the remaining options vesting ratably over the subsequent two years. Stock options for the purchase of 983 shares vest upon meeting the following performance criteria: (i) 197 shares vest when we in-license one new or additional drug; (ii) 197 shares vest when our current Phase 2A clinical trial for PCS499 is complete; and (iii) 589 shares vest when we up-list from the OTCQB to either the Nasdaq or NYSE markets. On August 29, 2019, we reached a license agreement with Akashi Therapeutics for PCS100 and as such, the performance condition related to the award for in-licensing one new or additional drug has been met, accordingly stock options to purchase 197 shares have vested.

## TRANSACTIONS WITH RELATED PERSONS, PROMOTERS AND CERTAIN CONTROL PERSONS

The audit committee has adopted written policies and procedures for the committee to review and approve, or ratify related party transactions. These transactions include:

- transactions that must be disclosed in proxy statements under SEC rules, and
- transactions that potentially could cause a non-employee director to cease to qualify as an independent director under Nasdaq Stock Market listing requirements.

Transactions that are deemed immaterial under applicable disclosure requirements are generally deemed pre-approved under these written policies and procedures, including transactions with an entity with which a director's sole relationship is as a non-employee director and the total amount involved does not exceed 1% of the entity's total annual revenues.

Criteria for committee approval or ratification of a related party transaction, in addition to factors that the committee otherwise deems appropriate under the circumstances, include:

- whether terms of the transaction are no less favorable than terms generally available from an unaffiliated third party; and
- in the case of a non-employee director, whether the transaction would disqualify the director from (1) being independent under Nasdaq Stock Market listing requirements, or (2) from serving on the audit committee, compensation committee or nominating and governance committee under Nasdaq Stock Market and other regulatory requirements.

With the exception of the transactions set forth below, we were not a party to any transaction (in which the amount involved exceeded the lesser of $120,000 or one percent of the average of our assets for the last two fiscal years) in which a director, executive officer, holder of more than five percent of our common stock, or any member of the immediate family of any such person has or will have a direct or indirect material interest and no such transactions are currently proposed.

**CorLyst, LLC and DKBK Enterprises, LLC**

CorLyst was a related party to Promet as one of the largest investors in Promet. As a result of the transaction with Heatwurx, all of Promet's assets were purchased in exchange for equity in the company. Promet has since distributed the shares to its stockholders and CorLyst is now considered a related party. We share certain administrative expenses with CorLyst (salaries, healthcare and office space). David Young, our CEO and Chairman of our Board of Directors, is also the CEO and Managing Member of CorLyst. David Young spends less than one hour per week on CorLyst activity, while averaging more than 40 hours per week on Processa activities. CorLyst beneficially owns 1,095,649 shares of our common stock.

On September 20, 2019, we entered into two separate LOC Agreements ("LOC Agreements") with DKBK Enterprises, LLC ("DKBK") and CorLyst, LLC ("CorLyst", and, together with DKBK, collectively, "Lenders"), both related parties, which provide a revolving commitment of up to $700,000 each ($1.4 million total). Under the LOC Agreements, all funds borrowed bear interest at an annual rate of 8%. The promissory notes issued in connection with the LOC Agreements provide that the Lenders have the right to convert all or any portion of the principal and accrued and unpaid interest into our common stock on the same terms as our 2019 Senior Convertible Notes. Therefore, the Lenders may convert the outstanding debt under the LOC Agreements into our common stock at a conversion price equal to the lower of (i) $14.28 per share, (ii) a price per share equal to a 10% discount to the pre-money valuation of an equity sale of the Company's common stock for cash, or (iii) at an adjusted price; all as more particularly described in the 2019 Senior Convertible Notes.

Our CEO is also the CEO and Managing Member of DKBK, which directly holds 16,166 shares of our common stock. In April and June 2020, we drew $500,000 under the LOC Agreement with DKBK. On July 21, 2020, we drew an additional $200,000, bringing the total amount drawn under the LOC Agreement with DKBK to $700,000.

The Lenders have informed us that they will convert the $700,000 principal amount outstanding under the LOC Agreement with DKBK simultaneously with the closing of this offering into 92,574 shares of common stock, based on a conversion price of $7.61 per share, which, pursuant to the LOC Agreement, is a 10% discount on an assumed public offering price of $8.45 per share, which represents the last reported sales price of our common stock as reported on the OTCQB on September 15, 2020.

**License Agreement with CoNCERT Pharmaceuticals, Inc.**

On October 4, 2017, Promet entered into a license agreement with CoNCERT ("the CoNCERT Agreement"). On March 19, 2018, we, Promet, and CoNCERT entered into an Amended Option Licensing Agreement ("March Amendment") that, among other things, assigned the CoNCERT Agreement from Promet to us and we exercised the exclusive commercial license option for the PCS499 compound from CoNCERT.

The CoNCERT Agreement provides us with an exclusive (including to CoNCERT) royalty-bearing license to CoNCERT's patent rights and know-how to develop, manufacture, use, sub-license and commercialize compounds (PCS499 and each metabolite thereof) and pharmaceutical products with such compounds worldwide. We are required to pay CoNCERT royalties, on a product by product basis, on worldwide net sales, as more fully described in the Description of Business.

## PRINCIPAL STOCKHOLDERS

The following table sets forth certain information with respect to the beneficial ownership of our common stock at August 31, 2020 for:

- Each of our directors;
- Each of our named executive officers;
- All of our current directors and executive officers as a group; and
- Each person, or group of affiliated persons, who beneficially owned more than 5% of our common stock.

The number of shares of our common stock beneficially owned by each entity, person, director or executive officer is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days of August 31, 2020, through the exercise of any stock option, warrants or other rights. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock held by that person.

The percentage of shares beneficially owned is computed on the basis of 5,515,447 shares of our common stock outstanding as of August 31, 2020. Shares of our common stock that a person has the right to acquire within 60 days of August 31, 2020, are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group. The percentage of ownership after this offering excludes any shares issued pursuant to the exercise of the underwriters' over-allotment option.

| | Shares beneficially owned prior to this offering | | Shares beneficially owned after this offering[13] | |
|---|---|---|---|---|
| | Shares | Percent | Shares | Percent |
| **Name and address of beneficial owner [1]** | | | | |
| **Officers and Directors** | | | | |
| David Young [2], [9] | 1,348,557 | 24.2% | | % |
| Sian Bigora [3] | 500,677 | 9.1% | 521,925 | % |
| Patrick Lin [7] | 345,448 | 6.3% | 366,696 | % |
| Wendy Guy [4] | 318,402 | 5.8% | 339,650 | % |
| Virgil Thompson [8] | 88,108 | 1.6% | 91,376 | % |
| Justin Yorke [5] | 446,946 | 7.9% | 450,214 | % |
| Geraldine Pannu | - | * | 3,268 | * |
| James Stanker [12] | 52,282 | * | 73,530 | * |
| **Total for all Officers and Directors** | 3,100,420 | 55.7% | | % |
| | | | | |
| **More than 5% Stockholders:** | | | | |
| CorLyst, LLC [6], [9], [11] | 1,095,649 | 19.8% | 1,095,649 | % |
| Young-Plaisance Revoc. Trust [9], [10] | 482,030 | 8.7% | 482,030 | % |
| CoNCERT Pharmaceuticals, Inc. | 298,615 | 5.4% | 298,615 | % |

* represents less than 1%

(1) Unless otherwise indicated, the address for each beneficial owner listed is c/o Processa Pharmaceuticals, Inc., 7380 Coca Cola Drive, Suite 106, Hanover, Maryland 21076.

(2) Consists of (i) 305,854 shares of common stock held directly by Dr. Young; (ii) 5,227 shares of common stock issuable pursuant to options held directly by Dr. Young exercisable within 60 days of August 31, 2020; (iii), 482,030 shares held by the Young-Plaisance Revoc. Trust; (iv) 161,672 shares held by three other family entities; (v) 390,627 shares held by CorLyst, LLC ("CorLyst") (317,446 shares held on behalf of entities controlled by Dr. Young, 52,872 shares held on behalf of unrelated stockholders, and stock purchase warrants to purchase 20,309 shares); and (vi) 3,147 shares that Dr. Young will receive on the exercise of stock purchase warrants. Dr. Young is the Trustee of the Young-Plaisance Revoc. Trust and the Chief Executive Officer and Managing Member of CorLyst. Dr. Young disclaims beneficial ownership of a portion of CorLyst shares.

(3) Consists of (i) 368,747 shares of common stock held directly by Dr. Bigora; (ii) 126,973 shares held by CorLyst; and (iii) 5,227 shares of common stock issuable pursuant to options held directly by Dr. Bigora exercisable within 60 days of August 31, 2020.

(4) Consists of (i) 154,452 shares of common stock held directly by Ms. Guy; (ii) 158,723 shares held by CorLyst; and (iii) 5,227 shares of common stock issuable pursuant to options held directly by Ms. Guy exercisable within 60 days of August 31, 2020.

(5) Justin Yorke, a member of our Board of Directors, is a manager of the San Gabriel Fund, LLC, JMW Fund, LLC and the Richland Fund, LLC. The shares of common stock reported for Mr. Yorke include the shares held by these Funds and 73,657 shares that the funds will receive on the exercise of stock purchase warrants. Also included are 679 shares of common stock issuable pursuant to options held directly by Mr. Yorke exercisable within 60 days of August 31, 2020.

(6) CorLyst is the beneficial holder of 1,095,649 shares. This beneficial ownership is allocated in the above table as follows: David Young related entities – 317,446, Sian Bigora – 126,973; Wendy Guy – 158,723; the Young-Plaisance Revoc. Trust – 419,326; other unrelated stockholders – 52,872; and stock purchase warrants to purchase 20,309 shares.

(7) Consists of (i) 335,752 shares of common stock held directly by Mr. Lin; (ii) 5,227 shares of common stock issuable pursuant to options held directly by Mr. Lin exercisable within 60 days of August 31, 2020; and (iii) 4,469 shares that Mr. Lin will receive on the exercise of stock purchase warrants.

(8) Consists of (i) 87,429 shares of common stock held directly by Mr. Thompson and (ii) 679 shares of common stock issuable pursuant to options held directly by Mr. Thompson exercisable within 60 days of August 31, 2020.

(9) Although David Young confers with all other members or parties associated with CorLyst and the Young-Plaisance Revoc Trust, Dr. Young has voting and investment control of these entities.

(10) Includes 30,465 shares of common stock that will be issued upon the exercise of stock purchase warrants.

(11) Includes 20,309 shares of common stock that will be issued upon the exercise of stock purchase warrants.

(12) Consists of (i) 20,000 shares of common stock held directly by Mr. Stanker and (ii) 32,282 shares of common stock issuable pursuant to options held directly by Mr. Stanker exercisable within 60 days of August 31, 2020.

(13) The number of shares beneficially owned after this offering includes (i) shares of common stock beneficially owned by David Young as a result of the conversion of the LOC Agreement with DKBK and (ii) the vesting of 21,248 shares of restricted common stock which were granted to each of David Young, Sian Bigora, Patrick Lin, Wendy Guy and James Stanker; and 3,268 shares of restricted common stock granted to each of Virgil Thompson, Justin York and Geraldine Pannu on August 5, 2020 pursuant to our 2019 Omnibus Incentive Plan, which shares vest upon the completion of this offering.

## DESCRIPTION OF OUR SECURITIES

The following description of our securities and provisions of our amended and restated certificate of incorporation and amended and restated bylaws is only a summary. You should also refer to the copies of our amended and restated certificate of incorporation and amended and restated bylaws which have been filed with the SEC.

We have the authority to issue an aggregate of 30,000,000 shares of $0.0001 par value common stock and 1,000,000 shares of $0.0001 par value preferred stock. As of August 31, 2020, there were 5,514,447 shares of common stock outstanding and no shares of preferred stock outstanding.

### Common Stock

***Dividend Rights.*** Subject to the rights of holders of preferred stock of any series that may be issued and outstanding from time to time, holders of our common stock are entitled to receive such dividends and other distributions as may be declared by our Board of Directors from time to time.

***Voting Rights.*** Each outstanding share of our common stock is entitled to one vote on all matters submitted to a vote of stockholders generally. In the event we issue one or more series of preferred or other securities in the future such preferred stock or other securities may be given rights to vote, either together with the common stock or as a separate class on one or more types of matters. The holders of our common stock do not have cumulative voting rights.

***Liquidation Rights.*** In the event of any liquidation, dissolution or winding up of the Company, the holders of our common stock will be entitled, subject to any preferential or other rights of any then outstanding preferred stock, to receive all assets of the Company available for distribution to stockholders.

***Preemptive Rights.*** As of the date hereof, the holders of our common stock have no preemptive rights in their capacities as such holders.

***Board of Directors.*** Holders of common stock do not have cumulative voting rights with respect to the election of directors. At any meeting to elect directors by holders of our common stock, the presence, in person or by proxy, of the holders of a majority of the voting power of shares of our capital stock then outstanding will constitute a quorum for such election. Directors may be elected by a plurality of the votes of the shares present and entitled to vote on the election of directors, except for directors whom the holders of any then outstanding preferred stock have the right to elect, if any.

### Preferred Stock

Our Board is authorized, subject to certain limitations prescribed by law, without further stockholder approval, to issue from time to time up to an aggregate of 1,000,000 shares of preferred stock in one or more series and to fix or alter the designations, preferences, rights and any qualifications, limitations or restrictions of the shares of each such series thereof, including the dividend rights, dividend rates, conversion rights, voting rights and terms of redemption of shares constituting any series or designations of such series. The rights of holders of our common stock may be subject to, and adversely affected by, the rights of the holders of any preferred stock that may be issued in the future. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change of control and may adversely affect the voting and other rights of holders of our common stock.

### Warrants

As of the date of this prospectus, we have outstanding warrants to purchase shares of our common stock to various persons and entities, under which we could be obligated to issue up to 533,959 shares of common stock, including:

(a) 275,828 shares of common stock issuable upon exercise of outstanding warrants allowing the holders to purchase shares of common stock at an exercise price of $19.07 per share through June 29, 2021; of which warrants for 18,819 shares of common stock contain cashless exercise provisions;

(b) 201,781 shares of common stock issuable upon exercise of outstanding warrants allowing the holders to purchase shares of common stock at an exercise price of $17.16 per share expiring between May 25, 2021 and July 2, 2022; of which warrants for 11,347 shares of common stock contain cashless exercise provisions; and

(c) 56,350 shares of common stock issuable upon exercise of outstanding warrants allowing the holders to purchase shares of common stock at an exercise price of $19.04 per share through December 19, 2023.

**Debt**

***8% Senior Convertible Notes***

During the fourth quarter of 2019, accredited investors purchased $805,000 of 8% Senior Convertible Notes ("2019 Senior Notes") from us. For every $1,000 principal amount purchased, the note holders received 70 warrants to purchase shares of our common stock. As a result, we granted 56,350 warrants to purchase shares of our common stock at an exercise price of $19.04, which expire on December 19, 2023. The 2019 Senior Notes bear interest at 8% per year and if converted, the interest is payable in common stock. The 2019 Senior Notes mature on December 15, 2020.

The 2019 Senior Notes are convertible by the holder upon (i) completion of listing our common stock on either the Nasdaq Capital Market or the New York Stock Exchange or if we raise at least $14 million, prior to December 15, 2020, the maturity date of the 2019 Senior Notes, in one or more qualified financings. If the 2019 Senior Notes are not paid or converted prior to their maturity date, the principal and any accrued interest will be automatically or mandatorily converted into our common stock. The 2019 Senior Notes, plus any accrued interest is convertible into shares of our common stock at a conversion price equal to the lower of (i) $14.28 per share or (ii) a price per share equal to a 10% discount to the pre-money valuation of an equity sale of the Company's common stock for cash as defined in the 2019 Senior Note agreement, occurring after the closing of the 2019 Senior Note financing. The noteholders have the option to convert their notes upon the closing of this offering. In the event that all of the principal and interest of the $805,000 2019 Senior Notes are converted upon the closing of this offering, we would issue 113,013 shares of common stock, based on a conversion price of $7.61 per share, which, pursuant to the 2019 Senior Note Agreement, is a 10% discount on an assumed public offering price of $8.45 per share, which represents the last reported sales price of our common stock as reported on the OTCQB on September 15, 2020.

The 2019 Senior Notes provide the holders with (a) the option of receiving 110% of principal plus accrued interest in the event there is a change of control prior to conversion of the 2019 Senior Notes; (b) weighted-average anti-dilution protection in event of any sale of securities at a net consideration per share that is less than the applicable conversion price per share to the holder until we have raised an additional $14 million from the sale of certain securities; and (c) certain preemptive rights pro rata to their respective interests through December 31, 2021.

The 2019 Senior Notes contains negative covenants that do not permit us to incur additional indebtedness or liens on property or assets owned, repurchase common stock, pay dividends, or enter into any transaction with affiliates of ours that would require disclosure in a public filing with the Securities and Exchange Commission. Upon an event of default, the outstanding principal amount of the Senior Notes, plus accrued but unpaid interest and other amounts owing in respect thereof through the date of acceleration, shall become immediately due and payable in cash at the holder's election, if not cured within the cure period.

We incurred $4,280 in debt issuance costs related to the 2019 Senior Notes. The debt issuance costs are amortized to interest expense using straight line amortization over the term of the 2019 Senior Notes. We recognized debt issuance costs incurred as a reduction of the carrying amount of the 2019 Senior Notes on the face of the consolidated balance sheet.

We determined the sale of 2019 Senior Notes, which are convertible into common stock at a conversion rate of $14.28 triggered the full ratchet anti-dilution provision of the common stock we sold in 2018 Private Placement Transactions, as described in our December 31, 2019 audited consolidated financial statements included elsewhere in this prospectus. As a result, those stockholders were entitled to 28,971 shares of common stock in the fourth quarter of 2019, which were issued on June 18, 2020. We determined the value of these shares to be $506,993 based on a price per share of $17.50, which represents the closing price per share on October 18, 2019, the last day investors had to rescind their investment. We recorded the triggering of the full ratchet anti-dilution provision as a deemed dividend payable at December 31, 2019 in our statement of changes in stockholders' equity at par value due to the fact that we have a retained deficit and are receiving no additional consideration for these shares.

***Related Party Lines of Credit***

On September 20, 2019, we entered into two separate LOC Agreements, one with DKBK and another with CorLyst ("the Lenders"), which provide a revolving commitment of up to $700,000 each ($1.4 million total). Our CEO is also the CEO and Managing Member of both Lenders. DKBK beneficially owns 16,166 shares of our common stock, while CorLyst beneficially owns 1,095,649 shares of our common stock. Under the LOC Agreements, all funds borrowed will bear an 8% annual interest rate, which is prorated monthly from the date money has been borrowed to the date money has been paid back. We agreed to furnish certified financial statements to the Lenders upon demand so long as indebted under the LOC Agreements and the Note remains unpaid. The Lenders have the right to convert all or any portion of the debt and interest into shares in our common stock on the same terms as our 2019 Senior Convertible Notes. We drew funds in April, June and July of 2020 totaling $700,000 under the LOC Agreement with DKBK.

DKBK has informed us that they will convert the $700,000 principal amount and related accrued interest outstanding under the LOC Agreement simultaneously with the closing of this offering into 92,574 shares of common stock based on a conversion price of $7.61 per share, which represents a 10% discount on the last reported sales price of $8.45 per share of our common stock as reported on the OTCQB on September 15, 2020.

**Registration Rights**

Following the offering, shares of our common stock will be subject to registration rights, as described below.

*Aposense, Ltd.* Pursuant to the License Agreement with Aposense, commencing 180 days after the effectiveness of this registration statement, upon Aposense's request, we will file a registration statement within 30 days for the shares issued to Aposense in connection with the License Agreement and will use commercially reasonable efforts to cause such registration statement to become effective. The obligation to register the shares will cease when such shares (A) have been sold or otherwise disposed of or (B) may be sold under Rule 144 without regard to volume restrictions.

*Yuhan Corporation.* Pursuant to the Yuhan License Agreement and the related Share Issuance Agreement, commencing 180 days after the completion of this offering, upon Yuhan's written request, we will file a resale registration statement on Form S-3 (or such other available registration statement) for the shares issued to Yuhan in connection with such agreements (including the 250,000 shares of common stock previously issued and any shares of common stock issued a result of the achievement of any milestones) and will use commercially reasonable efforts to cause such registration statement to become effective. The obligation to register the shares will cease when such shares (A) have been sold or otherwise disposed of or (B) may be sold under Rule 144 without regard to volume restrictions.

*Elion Oncology, Inc*. Pursuant to the Elion License Agreement, commencing 180 days after the agreement, upon Elion's request, we will use commercially reasonable efforts to file a registration statement for the shares issued to Elion in connection with the Elion License Agreement and will use commercially reasonable efforts to cause such registration statement to become effective. The obligation to register the shares will cease when such shares (A) have been sold or otherwise disposed of or (B) may be sold under Rule 144 without regard to volume restrictions.

**Indemnification of Directors and Officers**

Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by the Delaware General Corporate Law ("DGCL") as it may hereafter be amended, none of our directors will be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director. Under the DGCL as it now reads, such limitation of liability is not permitted:

- for any breach of the director's duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- for payments of unlawful dividends or unlawful stock purchases or redemptions under Section 174 of the DGCL; or
- for any transaction from which the director derived an improper personal benefit.

These provisions will have no effect on the availability of equitable remedies such as an injunction or rescission based on a director's breach of his or her duty of care.

Our amended and restated certificate of incorporation and our amended and restated bylaws include provisions that require us to indemnify and advance expenses, to the fullest extent allowable under the DGCL as it now exists or may hereafter be amended, to our directors or officers for actions taken as a director or officer of us, or for serving at our request as a director or officer at another corporation or enterprise, as the case may be.

Section 145 of the DGCL provides that a corporation may indemnify directors and officers, as well as other employees and individuals, against expenses, including attorneys' fees, judgments, fines and amounts paid in settlement, that are incurred in connection with various actions, suits or proceedings, whether civil, criminal, administrative or investigative, other than an action by or in the right of the corporation, known as a derivative action, if they acted in good faith and in a manner they reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, if they had no reasonable cause to believe their conduct was unlawful. A similar standard is applicable in the case of derivative actions, except that indemnification only extends to expenses, including attorneys' fees, incurred in connection with the defense or settlement of such actions, and the statute requires court approval before there can be any indemnification if the person seeking indemnification has been found liable to the corporation. The statute provides that it is not exclusive of other indemnification that may be granted by a corporation's bylaws, disinterested director vote, stockholder vote, agreement or otherwise.

Our amended and restated bylaws require us to indemnify any person who was or is a party or is threatened to be made a party to, or was otherwise involved in, a legal proceeding by reason of the fact that he or she is or was a director or officer of the Company or is or was serving at our request as a director or officer of another corporation or enterprise, as the case may be, to the fullest extent authorized by the DGCL as it now exists or may hereafter be amended, against all expense, liability and loss (including attorneys' fees, judgments, fines, Employee Retirement Income Security Act excise taxes or penalties and amounts paid in settlement) reasonably incurred or suffered by such director or officer in connection with such service. The right to indemnification in our amended and restated bylaws includes the right to be paid by the Company the expenses incurred in defending any proceeding for which indemnification may be sought in advance of the final disposition of such proceeding, subject to certain limitations. We carry directors' and officers' insurance protecting us, any director, officer, employee or agent of ours or who was serving at the request of the Company as a director, officer, employee or agent of another corporation or enterprise, as the case may be, against any expense, liability or loss, whether or not we would have the power to indemnify the person under the DGCL.

The limitation of liability and indemnification and advancement provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of fiduciary duty. These provisions also may reduce the likelihood of derivative litigation against our directors and officers, even though such an action, if successful, might otherwise benefit us and our stockholders. In addition, your investment in our common stock may be adversely affected to the extent we pay the costs of settlement and damage awards under these indemnification provisions.

**Certain Anti-Takeover Effects**

***Provisions of Delaware Law.*** We are a Delaware corporation and Section 203 of the DGCL applies to us. It is an anti-takeover statute that is designed to protect stockholders against coercive, unfair or inadequate tender offers and other abusive tactics and to encourage any person contemplating a business combination with us to negotiate with our Board of Directors for the fair and equitable treatment of all stockholders.

Under Section 203 of the DGCL, a Delaware corporation is not permitted to engage in a "business combination" with an "interested stockholder" for a period of three years following the date that the stockholder became an interested stockholder. As defined for this purpose, the term "business combination" includes a merger, consolidation, asset sale or other transaction resulting in a financial benefit to the interested stockholder. The term "interested stockholder" is defined to mean a person who, together with affiliates and associates, owns, or within three years did own, 15% or more of the corporation's outstanding voting stock. This prohibition does not apply if:

- prior to the time that the stockholder became an interested stockholder, the Board of Directors of the corporation approved either the business combination or the transaction resulting in the stockholder becoming an interested stockholder;

- upon completion of the transaction resulting in the stockholder becoming an interested stockholder, the stockholder owns at least 85% of the outstanding voting stock of the corporation, excluding voting stock owned by directors who are also officers and by certain employee stock plans; or

- at or subsequent to the time that the stockholder became an interested stockholder, the business combination is approved by the Board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock that the interested stockholder does not own.

A Delaware corporation may elect not to be governed by these restrictions. We have not opted out of Section 203.

***Advance Notice Procedures.*** Our bylaws establish an advance notice procedure for stockholder nominations of persons for election to our Board of Directors and for any proposals to be presented by stockholders at an annual meeting. Stockholders at an annual meeting will only be able to consider nominations and other proposals specified in the notice of meeting or brought before the meeting by or at the direction of our Board of Directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given our corporate secretary timely written notice, in proper form, of the stockholder's intention to nominate a person for election as a director or to bring a proposal for action at the meeting.

## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been a limited public market for our common stock. Future sales of substantial amounts of common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock. Although we have been approved for trading on Nasdaq, we cannot assure you that there will be an active public market for our common stock.

All shares of common stock sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares of common stock purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act or any shares subject to lock-up agreements. Shares purchased by our affiliates would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining shares of common stock outstanding after this offering, excluding 167,551 shares issued prior to our acquisition of Promet in 2017, shares issued pursuant to our Omnibus Plan and any shares sold pursuant to our Selling Stockholders Registration Statement on Form S-1 (Registration No. 333-226428), are "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or Rule 701 under the Securities Act, each of which is summarized below.

We may issue shares of common stock from time to time as consideration for future licensing transactions, investments or other corporate purposes and the number of shares of common stock that we may issue may also be significant. We may also grant registration rights covering those shares of common stock issued in connection with any such transaction. See "Registration Rights" below.

### Lock-Up Agreements

In connection with this offering, certain of our stockholders and our directors and executive officers have agreed with the underwriters that, subject to certain customary exceptions, without the prior written consent of Craig-Hallum Capital Group LLC and Benchmark Company, LLC on behalf of the underwriters, they will not, for 90 days (the "Lock-Up Period"), (a) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, make any short sale or otherwise transfer or dispose of, directly or indirectly, our common stock or any securities convertible into, exercisable or exchangeable for or that represent the right to receive our common stock; (b) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of such securities, whether any such transaction is to be settled by delivery of common stock or other securities, in cash or otherwise; (c) make any demand for or exercise any right with respect to the registration of any shares of our common stock or any security convertible into, exercisable or exchangeable for our common stock; or (d) publicly disclose the intention to do any of the foregoing. The underwriters may, in their sole discretion, permit any such transactions during the Lock-Up Period in whole or in part and at any time, with or without notice.

Upon the expiration of the Lock-Up Period, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above.

### Rule 144

Rule 144, as currently in effect, generally provides that, as we have been subject to the public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, a stockholder who is not deemed to have been one of our affiliates at any time during the preceding 90 days and who has beneficially owned the shares of our capital stock proposed to be sold for at least six months is entitled to sell such our securities in reliance upon Rule 144 without complying with the volume limitation, manner of sale or notice conditions of Rule 144. As the Company was previously a "shell company," as such term is defined in Rule 12b-2 of the Exchange Act, our stockholders, whether affiliates or non-affiliates, may never sell shares of our securities under Rule 144, unless current public information is available about us at the time of the sale of such shares.

Rule 144 also provides that a stockholder who is deemed to have been one of our affiliates at any time during the preceding 90 days and who has beneficially owned our securities that are proposed to be sold for at least six months is entitled to sell such securities in reliance upon Rule 144 within any three month period beginning 90 days after the date of this prospectus a number of shares that does not exceed the greater of the following:

- 1% of the number of shares of our capital stock then outstanding, which will equal shares immediately after the completion of this offering; or
- the average weekly trading volume of our Common Stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales of our securities made in reliance upon Rule 144 by a stockholder who is deemed to have been one of our affiliates at any time during the preceding 90 days are also subject to the current public information, manner of sale and notice conditions of Rule 144.

**Restrictions on the Use of Rule 144 by Shell Companies or Former Shell Companies**

Rule 144 is not available for the resale of securities initially issued by shell companies (other than business combination related shell companies) or issuers that have been at any time previously a shell company. However, Rule 144 also includes an important exception to this prohibition if the following conditions are met:

- the issuer of the securities that was formerly a shell company has ceased to be a shell company;
- the issuer of the securities is subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act;
- the issuer of the securities has filed all Exchange Act reports and materials required to be filed, as applicable, during the preceding 12 months (or such shorter period that the issuer was required to file such reports and materials), other than Current Reports on Form 8-K; and
- at least one year has elapsed from the time that the issuer filed current Form 10 type information with the SEC reflecting its status as an entity that is not a shell company.

As a result, our stockholders are able to sell shares pursuant to Rule 144, provided that there is current public information available on us and there has been compliance with other applicable requirements of Rule 144.

**Rule 701**

Rule 701 generally allows a stockholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been one of our affiliates during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation, or notice provisions of Rule 144. Rule 701 also permits our affiliates to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144.

**Registration Rights**

*Aposense, Ltd.* Pursuant to the License Agreement with Aposense, commencing 180 days after the effectiveness of this registration statement, upon Aposense's request, we will file a registration statement within 30 days for the shares issued to Aposense in connection with the License Agreement and will use commercially reasonable efforts to cause such registration statement to become effective. The obligation to register the shares will cease when such shares (A) have been sold or otherwise disposed of or (B) may be sold under Rule 144 without regard to volume restrictions.

*Yuhan Corporation.* Pursuant to the Yuhan License Agreement and the related Share Issuance Agreement, commencing 180 days after the completion of this offering, upon Yuhan's written request, we will file a resale registration statement on Form S-3 (or such other available registration statement) for the shares issued to Yuhan in connection with such agreements (including the 250,000 shares of common stock previously issued and any shares of common stock issued a result of the achievement of any milestones) and will use commercially reasonable efforts to cause such registration statement to become effective. The obligation to register the shares will cease when such shares (A) have been sold or otherwise disposed of or (B) may be sold under Rule 144 without regard to volume restrictions.

*Elion Oncology, Inc*. Pursuant to the Elion License Agreement, commencing 180 days after the agreement, upon Elion's request, we will use commercially reasonable efforts to file a registration statement for the shares issued to Elion in connection with the Elion License Agreement and will use commercially reasonable efforts to cause such registration statement to become effective. The obligation to register the shares will cease when such shares (A) have been sold or otherwise disposed of or (B) may be sold under Rule 144 without regard to volume restrictions.

## MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK

The following summary describes the material U.S. federal income tax consequences of the ownership and disposition of our common stock acquired in this offering by Non-U.S. Holders (as defined below). This discussion does not address all aspects of U.S. federal income taxes, does not discuss the potential application of the alternative minimum tax or the Medicare Contribution tax on net investment income, and does not deal with state or local taxes, U.S. federal gift, and estate tax laws, except to the limited extent provided below, or any non-U.S. tax consequences that may be relevant to Non-U.S. Holders in light of their particular circumstances.

Special rules different from those described below may apply to certain Non-U.S. Holders that are subject to special treatment under the Code, such as:

- insurance companies, banks, and other financial institutions;
- tax-exempt organizations (including private foundations) and tax-qualified retirement plans;
- "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities of which all interests are held by qualified foreign pension funds;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to our common stock being taken into account in an applicable financial statement;
- non-U.S. governments and international organizations;
- broker-dealers and traders in securities;
- U.S. expatriates and certain former citizens or long-term residents of the United States;
- persons that own, or are deemed to own, more than five percent of our common stock;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- persons that hold our common stock as part of a "straddle," "hedge," "conversion transaction," "synthetic security," or integrated investment or other risk reduction strategy;
- persons who do not hold our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, for investment purposes); and
- partnerships and other pass-through entities, and investors in such pass-through entities (regardless of their places of organization or formation).

Such Non-U.S. Holders are urged to consult their own tax advisors to determine the U.S. federal, state, local, and other tax consequences, including applicable non-U.S. tax consequences, that may be relevant to them.

Furthermore, the discussion below is based upon the provisions of the Code, and Treasury regulations, rulings, and judicial decisions thereunder as of the date hereof, and such authorities may be repealed, revoked, or modified, possibly retroactively, and are subject to differing interpretations which could result in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the Internal Revenue Service, or IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS will agree with such statements and conclusions or will not take a contrary position regarding the tax consequences described herein, or that any such contrary position would not be sustained by a court.

PERSONS CONSIDERING THE PURCHASE OF OUR COMMON STOCK PURSUANT TO THIS OFFERING SHOULD CONSULT THEIR OWN TAX ADVISORS CONCERNING THE U.S. FEDERAL INCOME TAX CONSEQUENCES OF ACQUIRING, OWNING, AND DISPOSING OF OUR COMMON STOCK IN LIGHT OF THEIR PARTICULAR SITUATIONS AS WELL AS ANY CONSEQUENCES ARISING UNDER THE LAWS OF ANY OTHER TAXING JURISDICTION, INCLUDING ANY STATE, LOCAL, OR NON-U.S. TAX CONSEQUENCES OR ANY U.S. FEDERAL NON-INCOME TAX CONSEQUENCES, AND THE POSSIBLE APPLICATION OF TAX TREATIES.

For the purposes of this discussion, a "Non-U.S. Holder" is a beneficial owner of common stock that is not a U.S. Holder for U.S. federal income tax purposes. A "U.S. Holder" means a beneficial owner of our common stock that is, for U.S. federal income tax purposes, (1) an individual who is a citizen or resident of the United States; (2) a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes), created or organized in or under the laws of the United States, any state thereof, or the District of Columbia; (3) an estate the income of which is subject to U.S. federal income taxation regardless of its source; or (4) a trust if it (i) is subject to the primary supervision of a court within the United States and one or more U.S. persons (within the meaning of Section 7701(a)(30) of the Code) have the authority to control all substantial decisions of the trust or (ii) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

For purposes of this discussion, a Non-U.S. Holder does not include a partnership or other pass-through entity (including for this purpose any entity that is treated as a partnership or other pass-through entity for U.S. federal income tax purposes). If a partnership or other pass-through entity is a beneficial owner of our common stock, the tax treatment of a partner (or other owner) will generally depend upon the status of the partner (or other owner) and the activities of the entity. If you are a partner (or other owner) of a partnership or other pass-through entity that acquires our common stock, you are urged to consult your tax advisor regarding the tax consequences of acquiring, owning and disposing of our common stock.

If you are an individual non-U.S. citizen, you may, in some cases, be deemed to be a resident alien (as opposed to a nonresident alien) by virtue of being present in the United States for at least 31 days in the calendar year and for an aggregate of at least 183 days during a three-year period ending in the current calendar year. Generally, for this purpose, all the days present in the current year, one-third of the days present in the immediately preceding year, and one-sixth of the days present in the second preceding year, are counted.

Resident aliens are generally subject to U.S. federal income tax as if they were U.S. citizens. Individuals who are uncertain of their status as resident or nonresident aliens for U.S. federal income tax purposes are urged to consult their own tax advisors regarding the U.S. federal income tax consequences of the ownership or disposition of our common stock.

**Distributions**

We do not expect to make any distributions on our common stock in the foreseeable future. If we do make distributions on our common stock, however, such distributions made to a Non-U.S. Holder of our common stock will constitute dividends for U.S. tax purposes to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Distributions in excess of our current and accumulated earnings and profits will constitute a return of capital that is applied against and reduces, but not below zero, a Non-U.S. Holder's adjusted tax basis in our common stock. Any remaining excess will be treated as gain recognized on the sale or exchange of our common stock as described below under "—Gain on Disposition of Our Common Stock."

Any distribution on our common stock that is treated as a dividend paid to a Non-U.S. Holder that is not effectively connected with such beneficial owner's conduct of a trade or business in the United States will generally be subject to withholding tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and the Non-U.S. Holder's country of residence. To obtain a reduced rate of withholding under a treaty, a Non-U.S. Holder generally will be required to provide the applicable withholding agent with a properly executed IRS Form W-8BEN, IRS Form W-8BEN-E, or other appropriate form, certifying the Non-U.S. Holder's entitlement to benefits under that treaty. Such form must be provided prior to the payment of dividends and must be updated periodically. If a Non-U.S. Holder holds stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to such agent. The holder's agent will then be required to provide certification to the applicable withholding agent, either directly or through other intermediaries. If you are eligible for a reduced rate of U.S. withholding tax under an income tax treaty, you should consult with your own tax advisor to determine if you are able to obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS.

Except to the extent that we elect (or the paying agent or other intermediary through which a Non-U.S. Holder holds our common stock elects) otherwise, we (or the intermediary) must generally withhold on the entire distribution, in which case the Non-U.S. Holder would be entitled to a refund from the IRS for the withholding tax on the portion of the distribution that exceeded our current and accumulated earnings and profits.

We generally are not required to withhold tax on dividends paid to a Non-U.S. Holder that are effectively connected with the beneficial owner's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment that the beneficial owner maintains in the United States) if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to the applicable withholding agent. In general, such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular rates applicable to U.S. persons. A corporate Non-U.S. Holder receiving effectively connected dividends may also be subject to an additional "branch profits tax," which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable treaty) on the corporate Non-U.S. Holder's effectively connected earnings and profits, subject to certain adjustments.

See also the section below titled "—Foreign Accounts" for additional withholding rules that may apply to dividends paid to certain foreign financial institutions or non-financial foreign entities.

**Gain on Disposition of Our Common Stock**

Subject to the discussions below under the sections titled "—Backup Withholding and Information Reporting," a Non-U.S. Holder generally will not be subject to U.S. federal income or withholding tax with respect to gain realized on a sale or other disposition of our common stock unless (1) the gain is effectively connected with a trade or business of such beneficial owner in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment that the beneficial owner maintains in the United States), (2) the Non-U.S. Holder is a nonresident alien individual and is present in the United States for 183 or more days in the taxable year of the disposition and certain other conditions are met, or (3) we are or have been a "United States real property holding corporation" within the meaning of Code Section 897(c)(2) at any time within the shorter of the five-year period preceding such disposition or the holder's holding period in the common stock.

If you are a Non-U.S. Holder described in (1) above, you will be required to pay tax on the net gain derived from the sale at the regular U.S. federal income tax rates applicable to U.S. persons. Corporate Non-U.S. Holders described in (1) above may also be subject to the additional branch profits tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. If you are an individual Non-U.S. Holder described in (2) above, you will be required to pay a flat 30% tax on the gain derived from the sale, which gain may be offset by U.S.-source capital losses (even though you are not considered a resident of the United States), provided you timely file a U.S. federal income tax return or returns with respect to such losses. With respect to (3) above, in general, we would be a United States real property holding corporation if United States real property interests (as defined in the Code and the Treasury Regulations) comprised (by fair market value) at least half of our assets. We believe that we are not, and do not anticipate becoming, a United States real property holding corporation. However, there can be no assurance that we will not become a United States real property holding corporation in the future. Even if we were treated as a United States real property holding corporation, gain realized by a Non-U.S. Holder on a disposition of our common stock would not be subject to U.S. federal income tax so long as (1) the Non-U.S. Holder owned, directly, indirectly, or constructively, no more than five percent of our common stock at all times within the shorter of (i) the five-year period preceding the disposition or (ii) such beneficial owner's holding period and (2) our common stock is regularly traded on an established securities market. We believe that our common stock, once listed on NASDAQ, will qualify as regularly traded on an established securities market, but there can be no assurance that this will always be the case.

**U.S. Federal Estate Tax**

The estates of nonresident alien individuals generally are subject to U.S. federal estate tax on property with a U.S. situs. Because we are a U.S. corporation, our common stock will be U.S.-situs property and, therefore, will be included in the taxable estate of a nonresident alien decedent, unless an applicable estate tax treaty between the United States and the decedent's country of residence provides otherwise. The terms "resident" and "nonresident" are defined differently for U.S. federal estate tax purposes than for U.S. federal income tax purposes. Investors are urged to consult their own tax advisors regarding the U.S. federal estate tax consequences of the ownership or disposition of our common stock.

**Backup Withholding and Information Reporting**

Generally, we or certain financial middlemen must report information to the IRS with respect to any dividends we pay on our common stock, including the amount of any such dividends, the name and address of the recipient, and the amount, if any, of tax withheld. A similar report is sent to the holder to whom any such dividends are paid. Pursuant to tax treaties or certain other agreements, the IRS may make its reports available to tax authorities in the recipient's country of residence.

Dividends paid by us (or our paying agents) to a Non-U.S. Holder may also be subject to U.S. backup withholding. U.S. backup withholding generally will not apply to a Non-U.S. Holder who provides a properly executed IRS Form W-8BEN or IRS Form W-8BEN-E, as applicable, or otherwise establishes an exemption, provided that the applicable withholding agent does not have actual knowledge or reason to know the holder is a U.S. person.

Under current U.S. federal income tax law, U.S. information reporting and backup withholding requirements generally will apply to the proceeds of a disposition of our common stock effected by or through a U.S. office of any broker, U.S. or non-U.S., unless the Non-U.S. Holder provides a properly executed IRS Form W-8BEN or IRS Form W-8BEN-E, as applicable, or otherwise meets documentary evidence requirements for establishing non-U.S. person status or otherwise establishes an exemption. Generally, U.S. information reporting and backup withholding requirements will not apply to a payment of disposition proceeds to a Non-U.S. Holder where the transaction is effected outside the United States through a non-U.S. office of a non-U.S. broker. Information reporting and backup withholding requirements may, however, apply to a payment of disposition proceeds if the broker has actual knowledge, or reason to know, that the holder is, in fact, a U.S. person. For information reporting purposes only, certain U.S.-related brokers may be treated in a manner similar to U.S. brokers.

Backup withholding is not an additional tax. If backup withholding is applied to you, you should consult with your own tax advisor to determine whether you have overpaid your U.S. federal income tax, and whether you are able to obtain a tax refund or credit of the overpaid amount.

**Foreign Accounts**

In addition, U.S. federal withholding taxes may apply under the Foreign Account Tax Compliance Act, or FATCA, on certain types of payments, including dividends on our common stock, made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution agrees to undertake certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. The 30% federal withholding tax described in this paragraph cannot be reduced under an income tax treaty with the United States. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States-owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules. Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock, and will apply to payments of gross proceeds from the sale or other disposition of such stock on or after January 1, 2019, except that under recently proposed regulations (the preamble to which specifies that taxpayers are permitted to rely on such proposed regulations pending finalization), no withholding will apply with respect to payments of gross proceeds.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING, AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAW, AS WELL AS TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, NON-U.S. OR U.S. FEDERAL NON-INCOME TAX LAWS SUCH AS ESTATE AND GIFT TAX.

## UNDERWRITING

Craig-Hallum Capital Group LLC and Benchmark Company, LLC are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in the underwriting agreement between us and the underwriters, each of the underwriters has agreed, severally and not jointly, to purchase from us the number of common stock set forth opposite its name below.

| Underwriter | Number of Shares |
|---|---|
| Craig-Hallum Capital Group LLC | |
| Benchmark Company, LLC | |
| National Securities Corporation | |
| Total | |

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased, or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares subject to their acceptance of the common stock from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

**Commissions and Discounts; Expenses**

The underwriters have advised us that they propose initially to offer the shares to the public at the public offering price set forth on the cover of this prospectus and to dealers at that price less a concession not in excess of $ per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discounts and commissions and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional common stock from us, as applicable.

| | | Total | |
|---|---|---|---|
| | Per Share | No Exercise | Full Exercise |
| Public offering price | | | |
| Underwriting discounts and commissions to be paid by us | | | |
| Proceeds, before expenses, to us | | | |

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately $473,000, which includes certain expenses incurred by the underwriters in connection with this offering that will be reimbursed by us. We have agreed to reimburse the underwriters for certain expenses incurred by them in connection with this offering (including certain fees and expenses of counsel for the underwriters and fees and expenses related to filings with and review by FINRA) in an amount not to exceed $135,000, plus an additional $9,500 reimbursement of an underwriter's previously incurred fees and expenses of counsel.

**Option to Purchase Additional Shares**

We have granted the underwriters an option to purchase up to an additional 322,500 shares of common stock at the public offering price, less the underwriting discounts and commissions, within 30 days from the date of this prospectus. If the underwriters exercise this option, each underwriter will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

**No Sales of Similar Securities**

In connection with this offering, we have agreed with the underwriters that, subject to certain customary exceptions, without the prior written consent of Craig-Hallum Capital Group LLC and Benchmark Company, LLC on behalf of the underwriters, we will not, for a period ending 90 days after the date of this prospectus (the Lock-Up Period) (a) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for common stock or (b) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of our common stock, whether any such transaction is to be settled by delivery of common stock or such other securities, in cash or otherwise.

In connection with this offering, certain of our stockholders and our directors and executive officers have agreed with the underwriters that, subject to certain customary exceptions, without the prior written consent of Craig-Hallum Capital Group LLC and Benchmark Company, LLC on behalf of the underwriters, they will not, for the Lock-Up Period, (a) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, make any short sale or otherwise transfer or dispose of, directly or indirectly, our common stock or any securities convertible into, exercisable or exchangeable for or that represent the right to receive our common stock; (b) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of such securities, whether any such transaction is to be settled by delivery of common stock or other securities, in cash or otherwise; (c) make any demand for or exercise any right with respect to the registration of any shares of our common stock or any security convertible into, exercisable or exchangeable for our common stock; or (d) publicly disclose the intention to do any of the foregoing. The underwriters may, in their sole discretion, permit any such transactions during the Lock-Up Period in whole or in part and at any time, with or without notice.

**Electronic Offer, Sale and Distribution of Securities**

A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The underwriters may agree to allocate a number of shares to selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of, nor incorporated by reference into, this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or the underwriters in their capacity as underwriter, and should not be relied upon by investors.

**Nasdaq Capital Market Listing**

We have applied to list our common stock on Nasdaq under the symbol “PCSA” and our common stock has been approved for listing contingent on the completion of this offering.

**Price Stabilization, Short Positions and Penalty Bids**

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representative may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. “Covered” short sales are sales made in an amount not greater than the underwriters’ option described above. The underwriters may close out any covered short position by either exercising their option or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them “naked” short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the closing of the offering.

Similar to other purchase transactions, the underwriters’ purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on the Nasdaq Capital Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representative will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

**Passive Market Making**

Any underwriters who are qualified market makers on the Nasdaq Capital Market may engage in passive market making transactions in the securities on the Nasdaq Capital Market in accordance with Rule 103 of Regulation M, during the business day prior to the pricing of the offering, before the commencement of offers or sales of the securities. Passive market makers must comply with applicable volume and price limitations and must be identified as passive market makers. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for such security; if all independent bids are lowered below the passive market maker's bid, however, the passive market maker's bid must then be lowered when certain purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

**Other Relationships**

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Some of the underwriters and certain of their affiliates may in the future engage in investment banking and other commercial dealings in the ordinary course of business with us and our affiliates, for which they may in the future receive customary fees, commissions and expenses.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers.

Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

**Selling Restrictions**

***Notice to Prospective Investors in the European Economic Area***

In relation to each Member State of the European Economic Area (a "Member State"), no shares have been offered or will be offered pursuant to the offering to the public in that Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Member State or, where appropriate, approved in another Member State and notified to the competent authority in that Member State, all in accordance with the Prospectus Regulation, except that offers of shares may be made to the public in that Member State at any time under the following exemptions under the Prospectus Regulation:

A to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

B. to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the underwriters; or

C. in any other circumstances falling within Article 1(4) of the Prospectus Regulation;

provided that no such offer of shares shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with us and each of the underwriters that it is a "qualified investor" within the meaning of Article 2(e) of the Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Member State to qualified investors as so defined or in circumstances in which the prior consent of the underwriters have been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an "offer to the public" in relation to shares in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

***MiFID II Product Governance***

Any person offering, selling or recommending the shares (a "distributor") should take into consideration the manufacturers' target market assessment; however, a distributor subject to MiFID II is responsible for undertaking its own target market assessment in respect of the shares (by either adopting or refining the manufacturers' target market assessment) and determining appropriate distribution channels.

***Notice to Prospective Investors in the United Kingdom***

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at, persons who are "qualified investors" (as defined in the Prospectus Regulation) who (i) have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the Order) and/or (ii) are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons") or otherwise in circumstances which have not resulted and will not result in an offer to the public of the shares in the United Kingdom within the meaning of the Financial Services and Markets Act 2000.

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons.

***Notice to Prospective Investors in Canada***

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriter is not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Equiniti Trust Company.

## LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Foley & Lardner LLP, Jacksonville, Florida. The underwriters have been represented in connection with this offering by Faegre Drinker Biddle & Reath LLP, Minneapolis, Minnesota.

## EXPERTS

The consolidated financial statements of Processa Pharmaceuticals, Inc. as of December 31, 2019 and 2018, and for the years then ended have been included herein and in the registration statement in reliance on the report of BD & Company, an independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1, including exhibits and schedules, under the Securities Act that registers the shares of our common stock to be sold in this offering. This prospectus does not contain all the information contained in the registration statement and the exhibits and schedules filed as part of the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and the exhibits and schedules filed as part of the registration statement. Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, we refer you to the copies of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit.

We file annual, quarterly and current reports, proxy statements and other information with the SEC under the Exchange Act. You can read our SEC filings, including the registration statement, at the SEC's website at www.sec.gov.

Our website address is www.processapharmaceuticals.com. The information contained in, and that can be accessed through, our website is not incorporated into and shall not be deemed to be part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

**INDEX TO FINANCIAL STATEMENTS**

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Processa Pharmaceuticals, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Processa Pharmaceuticals, Inc. (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations, stockholders' equity, and cash flows, for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

*/s/ BD & Company, Inc.*
Owings Mills, MD
March 6, 2020

We have served as the Company's auditor since 2017.

Processa Pharmaceuticals, Inc.
Consolidated Balance Sheets

| | December 31, 2019 | December 31, 2018 |
|---|---|---|
| **ASSETS** | | |
| **Current Assets** | | |
| Cash and cash equivalents | $ 691,536 | $ 1,740,961 |
| Due from related party | - | 21,583 |
| Prepaid expenses and other | 315,605 | 257,832 |
| Total Current Assets | 1,007,141 | 2,020,376 |
| **Property And Equipment** | | |
| Software | 19,740 | 19,740 |
| Office equipment | 9,327 | 9,327 |
| Total Cost | 29,067 | 29,067 |
| Less: accumulated depreciation | 20,137 | 11,692 |
| Property and equipment, net | 8,930 | 17,375 |
| **Other Assets** | | |
| Operating lease right-of-use assets, net of accumulated amortization | 219,074 | - |
| Intangible assets, net of accumulated amortization | 9,642,454 | 10,437,782 |
| Security deposit | 5,535 | 5,535 |
| Total Other Assets | 9,867,063 | 10,443,317 |
| **Total Assets** | $ 10,883,134 | $ 12,481,068 |
| | | |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| **Current Liabilities** | | |
| Senior convertible notes, net of debt issuance costs | $ 802,503 | $ 230,000 |
| Current maturities of operating lease liability | 77,992 | - |
| Accrued interest | 21,902 | 20,343 |
| Accounts payable | 75,612 | 292,102 |
| Due to related parties | 316 | - |
| Accrued expenses | 213,239 | 103,259 |
| Total Current Liabilities | 1,191,564 | 645,704 |
| **Non-current Liabilities** | | |
| Non-current operating lease liability | 147,390 | - |
| Net deferred tax liability | 1,531,630 | 2,134,346 |
| **Total Liabilities** | 2,870,584 | 2,780,050 |
| | | |
| **Commitments and Contingencies** | | |
| | | |
| **Stockholders' Equity** | | |
| Common stock, par value $0.0001, 100,000,000 and 350,000,000 shares authorized; 5,486,476 and 5,525,009 issued and outstanding at December 31, 2019 and 2018, respectively | 549 | 552 |
| Additional paid-in capital | 18,994,008 | 19,124,600 |
| Common stock deemed dividend payable: 28,971 shares at par value | 3 | - |
| Stock subscription receivable | - | (1,800,000) |
| Accumulated deficit | (10,982,010) | (7,624,134) |
| **Total Stockholders' Equity** | 8,012,550 | 9,701,018 |
| **Total Liabilities and Stockholders' Equity** | $ 10,883,134 | $ 12,481,068 |

The accompanying notes are an integral part of these consolidated financial statements.

Processa Pharmaceuticals, Inc.
Consolidated Statements of Operations
Years Ended December 31, 2019 and 2018

| | December 31, | |
|---|---|---|
| | 2019 | 2018 |
| **Operating Expenses** | | |
| Research and development expenses | $ 2,320,573 | $ 3,085,317 |
| General and administrative expenses | 1,614,909 | 1,439,623 |
| Operating Loss | (3,935,482) | (4,524,940) |
| Other Income (Expense) | | |
| Interest expense | (36,658) | (161,205) |
| Interest income | 11,548 | 18,297 |
| Net Operating Loss Before Income Tax Benefit | (3,960,592) | (4,667,848) |
| Income Tax Benefit | 602,716 | 902,801 |
| Net Loss | $ (3,357,876) | $ (3,765,047) |
| Net Loss Per Common Stock - Basic and Diluted | $ (0.70) | $ (0.71) |
| Weighted Average Common Stock Used to Compute Net Loss Per Common Stock - Basic and Diluted | 5,525,635 | 5,332,141 |

The accompanying notes are an integral part of these consolidated financial statements.

Processa Pharmaceuticals, Inc.
Consolidated Statement of Changes in Stockholders' Equity
Years Ended December 31, 2019 and 2018

| | Common Stock | | Additional Paid-In | Subscription | Common Stock Dividend | Accumulated | |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | Capital | Receivable | Payable | Deficit | Total |
| Balance, January 1, 2018 | 5,039,033 | $ 504 | $ 4,231,746 | $ - | $ - | $ (3,859,087) | $ 373,163 |
| Recognize the fair value of exclusive license intangible asset acquired from CoNCERT in exchange for 298,615 common stock of Processa held by Promet | - | - | 8,000,000 | - | - | - | 8,000,000 |
| Conversion of Senior convertible notes and accrued interest for common stock and stock purchase warrants, net of costs of $82,502 | 172,327 | 17 | 2,312,592 | - | - | - | 2,312,609 |
| Issuance of common stock units for cash, net of costs of $308,830 | 200,369 | 20 | 2,874,667 | - | - | - | 2,874,687 |
| Issuance of common stock units for a future research funding commitment, net of costs of $168,457 | 113,280 | 11 | 1,631,532 | (1,800,000) | - | - | (168,457) |
| Stock-based compensation | - | - | 74,063 | - | - | - | 74,063 |
| Net loss | - | - | - | - | - | (3,765,047) | (3,765,047) |
| Balance, January 1, 2019 | 5,525,009 | 552 | 19,124,600 | (1,800,000) | - | (7,624,134) | 9,701,018 |
| Conversion of Senior convertible debt for common stock and stock purchase warrants | 18,107 | 2 | 258,928 | - | - | - | 258,930 |
| Payments made by investor for clinical trial costs | - | - | - | 900,000 | - | - | 900,000 |
| Pledged shares of common stock forfeited upon revised research funding commitment | (56,640) | (5) | (899,995) | 900,000 | - | - | - |
| Stock-based compensation | - | - | 510,478 | - | - | - | 510,478 |
| Deemed stock dividend due to full ratchet anti-dilution adjustment | - | - | (3) | - | 3 | - | - |
| Net loss | - | - | - | - | - | (3,357,876) | (3,357,876) |
| Balance, December 31, 2019 | 5,486,476 | $ 549 | $ 18,994,008 | $ - | $ 3 | $ (10,982,010) | $ 8,012,550 |

The accompanying notes are an integral part of these consolidated financial statements.

Processa Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows
Years Ended December 31, 2019 and 2018

| | December 31, | |
|---|---|---|
| | 2019 | 2018 |
| **Cash Flows From Operating Activities** | | |
| Net Loss | $ (3,357,876) | $ (3,765,047) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 8,445 | 8,445 |
| Non-cash lease expense for right-of-use assets | 74,124 | - |
| Amortization of debt issuance costs | 1,783 | 67,069 |
| Amortization of intangible asset | 795,328 | 621,647 |
| Deferred income tax (benefit) expense | (602,716) | (902,801) |
| Stock-based compensation | 510,478 | 74,063 |
| Net changes in operating assets and liabilities: | | |
| Prepaid expenses and other | (57,773) | (216,386) |
| Operating lease liability | (77,779) | - |
| Accrued interest | 30,489 | 94,122 |
| Accounts payable | (216,490) | 241,416 |
| Due from related parties | 21,899 | 40,690 |
| Accrued expenses | 119,943 | 28,868 |
| Net cash (used in) operating activities | (2,750,145) | (3,707,914) |
| | | |
| **Cash Flows From Investing Activities** | | |
| Purchase of software license | - | (20,500) |
| Purchase of intangible asset | - | (1,782) |
| Net cash (used in) investing activities | - | (22,282) |
| | | |
| **Cash Flows From Financing Activities** | | |
| Net proceeds from issuance of stock | - | 2,874,687 |
| Proceeds from issuance of senior convertible notes | 805,000 | - |
| Proceeds received in satisfaction of stock subscription receivable | 900,000 | - |
| Transaction costs incurred on senior convertible notes | (4,280) | (82,502) |
| Payment of placement agent and legal fees associated with clinical funding commitment | - | (168,457) |
| Net cash provided by financing activities | 1,700,720 | 2,623,728 |
| | | |
| **Net (Decrease)/Increase in Cash and Cash Equivalents** | (1,049,425) | (1,106,468) |
| **Cash and Cash Equivalents - Beginning of Year** | 1,740,961 | 2,847,429 |
| **Cash and Cash Equivalents - End of Year** | $ 691,536 | $ 1,740,961 |

The accompanying notes are an integral part of these consolidated financial statements.

Processa Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows (continued)
Years Ended December 31, 2019 and 2018

| | 2019 | 2018 |
|---|---|---|
| **Supplemental Cash Flow Information:** | | |
| Cash paid for interest | $ - | $ - |
| Cash paid for income taxes | - | - |
| | | |
| **Non-Cash Investing and Financing Activities:** | | |
| Right-of-use asset obtained in exchange for operating lease liability | $ (293,198) | $ - |
| Reduction in deferred lease liability | (9,963) | - |
| Operating lease liability | 303,161 | - |
| Net | $ - | $ - |
| | | |
| Recognize the exclusive license intangible asset acquired from CoNCERT | $ - | $ (11,037,147) |
| Recognize deferred tax liability for basis difference of Intangible asset | - | 3,037,147 |
| Recognize additional paid-in capital for consideration paid from the transfer of 298,615 common stock of Processa released by Promet to CoNCERT for Processa | - | 8,000,000 |
| Net | $ - | $ - |
| | | |
| Conversion of $230,000 and $2,350,000, respectively, of Senior Convertible Debt and related accrued interest of $28,930 and $114,333, respectively, into 18,107 and 172,327 shares, respectively, of common stock and warrants | $ 258,930 | $ 2,464,333 |
| | | |
| Common stock and stock purchase warrants (forfeited)/issued in connection with a clinical trial funding commitment | $ (900,000) | $ 1,800,000 |

The accompanying notes are an integral part of these consolidated financial statements.

**Note 1 – Organization and Description of the Business**

Processa Pharmaceuticals, Inc. ("Processa" or "the Company") is an emerging clinical stage biopharmaceutical company focused on the development of drug products that are intended to provide treatment for and improve the survival and/or quality of life of patients who have a high unmet medical need condition or who have no alternative treatment. Within this group of pharmaceutical products, we currently are developing one product for multiple indications (i.e., the use of a drug to treat a particular disease), will begin developing a newly acquired drug once adequate funding has been obtained, and are searching for additional products for our portfolio.

*PCS499*

Our lead product, PCS499, is an oral tablet that is a deuterated analog of the major metabolites of pentoxifylline (Trental®). The advantage of PCS499 is that it potentially may work in many conditions because it has multiple pharmacological targets it affects that are important in the treatment of these conditions. Based on its pharmacological activity, we have identified multiple unmet medical need conditions where the use of PCS499 may result in clinical efficacy. The lead indication currently under development for PCS499 is Necrobiosis Lipoidica (NL). NL is a chronic, disfiguring condition affecting the skin and the tissue under the skin typically on the lower extremities with no currently approved FDA treatments. NL presents more commonly in women than in men and ulceration can occur in approximately 30% of NL patients. More severe complications can occur, such as deep tissue infections and osteonecrosis threatening life of the limb. Approximately 74,000 - 185,000 people in the United States and more than 200,000 – 500,000 people outside the United States are affected by NL.

The degeneration of tissue occurring at the NL lesion site may be caused by a number of pathophysiological changes, which has made it extremely difficult to develop effective treatments for this condition. PCS499 may provide a solution since PCS499 and its metabolites affect a number of biological pathways, several of which could contribute to the pathophysiology associated with NL.

On June 18, 2018, the FDA granted orphan-drug designation to PCS499 for the treatment of NL. On September 28, 2018, the IND for PCS499 in NL was made effective by the FDA, such that we could move forward with the Phase 2A safety and dose tolerability trial. We dosed our first NL patient in this Phase 2A clinical trial on January 29, 2019 and completed enrollment on August 23, 2019. The main objective of the trial is to evaluate the safety and tolerability of PCS499 in patients with NL and to use the collected safety and efficacy data to design future clinical trials. Based on toxicology studies and healthy human volunteer studies, Processa and the FDA agreed that a PCS499 dose of 1.8 grams/day would be the highest dose administered to NL patients in this Phase 2 trial. As anticipated, the PCS499 dose of 1.8 grams/day, 50% greater than the maximum tolerated dose of PTX, appeared to be well tolerated with no serious adverse events reported. To date, nine of the patients dosed at 1.8 grams/day have reported only mild adverse events related to the treatment, which occurred mostly in the first month of treatment and were quickly resolved. As expected, gastrointestinal or CNS adverse events were reported most often.

We have a meeting scheduled with the FDA in March 2020 to further discuss the development of PCS499, including a future clinical trial.

*PCS100*

On August 29, 2019, we entered into an exclusive license agreement with Akashi Therapeutics, Inc. ("Akashi") to develop and commercialize an anti-fibrotic, anti-inflammatory drug, PCS100, which also promotes healthy muscle fiber regeneration. In previous clinical trials in Duchenne Muscular Dystrophy (DMD), PCS100 showed promising improvement in the muscle strength of non-ambulant pediatric patients. Although the FDA placed a clinical hold on the DMD trial after a serious adverse event in a pediatric patient, the FDA has removed the clinical hold and defined how PCS100 can resume clinical trials in DMD. Once we have obtained adequate funding, we plan to develop PCS100 in rare adult fibrotic related diseases such as focal segmental glomerulosclerosis, idiopathic pulmonary fibrosis or Scleroderma.

**Note 2 – Going Concern and Management's Plans**

Our consolidated financial statements are prepared using U.S. GAAP and are based on the assumption that we will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. We face certain risks and uncertainties regarding product development and commercialization, limited working capital, recurring losses and negative cash flow from operations, future profitability, ability to obtain future capital, protection of patents, technologies and property rights, competition, rapid technological change, navigating the domestic and major foreign markets' regulatory and clinical environment, recruiting and retaining key personnel, dependence on third party manufacturing organizations, third party collaboration and licensing agreements, lack of sales and marketing activities and having no customers or pharmaceutical products to sell or distribute. These risks and other factors raised substantial doubt about our ability to continue as a going concern as of the date of the filing of this Annual Report on Form 10-K for the year ended December 31, 2019.

We have relied on private placements with a small group of accredited investors to finance our business and operations. We have not had any revenue since our inception, and we do not currently have any revenue under contract or any immediate sales prospects. As of December 31, 2019, we had an accumulated deficit of approximately $11.0 million. For the year ended December 31, 2019, we incurred a net loss from continuing operations of approximately $3.4 million and used approximately $2.8 million in net cash from operating activities. We expect our operating costs to be substantial as we incur costs related to the clinical trials for our product candidates and that we will operate at a loss for the foreseeable future.

On September 20, 2019, we entered into two separate LOC Agreements ("LOC Agreements") with DKBK Enterprises, LLC ("DKBK") and CorLyst, LLC ("CorLyst", and, together with DKBK, collectively, "Lenders"), both related parties, which provide a revolving commitment of up to $700,000 each ($1.4 million total). Under the LOC Agreements, all funds borrowed bear interest at an annual rate of 8%. The promissory notes issued in connection with the LOC Agreements provide that the Lenders have the right to convert all or any portion of the principal and accrued and unpaid interest into our common stock on the same terms as our 2019 Senior Convertible Notes. Therefore, the Lenders may convert the outstanding debt under the LOC Agreements into our common stock at a conversion price equal to the lower of (i) $14.28 per share, (ii) a price per share equal to a 10% discount to the pre-money valuation of an equity sale of the Company's common stock for cash, or (iii) at an adjusted price; all as more particularly described in the 2019 Senior Convertible Notes. Our CEO is also the CEO and Managing Member of both Lenders. CorLyst beneficially owns 996,376 shares of Processa common stock, representing approximately 17.8% of the Company's outstanding shares of voting capital stock. We have not drawn any amounts under these LOC agreements as of February 28, 2020.

In connection with the LOC Agreements, we amended the existing pledge agreement with PoC Capital on September 30, 2019 to reduce the committed funds from $1.8 million to $900,000, which has been paid in full as of December 31, 2019. As part of the original pledge agreement, we issued 113,280 shares of common stock and 113,280 warrants to purchase shares of common stock to PoC Capital but held 56,640 shares and 56,640 warrants as collateral until certain payment milestones were met. PoC Capital forfeited the pledged collateral in the amended agreement. The forfeited shares and warrants have been returned to us.

In December 2019, we closed our bridge financing and issued $805,000 of the 2019 Senior Notes to accredited investors (see Note 7). We have also delayed some of our cash outflows, primarily through the deferred payment of salaries ($122,175, which has been accrued and included in accrued expenses at December 31, 2019) until such time as we have raised sufficient funding.

Based on our current plan, we will need to raise additional capital to fund our future operations. While we believe our current resources are adequate to complete our current Phase 2A trial for NL, we do not currently have resources to conduct other future trials or develop PCS100 without raising additional capital. As noted above, the timing and extent of our spending will depend on the costs associated with, and the results of our Phase 2A trial for NL. Our anticipated spending and our cash flow needs could change significantly as the trial progresses. There may be costs we incur during our trial that we do not currently anticipate in order to complete the trial, requiring us to need additional capital sooner than currently expected.

The additional funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of, or suspend our current or future clinical trials, or research and development programs. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. To the extent that we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Uncertainty concerning our ability to continue as a going concern may hinder our ability to obtain future financing. Continued operations and our ability to continue as a going concern are dependent on our ability to obtain additional funding in the future and thereafter, and no assurances can be given that such funding will be available at all, in a sufficient amount, or on reasonable terms. Without additional funds from debt or equity financing, sales of assets, sales or out-licenses of intellectual property or technologies, or other transactions providing funds, we will rapidly exhaust our resources and be unable to continue operations. Absent additional funding, we believe that our cash and cash equivalents will not be sufficient to fund our operations for a period of one year or more after the date that these condensed consolidated financial statements are available to be issued based on the timing and amount of our projected net loss from continuing operations and cash to be used in operating activities during that period of time.

As a result, substantial doubt exists about our ability to continue as a going concern as of the date of the filing of the Annual Report on Form 10-K for the year ended December 31, 2019. The accompanying consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of recorded assets, or the amounts and classification of liabilities that might be different should we be unable to continue as a going concern based on the outcome of these uncertainties described above.

**Note 3 – Basis of Presentation and Summary of Significant Accounting Policies**

*Basis of Presentation*

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and pursuant to the rules and regulations of the United States Securities and Exchange Commission (the "SEC"), and reflect all of our activities, including those of our wholly-owned subsidiary. All material intercompany accounts and transactions have been eliminated in consolidation.

We have reclassified certain immaterial prior year amounts to conform to our current year presentation. The reclassification of prior period amounts had no effect on previously reported net income, stockholders' equity or cash flows.

On December 23, 2019, we effected a 1-for-7 reverse stock split, reducing the number of the Company's common stock outstanding on that date from 38,404,530 shares to 5,486,476 shares. The number of authorized shares of common stock remained unchanged at 100,000,000 shares and the number of authorized shares of preferred stock remained unchanged at 1,000,000 shares. Additionally, the conversion price of our 2019 Senior Notes, the exercise price of all then outstanding options and warrants, and the number of shares reserved for future issuance pursuant to our equity compensation plans were all adjusted proportionately in connection with the reverse stock split. All share and per share amounts and conversion and exercise prices presented herein have been adjusted retroactively to reflect this change.

*Use of Estimates*

In preparing our consolidated financial statements and related disclosures in conformity with U.S. GAAP and pursuant to the rules and regulations of the SEC, we make estimates and judgments that affect the amounts reported in the consolidated financial statements and accompanying notes. Estimates are used for, but not limited to stock-based compensation, determining the fair value of acquired assets and assumed liabilities, intangible assets, and income taxes. These estimates and assumptions are continuously evaluated and are based on management's experience and knowledge of the relevant facts and circumstances. While we believe the estimates to be reasonable, actual results could differ materially from those estimates and could impact future results of operations and cash flows.

*Cash and Cash Equivalents*

Cash and cash equivalents include cash on hand and money market funds. We consider all highly liquid investments with a maturity at the date of purchase of three months or less to be cash equivalents.

*Property and Equipment*

Property is stated at cost, less accumulated depreciation. Costs of renewals and improvements that extend the useful lives of the assets are capitalized. Expenditures for maintenance and routine repairs are charged to expense as incurred. Depreciation is recognized on a straight-line basis over the estimated useful lives of the assets, which generally range from 3 to 5 years. We amortize leasehold improvements over the shorter of the estimated useful life of the asset or the term of the related lease. Upon retirement or disposition of assets, the costs and related accumulated depreciation are removed from the accounts with the resulting net gain or loss, if any, reflected in the consolidated statement of operations.

*Intangible Assets*

Intangible assets acquired individually or with a group of other assets from others (other than in a business combination) are recognized at cost, including transaction costs, and allocated to the individual assets acquired based on relative fair values and no goodwill is recognized. Cost is measured based on cash consideration paid. If consideration given is in the form of non-cash assets, liabilities incurred, or equity interests issued, measurement of cost is based on either the fair value of the consideration given or the fair value of the assets (or net assets) acquired, whichever is more clearly evident and more reliably measurable. Costs of internally developing, maintaining or restoring intangible assets that are not specifically identifiable, have indeterminate lives or are inherent in a continuing business are expensed as incurred.

Intangible assets purchased from others for use in research and development activities and that have alternative future uses (in research and development projects or otherwise) are capitalized in accordance with ASC Topic 350, *Intangibles – Goodwill and Other.* Those that have no alternative future uses (in research and development projects or otherwise) and therefore no separate economic value are considered research and development costs and are expensed as incurred. Amortization of intangibles used in research and development activities is a research and development cost.

Intangibles with a finite useful life are amortized using the straight-line method unless the pattern in which the economic benefits of the intangible assets are consumed or used up are reliably determinable. The useful life is the best estimate of the period over which the asset is expected to contribute directly or indirectly to our future cash flows. The useful life is based on the duration of the expected use of the asset by us and the legal, regulatory or contractual provisions that constrain the useful life and future cash flows of the asset, including regulatory acceptance and approval, obsolescence, demand, competition and other economic factors. We evaluate the remaining useful life of intangible assets each reporting period to determine whether any revision to the remaining useful life is required. If the remaining useful life is changed, the remaining carrying amount of the intangible asset will be amortized prospectively over the revised remaining useful life. If an income approach is used to measure the fair value of an intangible asset, we consider the period of expected cash flows used to measure the fair value of the intangible asset, adjusted as appropriate for company-specific factors discussed above, to determine the useful life for amortization purposes.

If no regulatory, contractual, competitive, economic or other factors limit the useful life of the intangible to us, the useful life is considered indefinite. Intangibles with an indefinite useful life are not amortized until its useful life is determined to be no longer indefinite. If the useful life is determined to be finite, the intangible is tested for impairment and the carrying amount is amortized over the remaining useful life in accordance with intangibles subject to amortization. Indefinite-lived intangibles are tested for impairment annually and more frequently if events or circumstances indicate that it is more-likely-than-not that the asset is impaired.

*Impairment of Long-Lived Assets and Intangibles Other Than Goodwill*

We account for the impairment of long-lived assets in accordance with ASC 360, *Property, Plant and Equipment* and ASC 350, *Intangibles – Goodwill and Other,* which require that long-lived assets and certain identifiable intangibles be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to its expected future undiscounted net cash flows generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amounts of the assets exceed the fair value of the assets based on the present value of the expected future cash flows associated with the use of the asset. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. Based on management's evaluation, there was no impairment loss recorded during the years ended December 31, 2019 and 2018.

*Fair Value Measurements and Disclosure*

We apply ASC 820, *Fair Value Measurements and Disclosures*, which expands disclosures for assets and liabilities that are measured and reported at fair value on a recurring basis. Fair value is defined as an exit price, representing the amount that would be received upon the sale of an asset or payment to transfer a liability in an orderly transaction between market participants.

Fair value is a market-based measurement that is determined based on assumptions that market participants would use in pricing an asset or liability. A three-tier fair value hierarchy is used to prioritize the inputs in measuring fair value as follows:

Level 1 – Quoted market prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2 – Quoted market prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable, either directly or indirectly. Fair value determined through the use of models or other valuation methodologies.

Level 3 – Significant unobservable inputs for assets or liabilities that cannot be corroborated by market data. Fair value is determined by the reporting entity's own assumptions utilizing the best information available and includes situations where there is little market activity for the asset or liability.

The asset's or liability's fair value measurement within the fair value hierarchy is based upon the lowest level of any input that is significant to the fair value measurement. Our policy is to recognize transfers between levels of the fair value hierarchy in the period the event or change in circumstances that caused the transfer. There were no transfers into or out of Level 1, 2, or 3 during the periods presented.

*Stock-based Compensation*

Stock-based compensation expense is based on the grant-date fair value estimated in accordance with the provisions of ASC 718, *Compensation-Stock Compensation.* We expense stock-based compensation to employees over the requisite service period based on the estimated grant-date fair value of the awards. For awards that contain performance vesting conditions, we do not recognize compensation expense until achieving the performance condition is probable. Stock-based awards with graded-vesting schedules are recognized on a straight-line basis over the requisite service period for each separately vesting portion of the award. We estimate the fair value of stock option grants using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. Stock-based compensation costs are recorded as general and administrative or research and development costs in the consolidated statements of operations based upon the underlying individual's role.

*Net Loss Per Share*

Basic loss per share is computed by dividing our net loss available to common stockholders by the weighted average number of shares of common stock outstanding during the period. Diluted loss per share is computed by dividing our net loss available to common stockholders by the diluted weighted average number of shares of common stock during the period. Since we experienced a net loss for all periods presented, basic and diluted net loss per share are the same. As such, diluted loss per share for the years ended December 31, 2019 and 2018 excludes the impact of potentially dilutive common stock related to outstanding stock options and warrants and the conversion of our 2017 and 2019 Senior Notes since those shares would have an anti-dilutive effect on loss per share.

As more fully described in Note 11, we have determined the sale of the 2019 Senior Notes in late 2019 triggered the full ratchet anti-dilution provision of the common stock we sold in 2018 Private Placement Transactions. For purposes of computing our basic and diluted EPS, we increased our net loss available for common stockholders by the fair value of the additional shares to be issued since they did not affect all our common stockholders equally and there are no contingencies related to the issuance of these shares. We also included the related shares which will be issued in 2020 in our weighted number of shares of common stock outstanding.

Our diluted net loss per share for the years ended December 31, 2019 and 2018 excluded 715,452, and 588,586 of potentially dilutive common stock, respectively, related to the conversion of our Senior Notes and outstanding stock options and warrants since those shares would have had an anti-dilutive effect on loss per share during the years then ended.

*Segments*

We operate in one segment. Management uses one measurement of profitability and does not segregate its business for internal reporting. All our assets are located within the United States.

*Fair Value of Financial Instruments*

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable and the senior convertible notes approximate fair value because of the short-term maturity of these instruments, including the mandatory conversion of the Senior Notes into our common stock upon meeting certain conditions.

*Debt Issuance Costs*

We recognized the debt issuance costs incurred related to our 2017 and 2019 Senior Notes as a reduction of the carrying amount of the 2017 and 2019 Senior Notes on the face of the consolidated balance sheet. The debt issuance costs are amortized to interest expense using the straight-line method over the term of the 2019 Senior Notes and the interest method over the term of the 2017 Senior Notes.

*Research and development*

Research and development costs are expensed as incurred and consisted of direct and overhead-related expenses. Research and development costs totaled $2,320,573 and $3,085,317 for the years ended December 31, 2019 and 2018, respectively. Expenditures to acquire technologies, including licenses, which are utilized in research and development and that have no alternative future use are expensed when incurred. Technology we develop for use in our products is expensed as incurred until technological feasibility has been established after which it is capitalized and depreciated. No research and development costs were capitalized during the years ended December 31, 2019 and 2018.

*Income Taxes*

As a result of our reverse acquisition merger, there was an ownership change as defined by Internal Revenue Code Section 382. Prior to the closing of the transaction, Promet was treated as a partnership for federal income tax purposes and thus was not subject to income taxes at the entity level, and no provision or liability for income taxes has been included in the consolidated financial statements through October 4, 2017. In addition, Promet determined that it was not required to record a liability related to uncertain tax positions as a result of the requirements of ASC 740-10-25 *Income Taxes.* The net deferred tax assets of Heatwurx were principally federal and state net operating loss carry forwards, which are significantly limited following an ownership change as defined by Internal Revenue Code Section 382.

We account for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, we recognize the tax benefit from an uncertain tax position only if it is more-likely-than-not that the tax position will be sustained upon examination by the taxing authorities, based on the technical merits of the position. Estimated interest and penalties related to uncertain tax positions are included as a component of interest expense and general and administrative expense, respectively. We had no unrecognized tax benefits or uncertain tax positions for any periods presented.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 ("TCJA") was signed into law. In December 2017, the SEC issued Staff Accounting Bulletin 118 ("SAB 118") to provide clarification in implementing the TCJA when registrants do not have the necessary information available to complete the accounting for an element of the TCJA in the period of its enactment. SAB 118 provides for tax amounts to be classified as provisional and subject to remeasurement for up to one year from the enactment date for such elements when the accounting effect is not complete but can be reasonably estimated. We considered our estimates of the tax effects of the TCJA on the components of our tax provision to be reasonable and no provisional estimates subject to remeasurement were necessary to complete the accounting.

We file U.S. federal income and California and Maryland state tax returns. There are currently no income tax examinations underway for these jurisdictions. However, tax years from and including 2016 remain open for examination by federal and state income tax authorities.

*Recent Accounting Pronouncements*

From time to time, the Financial Accounting Standards Board ("FASB") or other standard setting bodies issue new accounting pronouncements. Updates to the FASB Accounting Standards Codification are communicated through issuance of an Accounting Standards Update ("ASU"). We have implemented all new accounting pronouncements that are in effect and that may impact our consolidated financial statements. We have evaluated recently issued accounting pronouncements and determined that there is no material impact on our financial position or results of operations.

*Recently adopted accounting pronouncements*

In July 2017, the FASB issued Accounting Standards Update 2017-11 (ASU 2017-11), which allows companies to exclude a down round feature when determining whether a financial instrument is considered indexed to the entity's own stock. As a result, financial instruments with round down features are no longer classified as liabilities and embedded conversion options with down round features are no longer bifurcated. For equity-classified freestanding financial instruments, such as warrants, an entity will treat the value of the effect of the round down, when triggered, as a dividend and a reduction of income available to common stockholders in computing basic earnings per share. The guidance in ASU 2017-11 is effective for fiscal year beginning after December 15, 2018, and interim periods within those fiscal years. We early adopted ASU 2017-11 effective January 1, 2018 without a material impact on our consolidated financial statements.

On January 1, 2019, we adopted Accounting Standards Codification (ASC) 842, *Leases*. ASC 842 was issued to increase transparency and comparability among entities by recognizing right-of-use assets and lease liabilities on the balance sheet and disclosing key information about our lease agreements. We elected practical expedients upon transition that allows us to not reassess the lease classification of our leases, whether initial direct costs qualify for capitalization for our leases or whether any expired contracts are or contain leases. Additionally, we elected the optional transition method that allows for a cumulative effect adjustment in the period of adoption and we did not restate prior periods. The adoption of the new guidance on leasing resulted in the recognition of a right-of-use asset of $293,198 and lease obligations of $303,161. The difference between the right-of-use asset and the lease obligations is due to deferred rent liability related to our facility operating lease at December 31, 2018.

The adoption of the new guidance did not have a material impact on the consolidated statement of operations. For further details regarding the adoption of this standard, see Note 12, "Operating Leases."

**Note 4 – Acquisition**

On October 4, 2017, in exchange for 90 percent or 4,535,121 shares of our common stock, we acquired the net assets of Promet, totaling $1,017,342, in a transaction that was accounted for as a reverse acquisition in accordance with ASC 805-40-45, *Business Combinations - Reverse Acquisitions*. We completed this transaction to provide improved access to the capital markets in order to obtain the resources necessary to continue the development of PCS499 and build a clinical development drug company. Immediately following the transaction, we had 5,039,033 shares of common stock issued and outstanding, which represented our total legal capital. Promet owned approximately 84% of our common stock, and as part of the Section 351 transaction, held approximately 6% for the benefit of CoNCERT until the CoNCERT transaction had been concluded, whereupon CoNCERT took title to their shares. Together, Promet's pre-transaction owners and CoNCERT held a 90% economic and voting interest in the combined company immediately following completion of the transaction and as such, Promet was considered the acquirer for accounting purposes. Subsequent to the Merger, we changed our name from "Heatwurx, Inc." to "Processa Pharmaceuticals, Inc." and our ticker symbol was changed from "HWRX" to "PCSA."

The transaction was considered a capital transaction in substance. Accordingly, for accounting purposes, it was assumed that Promet issued shares to Heatwurx at fair value, net of the assets and liabilities assumed from Heatwurx as shown below, which were recognized as a reduction of additional paid-in-capital at closing of the reverse merger. The net recognized value of Heatwurx identifiable assets and liabilities included the following:

| | | |
|---|---|---|
| Cash | $ | 6,280 |
| Accounts payable | | (26,098) |
| Accrued expenses | | (17,932) |
| Net liabilities assumed | $ | (37,750) |

Our consolidated financial statements present the financial position (with a retrospective adjustment to Promet's legal capital to reflect our pre-merger capital structure) and operations of Promet prior to October 4, 2017, and of the combined company from October 4, 2017 forward. The assets and liabilities of Promet are recognized and measured at their historical carrying amounts. The accumulated deficit and other equity balances of Promet have been carried forward and adjusted to reflect our legal shares and par value with the difference allocated to additional paid-in capital.

Promet incurred acquisition-related transaction costs of $58,763, which are included in general and administrative expense, a component of operating expenses in the consolidated statements of operations.

Earnings per share ("EPS") is calculated using our equity structure, including the equity interests issued to Promet in the asset acquisition transaction. Prior to the reverse acquisition, EPS was based on Promet's net income and weighted average common stock outstanding that were received in the asset purchase transaction. Subsequent to the reverse acquisition, EPS is based on the weighted actual number of common stock outstanding during that period (see Note 11).

**Note 5 - Intangible Assets**

Intangible assets at December 31, 2019 consisted of the capitalized costs of $20,500 for a purchased software license and $11,038,929 associated with our exercise of the option to acquire the exclusive license from CoNCERT related to patent rights and know-how to develop and commercialize compounds and products for PCS499 and each metabolite thereof and the related income tax effects. The capitalized costs for the license rights to PCS499 include $8 million purchase price, $1,782 in transaction costs and $3,037,147 associated with the initial recognition of an offsetting deferred tax liability related to the acquired temporary difference for an asset purchased that is not a business combination and has a tax basis of $1,782 in accordance with ASC 740-10-25-51 *Income Taxes*. In accordance with ASC Topic 730, *Research and Development*, we capitalized the costs of acquiring the exclusive license rights to PCS499 as the exclusive license rights represent intangible assets to be used in research and development activities that have future alternative uses.

*Acquisition of the CoNCERT License*

On March 19, 2018, Promet, Processa and CoNCERT amended the CoNCERT Agreement executed in October 2017. The Amendment assigned the CONCERT Agreement to us and we exercised the exclusive option for the PCS499 compound in exchange for CoNCERT receiving, in part, $8 million of our common stock that was held by Promet (298,615 shares at $26.79 per share) and for the benefit of Processa in satisfaction of the obligation due for the exclusive license for PCS499 acquired by us. There was no change in the total shares issued and outstanding of 5,039,033. Promet contributed the payment of the obligation due for the exclusive license to us without consideration paid to them. As a result of the transaction, we recognized an exclusive license intangible asset with a fair value of $8 million and an offsetting increase in additional paid-in capital resulting from the exchange.

The CoNCERT Agreement provides us with an exclusive (including to CoNCERT) royalty-bearing license to CoNCERT's patent rights and know-how to develop, manufacture, use, sub-license and commercialize compounds (PCS499 and each metabolite thereof) and pharmaceutical products with such compounds worldwide. We are required to pay CoNCERT royalties, on a product by product basis, on worldwide net sales, as follows:

- 4% of the net sales of the portion less than or equal to $100 million;
- 5% of the net sales of the portion greater than $100 million and less than or equal to $500 million;
- 6% of the net sales of the portion greater than $500 million and less than or equal to $1.0 billion; and
- 10% of the net sales of the portion greater than $1 billion if such sales are made by us or our affiliates.

With respect to net sales made by us or any of our affiliates, we will pay 10% of net sales and with respect to sales by our sublicensees, we will pay the greater of (i) 6% or (ii) 50% of all payment received by us with respect to such sublicensee. We will also pay 15% of any sublicense revenue earned by us for a period equivalent to the royalty term (as defined in the CoNCERT Agreement) until the earliest of (a) our raising $8 million of gross proceeds and (b) CoNCERT being able to sell its shares of our common stock without restrictions pursuant to the terms of the amended Agreement. All other terms of the CONCERT Agreement remained unchanged.

We estimated the fair value of the common stock issued based on the market approach and CoNCERT's requirement to receive shares valued at $8 million. The market approach was based on the final negotiated number of shares of stock determined on a volume weighted average price of our common stock over a 45 day period preceding the mid-February 2018 finalized negotiation of the modification to the option and license agreement with CoNCERT, an unrelated third party, for the exclusive license rights to PCS499. The total cost recognized for the exclusive license acquired represents the allocated fair value related to the stock transferred to CoNCERT plus the recognition of the deferred tax liability related to the acquired temporary difference and the transaction costs incurred to complete the transaction as discussed above.

Our intangible assets consist of the following at December 31, 2019:

| | License Rights to PCS499 | Software License | December 31, 2019 |
|---|---|---|---|
| Gross intangible assets | $ 11,038,929 | $ 20,500 | $ 11,059,429 |
| Less: accumulated amortization | (1,405,301) | (11,674) | (1,416,975) |
| Total intangible assets, net | $ 9,633,628 | $ 8,826 | $ 9,642,454 |

Our intangible assets consist of the following at December 31, 2018:

| | License Rights to PCS499 | Software License | December 31, 2018 |
|---|---|---|---|
| Gross intangible assets | $ 11,038,929 | $ 20,500 | $ 11,059,429 |
| Less: accumulated amortization | (616,807) | (4,840) | (621,647) |
| Total intangible assets, net | $ 10,422,122 | $ 15,660 | $ 10,437,782 |

Amortization expense was $795,328 and $621,647 for the years ended December 31, 2019 and 2018 and is included within research and development expense in the accompanying consolidated statements of operations. As of December 31, 2019, estimated amortization expense for the next year will be approximately $795,000 and approximately $788,000 per year for annual periods thereafter.

**Note 6 – License Agreement for PCS100**

On August 29, 2019, we entered into an exclusive license agreement with Akashi to develop and commercialize an anti-fibrotic, anti-inflammatory drug, PCS100, which also promotes healthy muscle fiber regeneration. In previous clinical trials in Duchenne Muscular Dystrophy (DMD), PCS100 showed promising improvement in the muscle strength of non-ambulant pediatric patients. Although the FDA placed a clinical hold on the DMD trial after a serious adverse event in a pediatric patient, the FDA has removed the clinical hold and defined how PCS100 can resume clinical trials in DMD. Once we have obtained adequate funding, we plan to develop PCS100 in rare adult fibrotic related diseases such as focal segmental glomerulosclerosis, idiopathic pulmonary fibrosis or Scleroderma.

The Akashi Agreement provides us with a worldwide license to research, develop, make and commercialize products comprising or containing PCS100. As partial consideration for the license, we paid $10,000 to Akashi upon full execution of the license agreement. This upfront payment was expensed as a research and development cost. As additional consideration, we will pay Akashi development and regulatory milestone payments (up to $3.0 million per milestone) upon the achievement of certain milestones, which primarily consist of having a drug indication approved by a regulatory authority in the United States or another country. In addition, we must pay Akashi one-time sales milestone payments based on the achievement during a calendar year of one or more thresholds for annual sales for products made and pay royalties based on annual licensing sales. Due to the early stage of PCS100, it is not possible to determine if any of the development or sales milestones will be achieved and no amounts have been accrued related to these contingent payments. We are also required to split any milestone payments we receive with Akashi based on any sub-license agreement we may enter into.

We are required to use commercially reasonable efforts, at our sole cost and expense, to research, develop and commercialize products in one or more countries, including meeting specific diligence milestones that consist of (i) requesting a meeting with the FDA for a first indication within 18 months of the date of the agreement, (ii) submitting an IND for a drug indication on or before June 30, 2022 and (iii) initiating a Phase 1 or 2 trial for a drug indication on or before December 30, 2022. Either party may terminate the agreement in the event of a material breach of the license agreement that has not been cured following written notice and a 60-day opportunity to cure such breach (which is shortened to 15 days for a payment breach).

**Note 7 – Notes Payable**

Line of Credit Agreements

On September 20, 2019, we entered into two separate LOC Agreements (“LOC Agreements”) with DKBK Enterprises, LLC (“DKBK”) and CorLyst, LLC (“CorLyst”, and, together with DKBK, collectively, “Lenders”), both related parties, which provide a revolving commitment of up to $700,000 each ($1.4 million total). Under the LOC Agreements, all funds borrowed bear interest at an annual rate of 8%. The promissory notes issued in connection with the LOC Agreements provide that the Lenders have the right to convert all or any portion of the principal and accrued and unpaid interest into our common stock on the same terms as are our 2019 Senior Convertible Notes. Therefore, the Lenders may convert the outstanding debt under the LOC Agreements into our common stock at a conversion price equal to the lower of (i) $14.28 per share, (ii) a price per share equal to a 10% discount to the pre-money valuation of an equity sale of the Company’s common stock for cash, or (iii) at an adjusted price; all as more particularly described in the 2019 Senior Convertible Notes. Our Chief Executive Officer (CEO) is also the CEO and Managing Member of both Lenders. CorLyst beneficially owns 996,376 shares of Processa common stock, representing approximately 17.8% of the Company’s outstanding shares of voting capital stock at December 31, 2019.

We have not drawn any amounts under these LOC Agreements as of February 28, 2020.

Senior Convertible Notes

The balance of our Senior Convertible Notes at December 31, 2019 and 2018 was as follows:

| | 2019 | 2018 |
|---|---|---|
| 2019 Senior Notes | $ 805,000 | $ - |
| 2017 Senior Notes | - | 230,000 |
| Less: Unamortized debt issuance costs | (2,497) | - |
| Balance | 802,503 | 230,000 |
| Current portion | (802,503) | (230,000) |
| Long term portion | $ - | $ - |

Interest expense totaled $36,658 and $161,205 for the years ended December 31, 2019 and 2018, respectively. Included in interest expense is the amortization of the related debt issuance costs of $1,783, and $67,069 for the years ended December 31, 2019 and 2018, respectively. The Senior Notes and related accrued interest are classified as current liabilities in our consolidated balance sheets.

*2019 Senior Notes*

During the fourth quarter of 2019, accredited investors purchased $805,000 of 8% Senior Convertible Notes ("2019 Senior Notes") from us. For every $1,000 principal amount purchased, the note holders received 70 warrants to purchase our common stock. As a result, we granted 56,350 warrants to purchase our common stock at an exercise price of $19.04, which expire on December 19, 2023. The 2019 Senior Notes bear interest at 8% per year and if converted, the interest is payable in kind (in common stock). The 2019 Senior Notes mature on December 15, 2020.

The 2019 Senior Notes are convertible by the holder upon (i) completion of listing our common stock on either the Nasdaq Capital Market or the New York Stock Exchange or if we raise at least $14 million, prior to December 15, 2020, the maturity date of the 2019 Senior Notes, in one or more qualified financings. If the 2019 Senior Notes are not paid or converted prior to their maturity date, the principal and any accrued interest will be automatically or mandatorily converted into our common stock. The 2019 Senior Notes, plus any accrued interest is convertible into shares of our common stock at a conversion price equal to the lower of (i) $14.28 per share or (ii) a price per share equal to a 10% discount to the pre-money valuation of an equity sale of the Company's common stock for cash, as defined in the 2019 Senior Note agreement, occurring after the closing of the 2019 Senior Note financing.

The 2019 Senior Notes provide the holders with (a) the option of receiving 110% of principal plus accrued interest in the event there is a change of control prior to conversion of the 2019 Senior Notes; (b) weighted-average anti-dilution protection in event of any sale of securities at a net consideration per share that is less than the applicable conversion price per share to the holder until we have raised an additional $14 million from the sale of certain securities; and (c) certain preemptive rights pro rata to their respective interests through December 31, 2021.

The 2019 Senior Notes contains negative covenants that do not permit us to incur additional indebtedness or liens on property or assets owned, repurchase common stock, pay dividends, or enter into any transaction with affiliates of ours that would require disclosure in a public filing with the Securities and Exchange Commission. Upon an event of default, the outstanding principal amount of the Senior Notes, plus accrued but unpaid interest and other amounts owing in respect thereof through the date of acceleration, shall become immediately due and payable in cash at the holder's election, if not cured within the cure period.

We incurred $4,280 in debt issuance costs related to the 2019 Senior Notes. The debt issuance costs are amortized to interest expense using straight line amortization over the term of the 2019 Senior Notes.

*2017 Senior Notes*

In October and November of 2017, certain entities affiliated with current stockholders and other accredited investors purchased $2.58 million of our 8% Senior Convertible Notes ("2017 Senior Notes") in a bridge financing undertaken by us to support our operations. The 2017 Senior Notes bore interest at 8% per year.

On May 25, 2018, pursuant to the mandatory and automatic conversion provisions of the Senior Notes, we converted $2,350,000 of the $2,580,000 outstanding Senior Notes, along with accrued interest of $114,333 into 172,327 shares of our common stock (at a conversion price of $14.30 per share) and issued to the debt holders warrants to purchase a total of 172,327 shares of common stock, exercisable for three years at an exercise price of $17.16. We also incurred costs totaling $82,502 related to our contractual obligations to file a resale registration statement related to this transaction with the SEC.

2017 Senior Notes totaling $230,000 held by Canadian investors remained outstanding at December 31, 2018. Although qualifying for automatic and mandatory conversion, they could not be converted until the Alberta Securities Commission released us from a cease trade order (which predated our merger with Heatwurx) and permitted us to issue common stock units (consisting of shares of our common stock and stock purchase warrants) to these Canadian investors. In June 2019, the Alberta Securities Commission released the cease trade order and assessed us a $10,000 fine, which was expensed. On July 2, 2019, we converted the remaining principal and related accrued interest of $28,930 into 18,107 shares of common stock and issued warrants to purchase 18,107 shares of common stock. We evaluated the warrants issued in this transaction and determined they should be classified as equity.

We incurred $154,800 in debt issuance costs on the 2017 Senior Notes in connection with a payment to the placement agent, which was reported as a reduction of the carrying amount of the 2017 Senior Notes on the face of the consolidated balance sheets. The debt issuance costs were amortized to interest expense using the effective interest rate method over the term of the Senior Convertible Notes. The effective interest rate on the 2017 Senior Notes was 7.72% before debt issuance costs, since no payments of interest are due until maturity and 13.96% including the debt issuance costs based on the repayment terms of the 2017 Senior Notes.

**Note 8 – Stockholders' Equity**

In August 2019, we amended our certificate of incorporation, reducing the authorized number of shares of our preferred stock from 10,000,000 to 1,000,000 and our common stock from 350,000,000 to 100,000,000.

We have not had any sales of our preferred stock since we were incorporated on March 29, 2011 and there were no issued or outstanding shares of preferred stock at December 31, 2019 or 2018.

*2019 Private Placement Transactions*

During 2019 we amended our Pledge Agreement with PoC Capital to reduce the committed funds from $1.8 million to $900,000, which has been paid in full as of December 31, 2019. As part of the original Pledge Agreement, we issued 113,280 shares of common stock and 113,280 warrants to purchase shares of common stock to PoC Capital but held 56,640 shares and 56,640 warrants as collateral until certain payment milestones were met. PoC Capital forfeited the pledged collateral in the amended agreement (see below). The forfeited shares and warrants have been returned to us.

*2018 Private Placement Transactions*

Between May 15, 2018 and June 29, 2018, we sold an aggregate of 200,369 units in a private placement transaction at a purchase price equal to $15.89 per unit for gross proceeds of approximately $3.2 million. Each unit consisted of one share of our common stock and a warrant to purchase one share of our common stock for $19.07, subject to adjustment thereunder for a period of three years. We paid $167,526 to our placement agent and issued placement agent warrants to purchase up to 12,021 shares of common stock, with a three-year term, at an exercise price equal to $19.07. We also incurred costs totaling $141,304 related to this transaction and our contractual obligation to file a resale registration statement related to the PIPE transaction with the SEC. The issuance costs were charged against additional paid in capital.

On May 25, 2018, we entered into an Agreement with PoC Capital, LLC ("PoC"), where PoC agreed to finance $1,800,000 in study costs associated with certain clinical studies, including our Phase 2A study to evaluate the safety, tolerability, efficacy and pharmacodynamics of PCS499 in patients with Necrosis Lipoidica in exchange for 113,280 shares of our common stock and a warrant for the purchase of 113,280 shares of common stock with an exercise price of $19.07, expiring on July 29, 2021. We paid $108,000 to our placement agent and issued our placement agent warrants to purchase 6,797 shares of common stock, with a three-year term, at an exercise price equal to $19.07. We also incurred costs totaling $60,457 related to this transaction and our contractual obligation to file a resale registration statement related to this transaction with the SEC. The issuance costs were charged against additional paid in capital.

As part of this transaction, we also entered into a Pledge Agreement with PoC, under which we received a security interest for 56,640 common stock units, or half the shares and warrants we issued to PoC, to hold as collateral. The Pledge Agreement with PoC Capital was amended on September 30, 2019 to reduce the committed funds from $1.8 million to $900,000, which has been paid in full as of December 31, 2019. As part of the Pledge Agreement amendment, PoC Capital forfeited the pledged collateral in the amended agreement. The forfeited shares and warrants have been returned to us.

We initially recorded the full amount of the commitment, $1.8 million, as a subscription receivable and reduced the subscription receivable in the period PoC made payments to our CRO or to us. We evaluated the warrants issued in the 2018 Private Placement Transactions and determined they should be classified as equity.

The common stock, but not the warrants, issued for the 2018 Private Placement Transactions and the conversion of the 2017 Senior Notes have, subject to certain customary exceptions, full ratchet anti-dilution protection. Until we have issued equity securities or securities convertible into equity securities for a total of an additional $20 million in cash or assets, including the proceeds from the exercise of the warrants issued above, in the event we issue additional equity securities or securities convertible into equity securities at a purchase price less than $15.89 per share of common stock, the above purchase prices shall be adjusted and new shares of common stock issued as if the purchase price was such lower amount (or, if such additional securities are issued without consideration, to a price equal to $0.01 per share).

We have determined the sale of 2019 Senior Notes, which are convertible into common stock at a conversion rate of $14.28 triggered the full ratchet anti-dilution provision of the common stock we sold in 2018 Private Placement Transactions described above. As a result, those stockholders were entitled to 28,971 shares of common stock in the fourth quarter of 2019. We will issue 28,971 shares of common stock to those stockholders in 2020. We determined the value of these shares to be $506,993 based on a price per share of $17.50, which represents the closing price per share on October 18, 2019, the last day investors had to rescind their investment. We recorded the triggering of the full ratchet anti-dilution provision as a deemed dividend payable at December 31, 2019 in our statement of changes in stockholders' equity at par value due to the fact that we have a retained deficit and are receiving no additional consideration for these shares.

**Note 9 – Income Taxes**

We account for income taxes in accordance with ASC Topic 740, *Income Taxes.* Deferred income taxes are recorded for the expected tax consequences of temporary differences between the tax basis of assets and liabilities for financial reporting purposes and amounts recognized for income tax purposes. We recorded a valuation allowance during the years ended December 31, 2019 and 2018 equal to the full recorded amount of our net deferred tax assets related to deferred start-up costs, federal orphan drug tax credit and other minor temporary differences since it is more-likely-than-not that such benefits will not be realized. The valuation allowance is reviewed quarterly and is maintained until sufficient positive evidence exists to support its reversal.

A deferred tax liability was recorded on March 19, 2018 when Processa received CoNCERT's license and "Know-How" in exchange for Processa stock that had been issued in an Internal Revenue Code Section 351 Transaction. The Section 351 Transaction treats the acquisition of the license and Know-How for stock as a tax-free exchange. As a result, under ASC 740-10-25-51 *Income Taxes*, Processa recorded a deferred tax liability of $3,037,147 for the acquired temporary difference between intangible assets for the financial reporting basis of $11,038,929 and the tax basis of $1,782. The deferred tax liability will be reduced for the effect of non-deductibility of the amortization of the intangible asset and may be offset by the deferred tax assets resulting from net operating tax losses.

During the years ended December 31, 2019 and 2018, we incurred net operating losses of $3,960,592 and $4,667,848, respectively. We did not record any income tax benefit for the $1,205,811 ($331,809 tax effected) and $1,356,840 ($373,368 tax effected) of general and administrative expenses treated as deferred start-up expenditures for tax purposes for the years ended December 31, 2019 and 2018, respectively. We did not record any income tax benefit for the $283,189 of federal orphan drug tax credits for the year ended December 31, 2019. Additionally, we did not record any income tax benefit in 2017 for the $259,049 ($71,284 tax effected) of tax losses incurred in 2017 which resulted in tax loss carryforwards. The benefit was recognized in 2018 in the calculation of the valuation allowance. The 2017 net operating loss carry forwards are available for application against future taxable income for 20 years expiring in 2037. Tax losses incurred after December 31, 2017 have an indefinite carry forward period. However, the tax loss incurred after December 31, 2017 and carried forward can only offset 80 percent of future taxable income in any one year, with any excess losses being carried forward indefinitely. We have recorded the benefit of our 2019 and 2018 net operating losses in our consolidated financial statements as a reduction in the deferred tax liability created by the future financial statement amortization of the intangible asset from the acquired CoNCERT license and "Know-How." The benefit associated with the net operating loss carry forward will more-likely-than-not go unrealized unless future operations are successful except for their offset against the deferred tax liability created by the acquired CoNCERT license and "Know-How."

For the years ended December 31, 2019 and 2018, we recorded a federal income tax benefit of $602,716 and $902,801, respectively, as a result of offsetting our deferred tax liability by the deferred tax assets resulting from our net operating losses and the income tax effect of the intangible asset amortization for financial statement purposes.

Our provision (benefit) for income taxes for the years ended December 31, 2019 and 2018 was as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Current: | | |
| Federal | $ - | $ - |
| State | - | - |
| Total deferred tax benefit | - | - |
| | | |
| Deferred: | | |
| Federal | (1,037,267) | (940,510) |
| State | (234,033) | (292,047) |
| Total deferred tax benefit | (1,271,300) | (1,232,557) |
| | | |
| Valuation allowance | 668,584 | 329,756 |
| Net deferred tax benefit | (602,716) | (902,801) |
| | | |
| Total tax provision (benefit) | $ (602,716) | $ (902,801) |

A reconciliation of our effective income tax rate and statutory income tax rate for the years ended December 31, 2019 and 2018 is as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Federal statutory income tax rate | 21.00% | 21.00% |
| State tax rate, net | 3.60% | 4.58% |
| Permanent differences | (1.96)% | (0.90)% |
| Federal orphan drug tax credit | 7.15% | -% |
| Deferred tax asset valuation allowance | (14.57)% | (5.33)% |
| | | |
| Effective income tax rate | 15.22% | 19.35% |

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 ("TCJA") was signed into law. Among its provisions, the TCJA reduces the statutory U.S. Corporate income tax rate from 34% to 21% effective January 1, 2018. The TCJA includes provisions that, in certain instances, impose U.S. income tax liabilities on future earnings of foreign subsidiaries and limit the deductibility of future interest expenses. The TCJA also provides for accelerated deductions of certain capital expenditures made after September 27, 2017 through bonus depreciation and an indefinite tax loss carryforward period for losses incurred after December 31, 2017. However, these tax-loss carry forwards can only offset 80 percent of future taxable income in any one year, with respect to any excess continuing to be carried forward indefinitely. Losses incurred prior to January 1, 2018 continue to carry forward for twenty years. The application of the TCJA may change due to regulations subsequently issued by the U.S. Treasury Department.

We applied the guidance in SAB 118 when accounting for the enactment-date effects of the TCJA in 2018 and throughout 2019. At December 31, 2019 and 2018, we had available federal net operating loss carryforwards of approximately $4.1 million and $2.7 million, respectively. The federal net operating loss generated in 2019 and 2018 of $1.4 million and $2.4 million, respectively, will carry forward indefinitely and be available to offset up to 80% of future taxable income each year. Net operating losses generated prior to 2018 will expire 2037. We are evaluating our qualified research expenditures for the federal orphan drug credit and the federal and state credit for increasing research activities to offset potential future tax liabilities. The federal research and development tax credits have a 20-year carryforward period. We have not recognized any deferred tax assets related to research and development tax credits as of December 31, 2019 or 2018. We also have available state net operating loss carryforwards of approximately $4.1 million and $2.7 million as of December 31, 2019 and 2018, respectively, which expire 2037. All federal and state net operating loss and credit carryforwards listed above are reflected after the reduction for amounts effectively eliminated under Section 382.

We do not recognize other deferred income tax assets at this time because the realization of the assets is not more-likely-than-not that they will be realized. As of December 31, 2019 and 2018, we had deferred start-up expenditures and other deductible expenses for both federal and state income tax purposes of $6,977,317 and $4,369,700, respectively. The benefit associated with the amortization of the deferred start-up expenditures and other deductible expenses will more-likely-than-not go unrealized unless future operations are successful. Since the success of future operations is indeterminable, the potential benefits resulting from these deferred tax assets have not been recorded in our consolidated financial statements.

The significant components of our deferred tax assets and liabilities for Federal and state income taxes consisted of the following:

| | December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Deferred tax assets: | | |
| Non-current: | | |
| Net operating loss carry forward – Federal | $ 854,196 | $ 559,817 |
| Net operating loss carry forward – State | 265,106 | 173,743 |
| Deferred rent | - | 2,742 |
| Stock option expense | 72,504 | 20,380 |
| Depreciation | 8,753 | 4,549 |
| Federal orphan drug credits | 283,189 | - |
| Start-up expenditures and amortization | 800,681 | 468,872 |
| Total non-current deferred tax assets | 2,284,429 | 1,230,103 |
| Valuation allowance for deferred tax assets | (1,165,126) | (496,542) |
| Total deferred tax assets | 1,119,303 | 733,561 |
| | | |
| Deferred Tax Liabilities: | | |
| Non-current: | | |
| Intangible asset | (2,650,933) | (2,867,907) |
| Total non-current deferred tax liabilities | (2,650,933) | (2,867,907) |
| | | |
| Total deferred tax asset (liability) | $ (1,531,630) | $ (2,134,346) |

The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, the projected future taxable income and tax planning strategies in making this assessment. Based on management's analysis, a reserve has been established against the deferred tax assets related to deferred start-up expenditures and other deductible expenses. The change in the valuation allowance in 2019 and 2018 was $668,584 and $329,755, respectively.

Our total deferred tax asset as of December 31, 2019 and 2018 include $2,909,715 ($800,681 tax effected) and $1,703,904 ($468,872 tax effected) of general and administrative expenses treated as deferred start-up expenditures for tax purposes, respectively, $4,067,602 ($1,119,302 tax effected) and $2,665,796 ($733,560 tax effected) of tax losses resulting in tax loss carryforwards as of the same periods and $283,189 of federal orphan drug tax credits as of December 31, 2019. We have had no revenues and recognized cumulative loses since inception. Due to the uncertainty regarding future profitability and recognition of taxable income to utilize the amortization of deferred start-up expenditures, federal orphan drug tax credits and the tax loss carryforwards, except for its offset against the deferred tax liability created by our acquisition of the CoNCERT license, a valuation allowance against any potential deferred tax assets has been recognized for the years ended December 31, 2019 and 2018.

We recognize potential liabilities for uncertain tax positions using a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. We have not recorded any uncertain tax positions.

We are subject to taxation in the United States and state jurisdictions where applicable. There are currently no income tax examinations underway for these jurisdictions. However, tax years from and including 2016 remain open for examination by federal and state income tax authorities.

**Note 10 - Stock-based Compensation**

On June 19, 2019, our stockholders approved and we adopted the Processa Pharmaceuticals Inc. 2019 Omnibus Equity Incentive Plan (the "Omnibus Plan") and we terminated our prior equity incentive compensation plan, the Heatwurx, Inc. 2011 Amended and Restated Equity Plan (the "2011 Plan"). The Omnibus Plan allows us, under the direction of our Board of Directors or a committee thereof, to make grants of stock options, restricted and unrestricted stock and other stock-based awards to employees, including our executive officers, consultants and directors. An aggregate of 500,000 shares of our common stock, adjusted for the one for seven reverse stock split completed on December 23, 2019, were initially available for issuance under the Omnibus Plan. Shares available under the Omnibus Plan may be authorized but unissued shares, shares purchased on the open market or treasury shares.

On June 20, 2019, our Board of Directors granted stock options for the purchase of 129,919 shares of our common stock to employees. The stock options awarded contained either service or performance vesting conditions, as described below, have a contractual term of five years and an exercise price equal to the closing price of our common stock on the OTCQB on the date of grant of $16.80. We granted 54,915 stock options to employees and non-employees during the year ended December 31, 2018.

Stock options representing the purchase of 65,148 shares of common stock (of the 129,919 stock options granted on June 20, 2019) contained service vesting conditions. The service condition related solely to employees rendering service over a three-year period. These awards vest one-third on the first anniversary of the grant date, and then vest ratably over the remaining twenty-four months, $1/36^{th}$ of the original award each month.

Stock options representing the purchase of 64,771 shares of common stock (of the 129,919 stock options granted on June 20, 2019) vest upon meeting the following performance criteria: (i) 12,958 shares vest when we in-license one new or additional drug; (ii) 12,958 shares vest when our current Phase 2A clinical trial for PCS499 is complete; and (iii) 38,855 shares vest when we up-list from the OTCQB to either the Nasdaq or NYSE markets. We are recognizing compensation cost for the awards related to completion of our current clinical trial and for in-licensing a new drug. The clinical trial is progressing as planned with no significant adverse events, is fully enrolled, and fully funded. Management does not foresee any reasons why this study will not be completed as planned and believes it is probable that this performance condition will be met in mid-2020. On August 29, 2019, we reached a license agreement with Akashi Therapeutics for PCS100 and as such, the performance condition related to the award for in-licensing one new or additional drug has been met. As for the last award with performance conditions related to up-listing on Nasdaq or NYSE markets, management has determined that until we complete the performance related condition, it is not probable to conclude the performance condition will be achieved. As such, no stock-based compensation expense is being recorded for those awards.

We recorded $510,478 and $74,063 of stock-based compensation expense for the years ended December 31, 2019 and 2018, respectively. The allocation of stock-based compensation expense between research and development and general and administrative expense was as follows:

| | Year ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Research and Development | $ 113,239 | $ - |
| General and Administrative | 397,239 | 74,063 |
| Total | $ 510,478 | $ 74,063 |

During the year ended December 31, 2018, there was one grant for the purchase of 7,143 shares of our common stock outstanding under the 2011 Plan. We also granted non-qualified stock options outside of the Plan for a total of 47,772 shares of common stock. An option for the purchase of 45,200 shares of common stock vests over a four-year term and an option for the purchase of 2,572 shares of common stock vests over one-year term. Stock option granted in 2018 all have a maximum contractual term of ten years. Vesting is subject to the holder's continuous service with us.

The fair value of each stock option grants was estimated using the Black-Scholes option-pricing model at the date of grant. We lack company-specific historical and implied volatility information and therefore, determined our expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expect to continue to do so until such time as it has adequate historical data regarding the volatility of our own traded stock price. Due to the lack of historical exercise history, the expected term of our stock options was determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that we have never paid cash dividends and do not expect to pay any cash dividends in the foreseeable future.

The fair value of our option awards granted during the year ended December 31, 2019 and 2018 was estimated using the following assumptions:

| | **2019** | **2018** |
|---|---|---|
| Average risk-free rate of interest | 1.85% | 3.09% |
| Expected term (years) | 3.75 to 5.00 | 5.00 to 6.25 |
| Expected stock price volatility | 81.77% | 85.31% |
| Dividend yield | 0% | 0% |

The following table summarizes our stock option activity for the years ended December 31, 2019 and 2018:

| | Total options Outstanding | Weighted average exercise price | Weighted average remaining contractual life (in years) |
|---|---|---|---|
| Outstanding as of January 1, 2018 | - | - | - |
| Options granted | 54,915 | 20.45 | 9.8 |
| Exercised | - | - | - |
| Forfeited | - | - | - |
| Outstanding as of December 31, 2018 | 54,915 | $ 20.45 | 9.8 |
| Options granted | 129,919 | 16.80 | 4.5 |
| Exercised | - | - | - |
| Forfeited | (7,872) | 16.80 | 4.5 |
| Outstanding as of December 31, 2019 | 176,962 | 17.93 | 5.8 |
| Exercisable (vested) at December 31, 2019 | 29,655 | 18.53 | 6.9 |

The weighted average grant date fair value per share of options granted during the year ended December 31, 2019 and 2018 was between $9.88 and $15.10. No forfeiture rate was applied to these stock options.

No tax benefits were attributed to the stock-based compensation expense because a valuation allowance was maintained for all net deferred tax assets.

As of December 31, 2019, there was $1,450,684 of total unrecognized compensation expense, related to the unvested stock options which are expected to be recognized over a weighted average period of 5.82 years.

**Note 11 – Net Loss per Share of Common Stock**

Basic net loss per share is computed by dividing net loss by the weighted average common stock outstanding. Diluted net loss per share is computed by dividing net loss by the weighted average common stock outstanding without the impact of potential dilutive common stock outstanding because they would have an anti-dilutive impact on diluted net loss per share. The treasury-stock method is used to determine the dilutive effect of our stock options and warrants grants, and the if-converted method is used to determine the dilutive effect of the 2017 and 2019 Senior Notes.

The computation of net loss per share for the year ended December 31, 2019 and 2018 was as follows:

| | 2019 | 2018 |
|---|---|---|
| **Basic and diluted net loss per share:** | | |
| Net loss | $ (3,357,876) | $ (3,765,047) |
| Deemed dividend related to the triggering of the full ratchet anti-dilution provision at fair value | (506,993) | - |
| Net loss available to common stockholders | (3,864,869) | (3,765,047) |
| | | |
| Weighted-average number of common stock-basic and diluted | 5,525,635 | 5,332,141 |
| | | |
| Basic and diluted net loss per share | $ (0.70) | $ (0.71) |

We have determined the sale of the 2019 Senior Notes in late 2019, which are convertible into common stock at a conversion rate of $14.28 per share triggered the full ratchet anti-dilution provision of the common stock we sold in 2018 Private Placement Transactions (see Note 8). As a result, those stockholders were entitled to 28,971 shares of common stock in the fourth quarter of 2019. We will issue 28,971 shares of common stock to these stockholders in 2020. We determined the value of these shares at $506,993 based on a price per share of $17.50 which represents the closing price per share on October 18, 2019, the last day investors had to rescind their investment. For purposes of computing our basic and diluted EPS, we increased our net loss available for common stockholders by the fair value of the additional shares to be issued since they did not affect all our common stockholders equally and there are no contingencies related to the issuance of these shares. We also included these shares in our weighted number of shares of common stock outstanding. Triggering the full ratchet anti-dilution provision increased our basic and diluted net loss per share by $0.09 per share, from $(0.61) to $(0.70).

The outstanding options and warrants to purchase common stock and the shares issuable under the 2017 and 2019 Senior Notes were excluded from the computation of diluted net income per share as their effect would have been anti-dilutive for the periods are presented below:

| | 2019 | 2018 |
|---|---|---|
| Stock options and purchase warrants | 654,569 | 571,055 |
| Senior convertible notes | 60,883 | 17,531 |

**Note 12 - Operating Leases**

We lease our office space under an operating lease agreement. This lease does not have significant rent escalation, concessions, leasehold improvement incentives, or other build-out clauses. Further, the lease does not contain contingent rent provisions. We also lease office equipment under an operating lease. Our office space lease includes both lease (e.g., fixed payments including rent, taxes, and insurance costs) and non-lease components (e.g., common-area or other maintenance costs), which are accounted for as a single lease component as we have elected the practical expedient to group lease and non-lease components for all leases. Our leases do not provide an implicit rate and, as such, we have used our incremental borrowing rate of 8% in determining the present value of the lease payments based on the information available at the lease commencement date.

Lease costs included in our consolidated statement of operations totaled $98,020 and $88,237 for the years ended December 31, 2019 and 2018, respectively. The weighted average remaining lease terms and discount rate for our operating leases were as follows at December 31, 2019:

| | |
|---|---|
| Weighted average remaining lease term (years) for our facility and equipment leases | 2.7 |
| Weighted average discount rate for our facility and equipment leases | 8% |

Maturities of our lease liabilities for all operating leases were as follows as of December 31, 2019:

| | | |
|---|---|---|
| 2020 | $ | 92,603 |
| 2021 | | 90,495 |
| 2022 | | 69,741 |
| Total lease payments | | 252,839 |
| Less: Interest | | (27,457) |
| Present value of lease liabilities | | 225,382 |
| Less: current maturities | | (77,992) |
| Non-current lease liability | $ | 147,390 |

**Note 13 – Related Party Transactions**

A stockholder, CorLyst, LLC, reimburses us for shared costs related to payroll, health care insurance and rent based on actual costs incurred, which are recognized as a reduction of our general and administrative operating expenses in our consolidated statements of operations. Reimbursable expenses from CorLyst totaled $103,047 and $107,402 for rent and other costs during the years ended December 31, 2019 and 2018, respectively. Amounts due from related parties at December 31, 2019 and 2018 were $0 and $21,583, respectively.

As described further in Note 7, we also entered into two separate Line of Credit Agreements with CorLyst, LLC and DKBK Enterprises, LLC, both related parties, on September 20, 2019.

**Note 14 – Commitments and Contingencies**

*Purchase Obligations*

We enter into contracts in the normal course of business with contract research organizations and subcontractors to further develop our products. The contracts are cancellable, with varying provisions regarding termination. If a contract with a specific vendor were to be terminated, we would only be obligated for products or services that we received as of the effective date of the termination and any applicable cancellation fees. We had a purchase obligation of approximately $0 and $35,000 at December 31, 2019 and 2018, respectively.

Due to the contingent nature of the amounts and timing of the payments, we have excluded our agreement with the CRO with whom we have contracted to conduct our Phase 2A clinical trial for NL. We were contractually obligated for up to approximately $487,000 of future services under the agreement, but our actual contractual obligations will vary depending on the progress and results of the clinical trial.

**Note 15 – Concentration of Credit Risk**

We maintain cash accounts in two commercial banks. Balances on deposit are insured by the Federal Deposit Insurance Corporation (FDIC) up to specified limits. Total cash held by one bank was $691,536 at December 31, 2019, which exceed FDIC limits.

Processa Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)

| | June 30, 2020 | December 31, 2019 |
|---|---|---|
| **ASSETS** | | |
| **Current Assets** | | |
| Cash and cash equivalents | $ 452,654 | $ 691,536 |
| Due from related party | 26,497 | - |
| Prepaid expenses and other | 97,682 | 315,605 |
| Total Current Assets | 576,833 | 1,007,141 |
| **Property and Equipment** | | |
| Property and equipment, net | 4,707 | 8,930 |
| **Other Assets** | | |
| Operating lease right-of-use assets, net of accumulated amortization | 179,591 | 219,074 |
| Intangible assets, net of accumulated amortization | 9,244,790 | 9,642,454 |
| Security deposit | 5,535 | 5,535 |
| Total Other Assets | 9,429,916 | 9,867,063 |
| **Total Assets** | $ 10,011,456 | $ 10,883,134 |
| | | |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| **Current Liabilities** | | |
| Senior convertible notes, net of debt issuance costs | $ 804,643 | $ 802,503 |
| Line of credit payable – related party | 500,000 | - |
| Note payable – Paycheck Protection Program, current portion | 72,203 | - |
| Current maturities of operating lease liability | 71,967 | 77,992 |
| Accrued interest | 58,483 | 21,902 |
| Accounts payable | 73,371 | 75,612 |
| Due to related parties | - | 316 |
| Accrued expenses | 317,252 | 213,239 |
| Total Current Liabilities | 1,897,919 | 1,191,564 |
| **Non-current Liabilities** | | |
| Note payable – Paycheck Protection Program | 90,256 | - |
| Non-current operating lease liability | 114,595 | 147,390 |
| Net deferred tax liability | 1,315,666 | 1,531,630 |
| **Total Liabilities** | 3,418,436 | 2,870,584 |
| | | |
| **Commitments and Contingencies** | - | - |
| | | |
| **Stockholders' Equity** | | |
| Common stock, par value $0.0001, 30,000,000 and 100,000,000 shares authorized; 5,514,447 and 5,486,476 issued and outstanding at June 30, 2020 and December 31, 2019 | 552 | 549 |
| Additional paid-in capital | 19,182,228 | 18,994,008 |
| Common stock deemed dividend payable: 28,971 shares at par value | - | 3 |
| Accumulated deficit | (12,589,760) | (10,982,010) |
| **Total Stockholders' Equity** | 6,593,020 | 8,012,550 |
| **Total Liabilities and Stockholders' Equity** | $ 10,011,456 | $ 10,883,134 |

The accompanying notes are an integral part of these condensed consolidated financial statements.

Processa Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
Three and Six Months Ended June 30, 2020 and 2019
(Unaudited)

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| **Operating Expenses** | | | | |
| Research and development expenses | $ 427,109 | $ 726,904 | $ 928,855 | $ 1,211,655 |
| General and administrative expenses | 374,878 | 410,072 | 859,255 | 807,837 |
| Total operating expenses | 801,987 | 1,136,976 | 1,788,110 | 2,019,492 |
| **Operating Loss** | (801,987) | (1,136,976) | (1,788,110) | (2,019,492) |
| **Other Income (Expense)** | | | | |
| Interest expense | (19,280) | (6,102) | (36,450) | (10,702) |
| Interest income | 18 | 3,398 | 846 | 9,383 |
| Total other income (expense) | (19,262) | (2,704) | (35,604) | (1,319) |
| **Net Operating Loss Before Income Tax Benefit** | (821,249) | (1,139,680) | (1,823,714) | (2,020,811) |
| **Income Tax Benefit** | 87,835 | 170,602 | 215,964 | 300,901 |
| **Net Loss** | $ (733,414) | $ (969,078) | $ (1,607,750) | $ (1,719,910) |
| **Net Loss per Common Stock - Basic and Diluted** | $ (0.13) | $ (0.18) | $ (0.29) | $ (0.31) |
| **Weighted Average Common Stock Used to Compute Net Loss Applicable to Common Stock - Basic and Diluted** | 5,515,447 | 5,525,009 | 5,515,447 | 5,525,009 |

The accompanying notes are an integral part of these condensed consolidated financial statements.

Processa Pharmaceuticals, Inc.
Condensed Consolidated Statements of Changes in Stockholders' Equity
Six Months Ended June 30, 2020 and 2019
(Unaudited)

Six Months Ended June 30, 2019

| | Common Stock | | Additional Paid-In | Common Stock Dividend | Accumulated | |
|---|---|---|---|---|---|---|
| | Shares | Amount | Capital | Payable | Deficit | Total |
| Balance at January 1, 2020 | 5,486,476 | $ 549 | $ 18,994,008 | $ 3 | $ (10,982,010) | $ 8,012,550 |
| Stock-based compensation | - | - | 98,663 | - | - | 98,663 |
| Transaction costs related to anticipated 2020 offering | - | - | (2,806) | - | - | (2,806) |
| Net loss | - | - | - | - | (874,336) | (874,336) |
| Balance, March 31, 2020 | 5,486,476 | 549 | 19,089,865 | 3 | (11,856,346) | 7,234,071 |
| Stock-based compensation | - | - | 93,869 | - | - | 93,869 |
| Stock dividend distributed due to full-ratchet anti-dilution adjustment | 28,971 | 3 | - | (3) | - | - |
| Transaction costs related to anticipated 2020 offering | - | - | (1,506) | - | - | (1,506) |
| Net loss | - | - | - | - | (733,414) | (733,414) |
| Balance, June 30, 2020 | 5,515,447 | $ 552 | $ 19,182,228 | $ - | $ (12,589,760) | $ 6,593,020 |

Six Months Ended June 30, 2019

| | Common Stock | | Additional Paid-In | Subscription | Accumulated | |
|---|---|---|---|---|---|---|
| | Shares | Amount | Capital | Receivable | Deficit | Total |
| Balance, January 1, 2019 | 5,525,009 | $ 552 | $ 19,124,600 | $ (1,800,000) | $ (7,624,134) | $ 9,701,018 |
| Stock-based compensation | - | - | 58,559 | - | - | 58,559 |
| Payments made directly by investor for clinical trial costs | - | - | - | 115,000 | - | 115,000 |
| Net loss | - | - | - | - | (750,832) | (750,832) |
| Balance, March 31, 2019 | 5,525,009 | 552 | 19,183,159 | (1,685,000) | (8,374,966) | 9,123,745 |
| Stock-based compensation | - | - | 66,476 | - | - | 66,476 |
| Payments made directly by investor for clinical trial costs | - | - | - | 280,927 | - | 280,927 |
| Net loss | - | - | - | - | (969,078) | (969,078) |
| Balance, June 30, 2019 | 5,525,009 | $ 552 | $ 19,249,635 | $ (1,404,073) | $ (9,344,044) | $ 8,502,070 |

The accompanying notes are an integral part of these condensed consolidated financial statements.

Processa Pharmaceuticals, Inc.
Condensed Consolidated Statements of Cash Flows
Six Months Ended June 30, 2020 and 2019
(Unaudited)

| | 2020 | 2019 |
|---|---|---|
| **Cash Flows From Operating Activities** | | |
| Net loss | $ (1,607,750) | $ (1,719,910) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 4,223 | 4,223 |
| Non-cash lease expense for right-of-use assets | 39,483 | 36,282 |
| Amortization of debt issuance costs | 2,140 | - |
| Amortization of intangible asset | 397,664 | 397,664 |
| Deferred income tax benefit | (215,964) | (300,901) |
| Stock-based compensation | 192,532 | 125,035 |
| | | |
| Net changes in operating assets and liabilities: | | |
| Prepaid expenses and other | 217,923 | (10,090) |
| Operating lease liability | (38,820) | (38,940) |
| Accrued interest | 36,581 | 8,587 |
| Accounts payable | (2,241) | (148,751) |
| Due (from) to related parties | (26,813) | 22,919 |
| Accrued expenses | 104,013 | 208,979 |
| Net cash used in operating activities | (897,029) | (1,414,903) |
| | | |
| **Cash Flows From Financing Activities** | | |
| Proceeds received in satisfaction of stock subscription receivable | - | 395,927 |
| Borrowings on line of credit payable from related party | 500,000 | - |
| Proceeds received from our Paycheck Protection Program note payable | 162,459 | - |
| Transaction costs related to anticipated 2020 offering | (4,312) | - |
| Net cash (used in) provided by financing activities | 658,147 | 395,927 |
| | | |
| **Net Decrease in Cash** | (238,882) | (1,018,976) |
| **Cash and Cash Equivalents – Beginning of Period** | 691,536 | 1,740,961 |
| **Cash and Cash Equivalents – End of Period** | $ 452,654 | $ 721,985 |
| | | |
| **Non-Cash Investing and Financing Activities** | | |
| Right-of-use asset obtained in exchange for operating lease liability | $ - | $ (293,198) |
| Reduction in deferred lease liability | - | (9,963) |
| Operating lease liability | - | 303,161 |
| Net | $ - | $ - |
| | | |
| Issuance of 28,971 shares of common stock due to triggering, in December 2019, the full ratchet anti-dilution provision of common stock sold in our 2018 Private Placement Transactions | $ 3 | $ - |

The accompanying notes are an integral part of these condensed consolidated financial statements.

**Note 1 – Organization and Summary of Significant Accounting Policies**

*Business Activities and Organization*

Processa is a clinical stage biopharmaceutical company focused on the development of drug products that are intended to improve the survival and/or quality of life for patients who have a high unmet medical need condition. Within this group of pharmaceutical products, we currently are developing one product for multiple indications (i.e., the use of a drug to treat a particular disease) and will begin developing our newly acquired drugs (PCS11T and PCS100) once adequate funding has been obtained. We continue searching for additional products for our portfolio that meet our criteria.

*PCS499*

Our lead product, PCS499, is an oral tablet that is a deuterated analog of one of the major metabolites of pentoxifylline (PTX or Trental®). The advantage of PCS499 is that it potentially may work in many conditions because PCS499 and its metabolites act on multiple pharmacological targets that are important in the treatment of these conditions. Based on its pharmacological activity, we have identified unmet medical need conditions where the use of PCS499 may result in clinical efficacy. The lead indication currently under development for PCS499 is Necrobiosis Lipoidica (NL). NL is a chronic, disfiguring condition affecting the skin and the tissue under the skin typically on the lower extremities with no currently approved FDA treatments. NL presents more commonly in women than in men and ulceration can occur in approximately 30% of NL patients which can lead to more severe complications, such as deep tissue infections and osteonecrosis threatening life of the limb. Approximately 22,000 - 55,000 people in the United States and more than 120,000 people outside the United States are affected with ulcerated NL.

The degeneration of tissue occurring at the NL lesion site may be caused by a number of pathophysiological changes which has made it extremely difficult to develop effective treatments for this condition. PCS499 may provide a solution since PCS499 and its metabolites affect a number of the biological pathways which could contribute to the pathophysiology associated with NL.

On June 18, 2018, the FDA granted orphan-drug designation for PCS499 for the treatment of NL. On September 28, 2018, the IND for PCS499 in NL was made effective by the FDA, such that we could move forward with a Phase 2A trial multicenter, open-label prospective trial designed to determine the safety and tolerability of PCS499 in patients with NL. The first enrolled NL patient in this Phase 2A clinical trial was dosed on January 29, 2019 and the study completed enrollment on August 23, 2019. The main objective of the trial was to evaluate the safety and tolerability of PCS499 in patients with NL and to use the collected safety and efficacy data to design future clinical trials. Based on toxicology studies and healthy human volunteer studies, Processa and the FDA agreed that a PCS499 dose of 1.8 grams/day would be the highest dose administered to NL patients in this Phase 2A trial. As anticipated, the PCS499 dose of 1.8 grams/day, 50% greater than the maximum tolerated dose of PTX, appeared to be well tolerated with no serious adverse events reported. All adverse events reported in the study were mild in severity. As expected, gastrointestinal symptoms were the most noted adverse events and reported in four patients, all of which were mild in severity and resolved within 1-2 weeks of starting dosing.

Two patients presenting with more severe ulcerated NL had ulcers for more than two months prior to dosing. At baseline, the reference ulcer in one of the two patients measured 3.5 $cm^2$ and had completely closed by Month 2 of treatment. The second patient had a baseline reference ulcer of 1.2 $cm^2$ which completely closed by Month 9. In addition, while in the trial both patients also developed small ulcers at other sites, possibly related to contact trauma, and these ulcers resolved within one month. The other ten patients presenting with mild to moderate NL and no ulceration had some improvement of the NL lesions but not as dramatic as the more serious ulcerated patients. Historically, less than 20% of all the patients with NL naturally progress to complete healing over many years after presenting with NL. Although the natural healing of the more severe NL patients with ulcers has not been evaluated independently, medical experts who treat NL patients believe that the natural progression of an open ulcerated wound to complete closure would be significantly less than the 20% reported as the maximum percentage of patients who naturally heal over several years after NL presentation. Although our study enrolled only two ulcerated patients, the existing ulcers and trauma ulcers in both patients completely closed supporting that the diverse pharmacology of PCS499 and its metabolites (similar to PTX) positively effects the open ulcers in NL. In addition, those patients without ulcers in our clinical trial also saw positive changes in their NL lesion, although to a much lesser extent than the closing of the more serious ulcers. We have completed the patient portion of our Phase 2A trial of PCS499 in NL, with the last patient completing the trial during the first quarter of 2020. We are in the process of closing the trial, but the close out of our two sites has been delayed as a result of COVID-19.

On March 25, 2020, we met with the FDA and discussed the clinical program, as well as the nonclinical and clinical pharmacology plans to support the submission of the PCS499 New Drug Application (NDA) in the U.S. for the treatment of ulcers in NL patients. With input from the FDA we will be designing the next trial as a randomized, placebo-controlled trial to evaluate the ability of PCS499 to completely close ulcers in patients with NL. We initially planned to begin recruiting for the randomized, placebo-controlled trial in the fourth quarter 2020, but we now expect to begin recruiting patients in 20201 due to the ongoing COVID-19 pandemic. This PCS499 NL study will be a randomized, placebo-controlled Phase 2B study to better understand the potential response of NL patients on drug and on placebo. After obtaining the results from this Phase 2B study, we expect to meet with FDA to discuss our Phase 2B drug and placebo response findings while further discussing the next steps to obtain approval.

*PCS11T*

On May 24, 2020, we entered into a condition precedent License Agreement (the "Aposense Agreement") with Aposense, Ltd., ("Aposense"), pursuant to which we were granted a contingent license in Aposense's patent rights and know-how to develop and commercialize their next generation irinotecan cancer drug, PCS11T (formerly known as ATT-11T). Granting of the license is conditioned on the following being satisfied within 9 months of May 24, 2020 (or the Aposense Agreement shall terminate): (i) our closing of an equity financing and successful up-listing to Nasdaq and (ii) Aposense obtaining the approval of the Israel Innovation Authority for the consummation of the transactions contemplated by the Aposense Agreement.

PCS11T is a novel lipophilic anti-cancer pro-drug that is being developed for the treatment of the same solid tumors as prescribed for irinotecan. This pro-drug is a conjugate of a specific proprietary Aposense molecule connected to SN-38, the active metabolite of irinotecan. The proprietary molecule in PCS11T has been designed to allow PCS11T to bind to cell membranes to form an inactive pro-drug depot on the cell with SN-38 preferentially accumulating in the membrane of tumors cells and the tumor core. This unique characteristic is expected to make the therapeutic window of PCS11T wider than all other irinotecan products such that the antitumor effect of PCS11T will occur at a much lower dose with a milder adverse effect profile than irinotecan. Irinotecan serves as a water-soluble pro-drug of SN-38, with SN-38 being significantly more potent as a topoisomerase I inhibitor than irinotecan. Despite the widespread use of commercially marketed irinotecan products in the treatment of metastatic colorectal cancer and other cancers resulting in peak annual sales of approximately $1.1 billion, irinotecan has a narrow therapeutic window and includes an FDA "Black Box" warning for both neutropenia and severe diarrhea. Its adverse effects include diarrhea, neutropenia, leucopenia, lymphocytopenia, and anemia, which are major impediments to optimal dosing for efficacy since the dose must often be reduced with repeated treatment cycles. There is, therefore, a substantial unmet need to overcome the limitations of the current commercially marketed irinotecan products, improving efficacy and reducing the severity of treatment emergent adverse events. The potential wider therapeutic window of PCS11T will likely lead to more patients responding with less side effects when on PCS11T compared to other irinotecan products.

Pre-clinical studies conducted to date showed that that PCS11T has an efficacy advantage over Irinotecan as demonstrated by tumor eradication at much lower doses than irinotecan across various tumor xenograft models. PCS11T produced a marked, dose-related sustained tumor growth inhibition (TGI) in all the evaluated models. TGI in these models was significantly improved in comparison to irinotecan. Tumor regression was also observed in several models. PCS11T does not affect acetyl choline esterase (AChE) activity in human and rat plasma in vitro, which would suggest that PCS11T will show an improved safety profile, unlike irinotecan which is known for its cholinergic related side-effects.

Prior to the License Agreement, Aposense had met with the FDA at a Pre-IND meeting. At that meeting, agreement was reached related to the necessary manufacturing and toxicological study requirements for filing the IND and the subsequent design of the Phase 1B study for PCS11T in the treatment of solid tumors. Depending upon our available funds, we are currently planning to manufacture the product at a GMP facility, conduct the required toxicological studies required to file the IND and initiate the Phase 1B study in oncology patients with solid tumors in late 2021.

*PCS100*

On August 29, 2019, we entered into an exclusive license agreement with Akashi Therapeutics, Inc. ("Akashi") to develop and commercialize an anti-fibrotic, anti-inflammatory drug, PCS100, which also promotes healthy muscle fiber regeneration. In previous clinical trials in Duchenne Muscular Dystrophy (DMD), PCS100 showed promising improvement in the muscle strength of non-ambulant pediatric patients. Although the FDA placed a clinical hold on the DMD trial after a serious adverse event in a pediatric patient, the FDA has removed the drug off clinical hold and defined how PCS100 can resume clinical trials in DMD. Once we have obtained adequate funding, we plan to develop PCS100 in rare adult fibrotic related diseases such as focal segmental glomerulosclerosis, idiopathic pulmonary fibrosis or Scleroderma. At the present time we are evaluating the potential GMP manufacturing facilities and the potential indications for PCS100.

*Basis of Presentation*

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and with the instructions of the Securities and Exchange Commission ("SEC") on Form 10-Q and Article 8 of Regulation S-X.

Accordingly, they do not include all the information and disclosures required by U.S. GAAP for complete financial statements. All material intercompany accounts and transactions have been eliminated in consolidation. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments necessary, which are of a normal and recurring nature, for the fair presentation of the Company's financial position and of the results of operations and cash flows for the periods presented. These condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the SEC. The results of operations for the interim periods shown in this report are not necessarily indicative of the results that may be expected for any other interim period or for the full year.

*Going Concern and Management's Plans*

Our condensed consolidated financial statements have been prepared using U.S. GAAP and are based on the assumption that we will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. We face certain risks and uncertainties that are present in many emerging pharmaceutical company regarding product development and commercialization, limited working capital, recurring losses and negative cash flow from operations, future profitability, ability to obtain future capital, protection of patents, technologies and property rights, competition, rapid technological change, navigating the domestic and major foreign markets' regulatory and clinical environment, recruiting and retaining key personnel, dependence on third party manufacturing organizations, third party collaboration and licensing agreements, lack of sales and marketing activities. We currently have no customers or pharmaceutical products to sell or distribute. These risks and other factors raise substantial doubt about our ability to continue as a going concern.

We have relied primarily on private placements with a small group of accredited investors to finance our business and operations. As described in more detail below, we entered into two line of credit agreements last year with related parties providing a revolving commitment of an aggregate of up to $1.4 million. We have not had any revenue since our inception. We are looking at ways to add a revenue stream to offset some of our expenses but do not currently have any revenue under contract or any immediate sales prospects. At June 30, 2020, we had an accumulated deficit of $12.6 million, and during the six months ended June 30, 2020, we incurred a net loss of $1,607,750 and used $897,029 in net cash from operating activities from continuing operations. At June 30, 2020, we had cash and cash equivalents totaling $452,654.

On September 20, 2019, we entered into two separate Line of Credit Agreements ("LOC Agreements") to borrow up to $700,000 with current stockholders and related parties: DKBK Enterprises, LLC ("DKBK") and CorLyst, LLC ("CorLyst") ($1.4 million total). Under the LOC Agreements, all funds borrowed bear an 8% annual interest rate. The lenders have the right to convert all or any portion of the debt and interest into shares of our common stock. Our Chief Executive Officer (CEO) is also the CEO and Managing Member of both lenders. DKBK directly holds 16,166 shares of our common stock, less than 1% of our outstanding common stock, and CorLyst beneficially owns 1,095,649 shares, representing 19.8% of our outstanding common stock. In April and June 2020, we drew $500,000 under the LOC Agreement with DKBK. On July 21, 2020, we drew an additional $200,000, bringing the total amount drawn under the LOC Agreement with DKBK to $700,000.

In December 2019, we closed our bridge financing and issued $805,000 of 2019 Senior Notes to accredited investors. In order to preserve cash, in August 2019 we began delaying some cash outflows, primarily through the deferred payment of certain salaries ($210,800 has been included in accrued expenses at June 30, 2020) until such time as we have raised sufficient funding.

In May 2020, we entered into a promissory note in favor of the Bank of America under the Small Business Administration Paycheck Protection Program of the Coronavirus Aid, Relief and Economic Security Act of 2020 (the "CARES Act") for a $162,459 loan ("the PPP Loan"). We plan to use the loan proceeds for payroll costs, rent and utilities in accordance with the relevant terms and conditions of the CARES Act.

We have begun the process of raising capital in an underwritten public offering, however, we have faced delays due to the global pandemic caused by the novel coronavirus, COVID-19. Based on our current plan, we will need to raise additional capital to fund our future operations. While we believe our current resources are adequate to complete the closeout of our current Phase 2A trial for NL, we do not currently have resources to conduct other future trials, such as the Phase 2B clinical trial approved by the FDA, or to develop our other drug candidates without raising additional capital. We believe that our existing cash and LOC Agreements will enable us to fund our operating expenses and capital expenditure requirements through the end of 2020.

Additional funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of, or suspend our current or future clinical trial plans, or research and development programs. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. To the extent that we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Uncertainty concerning our ability to continue as a going concern may hinder our ability to obtain future financing. Continued operations and our ability to continue as a going concern are dependent on our ability to obtain additional funding in the future and thereafter, and no assurances can be given that such funding will be available at all, in a sufficient amount, or on reasonable terms. Without additional funds from debt or equity financing, sales of assets, sales or out-licenses of intellectual property or technologies, or other transactions providing funds, we will rapidly exhaust our resources and be unable to continue operations. Absent additional funding, we believe that our cash and cash equivalents will not be sufficient to fund our operations for a period of one year or more after the date that these condensed consolidated financial statements are available to be issued based on the timing and amount of our projected net loss from continuing operations and cash to be used in operating activities during that period of time.

As a result, substantial doubt exists about our ability to continue as a going concern within one year after the date that these condensed consolidated financial statements are available to be issued. The accompanying condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of recorded assets, or the amounts and classification of liabilities that might be different should we be unable to continue as a going concern based on the outcome of these uncertainties described above.

*Use of Estimates*

In preparing our condensed consolidated financial statements and related disclosures in conformity with GAAP and pursuant to the rules and regulations of the SEC, we make estimates and judgments that affect the amounts reported in the consolidated financial statements and accompanying notes. Estimates are used for, but not limited to: stock-based compensation, determining the fair value of acquired assets and assumed liabilities, intangible assets, and income taxes. These estimates and assumptions are continuously evaluated and are based on management's experience and knowledge of the relevant facts and circumstances. While we believe the estimates to be reasonable, actual results could differ materially from those estimates and could impact future results of operations and cash flows.

*Intangible Assets*

Intangible assets acquired individually or with a group of other assets from others (other than in a business combination) are recognized at cost, including transaction costs, and allocated to the individual assets acquired based on relative fair values and no goodwill is recognized. Cost is measured based on cash consideration paid. If consideration given is in the form of non-cash assets, liabilities incurred, or equity interests issued, measurement of cost is based on either the fair value of the consideration given or the fair value of the assets (or net assets) acquired, whichever is more clearly evident and more reliably measurable. Costs of internally developing, maintaining or restoring intangible assets that are not specifically identifiable, have indeterminate lives or are inherent in a continuing business are expensed as incurred.

Intangible assets purchased from others for use in research and development activities and that have alternative future uses (in research and development projects or otherwise) are capitalized in accordance with ASC Topic 350, *Intangibles – Goodwill and Other.* Those that have no alternative future uses (in research and development projects or otherwise) and therefore no separate economic value are considered research and development costs and are expensed as incurred. Amortization of intangibles used in research and development activities is a research and development cost.

Intangibles with a finite useful life are amortized using the straight-line method unless the pattern in which the economic benefits of the intangible assets are consumed or used up are reliably determinable. The useful life is the best estimate of the period over which the asset is expected to contribute directly or indirectly to our future cash flows. The useful life is based on the duration of the expected use of the asset by us and the legal, regulatory or contractual provisions that constrain the useful life and future cash flows of the asset, including regulatory acceptance and approval, obsolescence, demand, competition and other economic factors. We evaluate the remaining useful life of intangible assets each reporting period to determine whether any revision to the remaining useful life is required. If the remaining useful life is changed, the remaining carrying amount of the intangible asset will be amortized prospectively over the revised remaining useful life. If an income approach is used to measure the fair value of an intangible asset, we consider the period of expected cash flows used to measure the fair value of the intangible asset, adjusted as appropriate for company-specific factors discussed above, to determine the useful life for amortization purposes.

If no regulatory, contractual, competitive, economic or other factors limit the useful life of the intangible to us, the useful life is considered indefinite. Intangibles with an indefinite useful life are not amortized until its useful life is determined to be no longer indefinite. If the useful life is determined to be finite, the intangible is tested for impairment and the carrying amount is amortized over the remaining useful life in accordance with intangibles subject to amortization. Indefinite-lived intangibles are tested for impairment annually and more frequently if events or circumstances indicate that it is more-likely-than-not that the asset is impaired.

*Impairment of Long-Lived Assets and Intangibles Other Than Goodwill*

We account for the impairment of long-lived assets in accordance with ASC 360, *Property, Plant and Equipment* and ASC 350, *Intangibles – Goodwill and Other,* which require that long-lived assets and certain identifiable intangibles be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to its expected future undiscounted net cash flows generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amounts of the assets exceed the fair value of the assets based on the present value of the expected future cash flows associated with the use of the asset. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. Based on management's evaluation, there was no impairment loss recorded during the six months ended June 30, 2020.

*Stock-based Compensation*

Stock-based compensation expense is based on the grant-date fair value estimated in accordance with the provisions of ASC 718, *Compensation-Stock Compensation.* We expense stock-based compensation to employees over the requisite service period based on the estimated grant-date fair value of the awards. For awards that contain performance vesting conditions, we do not recognize compensation expense until achieving the performance condition is probable. Stock-based awards with graded-vesting schedules are recognized on a straight-line basis over the requisite service period for each separately vesting portion of the award. We estimate the fair value of stock option grants using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. Stock-based compensation costs are recorded as general and administrative or research and development costs in the statements of operations based upon the underlying individual's role.

*Net Loss Per Share*

Basic loss per share is computed by dividing our net loss available to common stockholders by the weighted average number of shares of common stock outstanding during the year. Diluted loss per share is computed by dividing our net loss available to common stockholders by the diluted weighted average number of shares of common stock during the period. Since we experienced a net loss for both periods presented, basic and diluted net loss per share are the same. As such, diluted loss per share for the six months ended June 30, 2020 and 2019 excludes the impact of 740,899 and 719,083 potentially dilutive common stock, respectively, related to outstanding stock options and warrants and the conversion of our 2017 and 2019 Senior Notes since those shares would have an anti-dilutive effect on loss per share.

*Recent Accounting Pronouncements*

From time to time, the Financial Accounting Standards Board ("FASB") or other standard setting bodies issue new accounting pronouncements. Updates to the FASB Accounting Standards Codification are communicated through issuance of an Accounting Standards Update ("ASU"). We have implemented all new accounting pronouncements that are in effect and that may impact our consolidated financial statements. We have evaluated recently issued accounting pronouncements and determined that there is no material impact on our financial position or results of operations.

**Note 2 – Intangible Assets**

Intangible assets at June 30, 2020 and December 31, 2019 consisted of the following:

| | June 30, 2020 | December 31, 2019 |
|---|---|---|
| Gross intangible assets | $ 11,059,429 | $ 11,059,429 |
| Less: accumulated amortization | (1,814,639) | (1,416,975) |
| Total intangible assets, net | $ 9,244,790 | $ 9,642,454 |

Amortization expense was $397,664 for the six months ended June 30, 2020 and 2019 and is included within research and development expense in the accompanying condensed consolidated statements of operations. Our estimated amortization expense for the next year will be approximately $795,000 per year and for annual periods thereafter approximately $788,000 per year.

The capitalized costs for the license rights to PCS499 included the $8 million purchase price, $1,782 in transaction costs and $3,037,147 associated with the initial recognition of an offsetting deferred tax liability related to the acquired temporary difference for an asset purchased that is not a business combination and has a tax basis of $1,782 in accordance with ASC 740-10-25-51 *Income Taxes*. In accordance with ASC Topic 730, *Research and Development*, we capitalized the costs of acquiring the exclusive license rights to PCS499, as the exclusive license rights represent intangible assets to be used in research and development activities that management believes has future alternative uses.

**Note 3 – Income Taxes**

We account for income taxes in accordance with ASC Topic 740, *Income Taxes.* Deferred income taxes are recorded for the expected tax consequences of temporary differences between the tax basis of assets and liabilities for financial reporting purposes and amounts recognized for income tax purposes. As of June 30, 2020, and December 31, 2019, we recorded a valuation allowance equal to the full recorded amount of our net deferred tax assets related to deferred start-up costs and other minor temporary differences since it is more-likely-than-not that such benefits will not be realized. The valuation allowance is reviewed quarterly and is maintained until sufficient positive evidence exists to support its reversal.

A deferred tax liability was recorded on March 19, 2018 when we received CoNCERT's license and "Know-How" in exchange for Processa stock that had been issued in the Internal Revenue Code Section 351 Transaction. The Section 351 Transaction treats the acquisition of the license and Know-How for stock as a tax-free exchange. As a result, under ASC 740-10-25-51 *Income Taxes*, we recorded a deferred tax liability of $3,037,147 for the acquired temporary difference between intangible assets (see Note 2) for the financial reporting basis of $11,038,929 and the tax basis of $1,782. The deferred tax liability will be reduced for the effect of non-deductibility of the amortization of the intangible asset and may be offset by the deferred tax assets resulting from net operating tax losses.

Under ACS 740-270 *Income Taxes – Interim Reporting*, we are required to project our annual federal and state effective income tax rate and apply it to the year to date ordinary operating tax basis loss before income taxes. Based on the projection, we expect to recognize the tax benefit from our projected ordinary tax loss, which can be used to offset the deferred tax liabilities related to the intangible assets and resulted in the recognition of a deferred tax benefit shown in the condensed consolidated statements of operations for six months ended June 30, 2020 and 2019. No current income tax expense is expected for the foreseeable future as we expect to generate taxable net operating losses.

**Note 4 – Stock-based Compensation**

We did not grant any stock options to our employees or non-employees during the six months ended June 30, 2020. During the six months ended June 30, 2019, we granted 129,919 stock options to employees and non-employees under the 2019 Omnibus Incentive Plan. At June 30, 2020, we had outstanding options to purchase 169,329 shares of our common stock of which options for the purchase of 56,853 shares of our common stock were vested. We recorded $192,532 and $125,035 of stock-based compensation expense for the six months ended June 30, 2020 and 2019, respectively.

**Note 5 – 2019 Senior 8% Convertible Notes Payable**

During the fourth quarter of 2019, accredited investors purchased $805,000 of 8% Senior Convertible Notes ("2019 Senior Notes") from us. For every $1,000 principal amount purchased, the note holders received 70 warrants to purchase our common stock. As a result, we granted 56,350 warrants to purchase our common stock at an exercise price of $19.04, which expire on December 19, 2023. The 2019 Senior Notes bear interest at 8% per year and if converted, the interest is payable in kind (in common stock). The 2019 Senior Notes mature on December 15, 2020. At June 30, 2020 and December 31, 2019, we had $805,000 of 2019 Senior Notes outstanding.

The 2019 Senior Notes are convertible by the holder upon (i) completion of listing our common stock on either the Nasdaq Capital Market or the New York Stock Exchange or if we raise at least $14 million, prior to December 15, 2020, the maturity date of the 2019 Senior Notes, in one or more qualified financings. If the 2019 Senior Notes are not paid or converted prior to their maturity date, the principal and any accrued interest will be automatically or mandatorily converted into our common stock. The 2019 Senior Notes, plus any accrued interest, is convertible into shares of our common stock at a conversion price equal to the lower of (i) $14.28 per share or (ii) a price per share equal to a 10% discount to the pre-money valuation of an equity sale of the Company's common stock for cash, as defined in the 2019 Senior Note agreement, occurring after the closing of the 2019 Senior Note financing.

The 2019 Senior Notes provide the holders with (a) the option of receiving 110% of principal plus accrued interest in the event there is a change of control prior to conversion of the 2019 Senior Notes; (b) weighted-average anti-dilution protection in event of any sale of securities at a net consideration per share that is less than the applicable conversion price per share to the holder until we have raised an additional $14 million from the sale of certain securities; and (c) certain preemptive rights pro rata to their respective interests through December 31, 2021.

The 2019 Senior Notes contains negative covenants that do not permit us to incur additional indebtedness or liens on property or assets owned, repurchase common stock, pay dividends, or enter into any transaction with affiliates of ours that would require disclosure in a public filing with the Securities and Exchange Commission. Upon an event of default, the outstanding principal amount of the Senior Notes, plus accrued but unpaid interest and other amounts owing in respect thereof through the date of acceleration, shall become immediately due and payable in cash at the holder's election, if not cured within the cure period.

We incurred $4,280 in debt issuance costs related to the 2019 Senior Notes. The debt issuance costs are amortized to interest expense using straight line amortization over the term of the 2019 Senior Notes.

**Note 6 – Related Party Line of Credit Agreements**

On September 20, 2019, we entered into two separate LOC Agreements ("LOC Agreements") with DKBK Enterprises, LLC ("DKBK") and CorLyst, LLC ("CorLyst", and, together with DKBK, collectively, "Lenders"), both related parties, which provide a revolving commitment of up to $700,000 each ($1.4 million total). Under the LOC Agreements, all funds borrowed bear interest at an annual rate of 8%. The promissory notes issued in connection with the LOC Agreements provide that the Lenders have the right to convert all or any portion of the principal and accrued and unpaid interest into our common stock on the same terms as our 2019 Senior Convertible Notes. Therefore, the Lenders may convert the outstanding debt under the LOC Agreements into our common stock at a conversion price equal to the lower of (i) $14.28 per share, (ii) a price per share equal to a 10% discount to the pre-money valuation of an equity sale of the Company's common stock for cash, or (iii) at an adjusted price; all as more particularly described in the 2019 Senior Convertible Notes.

Our Chief Executive Officer (CEO) is also the CEO and Managing Member of both lenders. DKBK directly holds 16,166 shares of our common stock, representing less than 1% of our outstanding common stock, and CorLyst beneficially owns 1,095,649 shares of our common stock, representing 19.8% of our outstanding common stock at June 30, 2020. In April and June 2020, we drew $500,000 under the LOC Agreement with DKBK. On July 21, 2020, we drew an additional $200,000, bringing the total amount drawn under the LOC Agreement with DKBK to $700,000.

**Note 7 – Paycheck Protection Program Loan**

In May 2020, we entered into a $162,459 Paycheck Protection Promissory Note (the "PPP Loan") with the Bank of America. The PPP Loan was made under, and is subject to the terms and conditions of, the PPP which was established under the CARES Act and is administered by the U.S. Small Business Administration. The current terms of the loan is two years with a maturity date of May 5, 2022 and it contains a favorable fixed annual interest rate of 1.00%. Payments of principal and interest on the PPP Loan is deferred for the first six months of the term of the PPP Loan until November 5, 2020. Principal and interest are payable monthly and may be prepaid by us at any time prior to maturity with no prepayment penalties. Under the terms of the CARES Act, recipients can apply for and receive forgiveness for all, or a portion of the loan granted under the PPP. Such forgiveness will be determined, subject to limitations, based on the use of loan proceeds for certain permissible purposes as set forth in the PPP, including, but not limited to, payroll costs, mortgage interest, rent or utility costs (collectively, "Qualifying Expenses"), and on the maintenance of employee and compensation levels during a certain time period following the funding of the PPP Loan. We have used the proceeds of our PPP Loan for payroll costs. However, no assurance is provided that we will be able to obtain forgiveness of the PPP Loan in whole or in part. As of June 30, 2020, $72,203 of the total $162,459 PPP-related debt is classified as a current liability on our condensed consolidated balances sheets.

**Note 8 – Stockholders' Equity**

On September 30, 2019, our Pledge Agreement with PoC Capital was amended to reduce the committed funds under this Agreement from $1.8 million to $900,000, which was paid in full as of December 31, 2019. As part of the Pledge Agreement amendment, PoC Capital forfeited the pledged collateral (56,640 shares of our common stock and warrants to purchase 56,640 shares of our common stock) in the amended agreement. The forfeited shares of our common stock and stock purchase warrants have been returned to us.

We determined the sale of the 2019 Senior Notes in late 2019 which are convertible into common stock at a conversion rate of $14.28 per share, triggered the full ratchet anti-dilution provision of common stock we sold in our 2018 Private Placement Transactions. As a result, those stockholders were entitled to 28,971 shares of common stock in the fourth quarter of 2019, which we issued on June 18, 2020. We accounted for these shares at December 31, 2019 as a deemed dividend payable at their par value.

On June 25, 2020, we amended our Certificate of Incorporation reducing the number of authorized shares of our common stock from 100,000,000 to 30,000,000. We believe 100,000,000 authorized shares of common stock was disproportionately large in relation to the Company's outstanding common stock and our anticipated future needs, and the reduction will reduce our future Delaware franchise tax.

We have not had any sales of our preferred stock since we were incorporated on March 29, 2011 and there were no issued or outstanding shares of preferred stock at June 30, 2020 or December 31, 2019.

**Note 9 – Net Loss per Share of Common Stock**

Basic net loss per share is computed by dividing net loss by the weighted average common stock outstanding. Diluted net loss per share is computed by dividing net loss by the weighted average common stock outstanding, which includes potentially dilutive effect of stock options, warrants and senior convertible notes. Since we experienced a loss for both periods presented, including any dilutive common stock outstanding would have an anti-dilutive impact on diluted net loss per share, and as shown below were excluded from the computation. The treasury-stock method is used to determine the dilutive effect of our stock options and warrants grants, and the if-converted method is used to determine the dilutive effect of the Senior Notes.

The computation of net loss per share for the six months ended June 30, 2020 and 2019 was as follows:

| | Six months ended June 30, | |
|---|---|---|
| | **2020** | **2019** |
| **Basic and diluted net loss per share:** | | |
| Net loss | $ (1,607,750) | $ (1,719,910) |
| Weighted average number of common stock-basic and diluted | 5,515,447 | 5,524,895 |
| Basic and diluted net loss per share | $ (0.29) | $ (0.31) |

The following potentially dilutive securities were excluded from the computation of diluted net income per share as their effect would have been anti-dilutive for the periods presented.

| | 2020 | 2019 |
|---|---|---|
| Stock options and purchase warrants | 646,938 | 700,976 |
| Senior convertible notes and LOC, plus related accrued interest | 93,961 | 18,107 |
| | 740,899 | 719,083 |

**Note 10 – Leases**

We lease our office space under an operating lease agreement. This lease does not have significant rent escalation, concessions, leasehold improvement incentives, or other build-out clauses. Further, the lease does not contain contingent rent provisions. We also lease office equipment under an operating lease. Our office space lease includes both lease (e.g., fixed payments including rent, taxes, and insurance costs) and non-lease components (e.g., common-area or other maintenance costs), which are accounted for as a single lease component as we have elected the practical expedient to group lease and non-lease components for all leases. Our leases do not provide an implicit rate and, as such, we have used our incremental borrowing rate of 8% in determining the present value of the lease payments based on the information available at the lease commencement date.

Lease costs included in our condensed consolidated statement of operations totaled $23,995 and $24,729 for the three months ended June 30, 2020 and 2019, respectively, and $48,201 and $49,302 for the six months ended June 30, 2020 and 2019, respectively. The weighted average remaining lease terms and discount rate for our operating leases were as follows at June 30, 2020:

| | |
|---|---|
| Weighted average remaining lease term (years) for our facility and equipment leases | 2.23 |
| Weighted average discount rate for our facility and equipment leases | 8.00% |

Maturities of our lease liabilities for all operating leases were as follows as of June 30, 2020:

| | | |
|---|---|---|
| 2020 | $ | 45,869 |
| 2021 | | 90,495 |
| 2022 | | 69,741 |
| Total lease payments | | 206,105 |
| Less: Interest | | (19,543) |
| Present value of lease liabilities | | 186,562 |
| Less: current maturities | | (71,967) |
| Non-current lease liability | $ | 114,595 |

**Note 11 – License Agreement with Aposense, Ltd.**

On May 24, 2020 we executed a condition precedent License Agreement (“Aposense Agreement”) with Aposense under which they will provide us with an exclusive worldwide license (excluding China) to research, develop and commercialize products comprising or containing PCS11T. The grant of license is conditioned on the following being satisfied within 9 months of May 24, 2020 (or the Aposense Agreement shall terminate): (i) our closing of an equity financing and successful up-listing to Nasdaq and (ii) Aposense obtaining the approval of the Israel Innovation Authority for the consummation of the transactions contemplated by the Aposense Agreement. Within five business days of satisfying the conditions, we must issue Aposense a number of shares of common stock determined by dividing $2.5 million by the price per share paid by such investors in equity financing. Such shares will be subject to a lock-up, with 40% of such shares released from such lock up after six months and the remaining two 30% tranches to be released upon completion of the next two subsequent quarters. As additional consideration, we will pay Aposense development and regulatory milestone payments (up to $3.0 million per milestone) upon the achievement of certain milestones, which primarily consist of having a drug indication approved by a regulatory authority in the United States or another country. In addition, we must pay Aposense one-time sales milestone payments based on the achievement during a calendar year of one or more thresholds for annual sales for products made and pay royalties based on annual licensing sales. We are also required to split any milestone payments we receive with Aposense based on any sub-license agreement we may enter into.

We are required to use commercially reasonable efforts, at our sole cost and expense, to research, develop and commercialize products in one or more countries, including meeting specific diligence milestones that consist of (i) submitting an IND for a drug indication within 30 months following the satisfaction of the license conditions above; (ii) dosing of a first patient with a product within 42 months following the satisfaction of the license conditions above; (iii) dosing of a first patient with a product in a pivotal clinical trial within 72 months following the satisfaction of the license conditions above and (iv) an NDA submission within 120 months following the satisfaction of the license conditions above. Either party may terminate the Aposense Agreement in the event of a material breach of the license agreement that has not been cured following written notice and a 90-day opportunity to cure such breach (which is shortened to 15 days for a payment breach).

**Note 12 – Related Party Transactions**

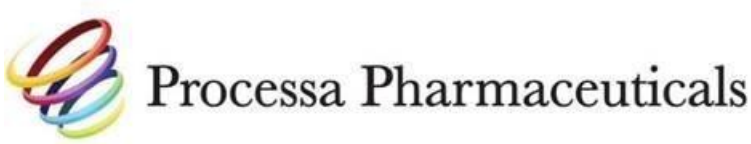
CorLyst reimburses us for shared costs related to payroll, health care insurance and rent based on actual costs incurred, which are recognized as a reduction of our general and administrative operating expenses being reimbursed in our condensed consolidated statement of operations. We recorded $25,928 and $52,464 of reimbursements during the six months ended June 30, 2020 and 2019, respectively. Amounts due from CorLyst at June 30, 2020 and December 31, 2019 were $24,713 and $0, respectively.

At June 30, 2020, we also had approximately $1,700 due from certain employees for health insurance contributions. We did not have comparable a similar receivable at December 31, 2019.

**Note 13 – Commitments and Contingencies**

*Purchase Obligations*

We enter into contracts in the normal course of business with contract research organizations and subcontractors to further develop our products. The contracts are cancellable, with varying provisions regarding termination. If a contract with a specific vendor were to be terminated, we would only be obligated for products or services that we received as of the effective date of the termination and any applicable cancellation fees. We had no purchase obligations at June 30, 2020.



**Processa Pharmaceuticals, Inc.**

**2,150,000 Shares of Common Stock**

**PRELIMINARY PROSPECTUS**

*Joint Bookrunning Managers*

**Craig-Hallum Capital Group** **The Benchmark Company**

*Co-Manager*

**National Securities Corporation**

**, 2020**

**PART II**

## INFORMATION NOT REQUIRED IN PROSPECTUS

**Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, paid or payable by the Registrant in connection with the issuance and sale of the common stock being registered. All amounts shown are estimates except for the SEC registration fee and the FINRA filing fee:

| | Amount |
|---|---|
| SEC registration fee | $ 2,712 |
| FINRA filing fee | 10,000 |
| Initial Nasdaq Global Market listing fee | 25,000 |
| Blue sky qualification fees and expenses | 10,000 |
| Printing and engraving expenses | 50,000 |
| Legal fees and expenses | 300,000 |
| Accounting fees and expenses | 50,000 |
| Transfer agent and registrar fees and expenses | 10,000 |
| Miscellaneous expenses | 15,288 |
| Total | $ 473,000 |

**Item 14. Indemnification of Directors and Officers.**

Processa Pharmaceuticals, Inc. is incorporated under the laws of the State of Delaware.

Section 102(b)(7) of the General Corporation Law of the State of Delaware, or the "DGCL," permits a Delaware corporation to include a provision in its certificate of incorporation eliminating or limiting the personal liability of directors to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. This provision, however, may not eliminate or limit a director's liability (1) for breach of the director's duty of loyalty to the corporation or its stockholders, (2) for acts or omissions not in good faith or involving intentional misconduct or a knowing violation of law, (3) under Section 174 of the DGCL, or (4) for any transaction from which the director derived an improper personal benefit. The amended and restated certificate of incorporation of Processa contains such a provision.

Section 145(a) of the DGCL provides that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation), by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's conduct was unlawful.

Section 145(b) of the DGCL provides that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Delaware Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Delaware Court of Chancery or such other court shall deem proper.

Section 145(c) of the DGCL provides that to the extent that a present or former director or officer of a corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding referred to in subsections (a) and (b) of Section 145 of the DGCL, or in defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith.

Section 145(e) of the DGCL permits a Delaware corporation to advance litigation expenses, including attorneys' fees, incurred by present and former directors and officers prior to the final disposition of the relevant proceedings. The advancement of expenses to a present director or officer is conditioned upon receipt of an undertaking by or on behalf of such director or officer to repay the advancement if it is ultimately determined that such director or officer is not entitled to be indemnified by the corporation. Advancement to former officers and directors may be conditioned upon such terms and conditions, if any, as the corporation may deem appropriate.

Section 145(g) of the DGCL specifically allows a Delaware corporation to purchase liability insurance on behalf of its directors and officers and to insure against potential liability of such directors and officers regardless of whether the corporation would have the power to indemnify such directors and officers under Section 145 of the DGCL.

The amended and restated certificate of incorporation and the amended and restated bylaws of Processa authorize the corporation to indemnify its directors and officers to the fullest extent permitted by law.

The foregoing summaries are necessarily subject to the complete text of the DGCL and Processa's amended and restated certificate of incorporation and amended and restated bylaws.

**Item 15. Recent Sales of Unregistered Securities.**

In the three years preceding the filing of this registration statement, we have issued the following securities that were not registered under the Securities Act:

- On September 29, 2017, prior to the consummation of the Asset Purchase Agreement, Heatwurx converted 178,924 shares of Series D Preferred Stock and all accrued dividends in the amount of $118,658 into 102,786 shares of Common Stock.

- On October 4, 2017 and November 21, 2017, accredited investors purchased $1.25 million and $1.33 million of our senior secured convertible notes in a bridge financing undertaken by us to support our operations. The Notes were issued in reliance on the exemptions from registration under Regulation D and Securities Act Section 4(a)(2).

- On October 4, 2017, in connection with the Asset Purchase Agreement dated October 2, 2017, among the Company, Promet Therapeutics LLC ("Promet") and Processa Therapeutics LLC, the Company's wholly owned subsidiary ("Asset Purchase Agreement"), we issued 4,535,035 shares of the Company's Common Stock to Promet in exchange for all the assets of Promet. On December 30, 2019, Promet distributed these shares to the beneficial holders. The issuance of our shares was made in reliance on the exemption provided by Section 4(a)(2) of the Securities Act for the offer and sale of securities not involving a public offering, and Regulation D promulgated under the Securities Act.

- On May 15, 2018 and June 29, 2018, the Company entered into subscription and purchase agreements with certain accredited investors and conducted a closing pursuant to which the Company sold 157,392 shares of common stock and 42,977 shares of common stock at a purchase price of $15.89 per share. In addition, each investor received a warrant to purchase one share of common stock for each share of common stock purchased by such investor at an exercise price equal to $19.07, subject to adjustment thereunder. The Company received total gross proceeds of approximately $3.2 million from the closings, prior to deducting placement agent fees and estimated expenses payable by the Company associated with the closing. The common stock was sold in a private placement pursuant to exemptions from the registration requirements of the Securities Act, afforded by Rule 506 of Regulation D promulgated thereunder. Boustead acted as placement agent. The placement agent received approximately $168,000 in connection with the closing and a warrant to purchase up to 12,022 shares of common stock at an exercise price equal to $19.07. We have used the proceeds to fund research and development of our lead product candidate, PCS499, including clinical trial activities, and for general corporate purposes.

- On May 25, 2018, we entered into an agreement with an accredited investor to whom we sold 113,280 shares of common stock at a purchase price of $15.89 per share for $1.80 million of gross proceeds. The investor also received warrants to purchase one share of common stock for each share of common stock purchased at an exercise price equal to $19.07. The investor pledged 56,640 shares and warrants to purchase 56,640 shares to us to secure the investor's funding obligation. The $1.80 million private placement was applied to funding the Phase 2A Necrobiosis Lipoidica Trial, which began in the fourth quarter of 2018. The investor made payments totaling $689,168 directly to the CRO conducting our Phase 2A Necrobiosis Lipoidica Trial based on their invoicing. The investor also repaid us $210,832 for clinical trial expenses we previously paid to our CRO. On September 30, 2019, we amended the existing pledge agreement to reduce the committed funds from $1.8 million to $900,000, which has now been paid in full. The investor forfeited the pledged collateral in the amended agreement and the shares have been reissued to Processa and will be retired. Boustead Securities, placement agent, received as fees approximately $108,000 and a warrant to purchase up to 6,797 shares of common stock at an exercise price equal to $19.07. The Securities were sold in a private placement pursuant to exemptions from the registration requirements of the Securities Act afforded by Rule 506 of Regulation D promulgated thereunder.

- In addition, on May 25, 2018 and July 2, 2019, we converted approximately $2.5 million of our mandatory convertible 8% Senior Notes and accrued interest of $143,263 into 190,427 shares of common stock, at a price of $14.30 per share. The noteholders also received warrants to purchase one share of common stock for each share of common stock purchased at an exercise price equal to $17.16. Boustead Securities, our placement agent, received as fees $154,800 and a warrant to purchase up to 11,347 shares of common stock at an exercise price equal to $17.16.

- In December 2019, we sold $805,000 principal amount of 8.0% Senior Convertible Notes and 56,350 warrants to purchase shares of our common stock to accredited investors.

- In September 2020, we issued 250,000 shares of common stock to Yuhan Corporation, an accredited investor, in connection with a license agreement, based on $8.00 per share. The number of shares is subject to adjustment based on the offering price in this offering, but not less than 181,818 shares.

- Upon the closing of this offering, we will issue $2.5 million of shares of common stock (based on the offering price in this offering) to Aposense, Ltd., an accredited investor, in connection with a license agreement.

- Upon the closing of this offering, we will issue a minimum of 500,000 shares of common stock to Elion Oncology, Inc., an accredited investor, in connection with a license agreement. The number of shares will be adjusted based on the offering price in this offering.

All sales of securities described above were exempt from the registration requirements of the Securities Act in reliance on Section 4(a)(2) of the Securities Act, Rule 701 promulgated under the Securities Act or Regulation D promulgated under the Securities Act, relating to transactions by an issuer not involving a public offering. All of the foregoing securities are deemed restricted securities for purposes of the Securities Act.

**Item 16. Exhibits and Financial Statement Schedules.**

(a) Exhibits.

The exhibits to the registration statement are listed in the Exhibit Index attached hereto and are incorporated by reference herein.

(b) Financial Statement Schedules.

All other schedules are omitted because they are not required, are not applicable, or the information is included in the financial statements or the related notes to financial statements thereto.

**Item 17. Undertakings.**

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the “Calculation of Registration Fee” table in the effective registration statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(5) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities: the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(6) Provide to the underwriter at the closing specified in the underwriting agreements certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

(7) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b) (1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(8) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

## EXHIBIT INDEX

In reviewing the agreements included as exhibits to this registration statement, please remember they are included to provide you with information regarding their terms and are not intended to provide any other factual or disclosure information about us, our subsidiaries or other parties to the agreements. The agreements contain representations and warranties by each of the parties to the applicable agreement. These representations and warranties have been made solely for the benefit of the other parties to the applicable agreement and:

- should not in all instances be treated as categorical statements of fact, but rather as a way of allocating the risk to one of the parties if those statements prove to be inaccurate;
- have been qualified by disclosures that were made to the other party in connection with the negotiation of the applicable agreement, which disclosures are not necessarily reflected in the agreement;
- may apply standards of materiality in a way that is different from what may be viewed as material to you or other investors; and
- were made only as of the date of the applicable agreement or such other date or dates as may be specified in the agreement and are subject to more recent developments.

Accordingly, these representations and warranties may not describe the actual state of affairs as of the date they were made or at any other time. We acknowledge that, notwithstanding the inclusion of the foregoing cautionary statements, we are responsible for considering whether additional specific disclosures of material information regarding material contractual provisions are required to make the statements in this registration statement not misleading. Additional information about us may be found elsewhere in the prospectus included in this registration statement.

| Exhibit Number | Description of the Exhibit |
|---|---|
| 1.1 | Form of Underwriting Agreement |
| 2.1 | Asset Purchase Agreement. Dated October 2, 2017, among the Company, Promet Therapeutics LLC and Processa Therapeutics LLC |
| 3.1 | Fourth Amended and Restated Certificate of Incorporation of Heatwurx, Inc. |
| 3.1.1 | Amendment to Fourth Amended and Restated Certificate of Incorporation of Heatwurx, Inc. |
| 3.1.2 | Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation |
| 3.1.3 | Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation |
| 3.1.4 | Amendment to Fourth Amended and Restated Certificate of Incorporation of Processa Pharmaceuticals, Inc. dated June 25, 2020 |
| 3.2 | Amended and Restated Bylaws |
| 4.1 | Specimen of Common Stock Certificate |
| 4.2 | Warrant issued to PoC Capital, LLC |
| 4.3 | Warrants issued to Boustead Securities |
| 4.4* | Form of 8% Senior Convertible Notes |
| 4.5 | Form of Subscription Agreement for Senior Convertible Notes |
| 4.6 | Form of Warrant |
| 5.1 | Opinion of Foley & Lardner LLP |
| 10.1+ | Amended and Restated 2011 Equity Incentive Plan |
| 10.2 | License Option Agreement with CoNCERT |
| 10.3 | Amendment to License Agreement and Securities Purchase Agreement with CoNCERT Pharmaceuticals |
| 10.4+ | Employment Agreement dated September 5, 2018, between Processa and James Stanker |
| 10.5+ | Processa Pharmaceuticals, Inc. 2019 Omnibus Incentive Plan |
| 10.6 | Line of Credit Agreement dated September 20, 2019 between Processa Pharmaceuticals and DKBK Enterprises, LLC |
| 10.7 | Line of Credit Agreement dated September 20, 2019 between Processa Pharmaceuticals and CorLyst, LLC |
| 10.8 | License Agreement with Akashi Therapeutics, Inc. dated August 29, 2019 |
| 10.9 | License Agreement with Aposense, Ltd. dated May 24, 2020 |
| 10.10* | Promissory Note, dated May 1, 2020, with Processa Pharmaceuticals, Inc. and Bank of America, N.A., received by the company under the Small Business Administration Paycheck Protection Program of the Coronavirus Aid, Relief and Economic Securities Act of 2020 |
| 10.11 | License Agreement with Yuhan Corporation |
| 10.12 | Share Issuance Agreement pursuant to License Agreement with Yuhan Corporation |
| 10.13 | License Agreement with Elion Oncology, Inc. |
| 21.1 | List of Subsidiaries |
| 23.1 | Consent of Foley & Lardner LLP (included in Exhibit 5.1) |
| 23.2 | Consent of Independent Registered Public Accounting Firm, BD & Co. Inc. |
| 24.1* | Power of Attorney |
| 99.1** | XBRL Files |

\+ Indicates a management contract or compensatory plan or arrangement.

* Previously filed.

** Furnished herewith. XBRL (eXtensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act is deemed not filed for purposes of Section 18 of the Exchange Act and otherwise is not subject to liability under these sections.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Amendment No. 2 to Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in Hanover, Maryland, on the 16th day of September, 2020.

**Processa Pharmaceuticals, Inc.**

*/s/ David Young, Pharm.D, Ph.D.*
David Young, Pharm. D, Ph.D.
Chairman and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

| Signature | Title | Date |
|---|---|---|
| */s/ David Young, Pharm.D, Ph.D.*<br>David Young, Pharm.D, Ph.D. | Chairman and Chief Executive Officer<br>*(principal executive officer)* | September 16, 2020 |
| */s/ James Stanker*<br>James Stanker | Chief Financial Officer<br>*(principal accounting officer and principal financial officer)* | September 16, 2020 |
| */s/ Patrick Lin**<br>Patrick Lin | Director | September 16, 2020 |
| */s/ Justin Yorke**<br>Justin Yorke | Director | September 16, 2020 |
| */s/ Virgil Thompson**<br>Virgil Thompson | Director | September 16, 2020 |
| */s/ Geraldine Pannu*<br>Geraldine Pannu | Director | September 16, 2020 |

*By:
*/s/ David Young, Pharm.D, Ph.D.*
David Young, Pharm.D, Ph.D., Attorney-in-Fact

**Exhibit 1.1**

**[●] Shares**

**PROCESSA PHARMACEUTICALS, INC.**

**Common Stock, $0.0001 Par Value per Share**

**UNDERWRITING AGREEMENT**

[●], 2020

CRAIG-HALLUM CAPITAL GROUP LLC
BENCHMARK COMPANY, LLC
As Representatives of the several Underwriters
Named in Schedule I hereto
c/o Craig-Hallum Capital Group LLC
222 South Ninth Street, Suite 350
Minneapolis, Minnesota 55402

Ladies and Gentlemen:

Processa Pharmaceuticals, Inc., a Delaware corporation (the "***Company***"), proposes to sell to the several Underwriters named in Schedule I hereto (the "***Underwriters***") an aggregate of [●] authorized but unissued shares (the "***Firm Shares***") of Common Stock, $0.0001 par value per share (the "***Common Stock***"), of the Company. The Company also proposes to grant to the several Underwriters an option to purchase up to [●] additional shares of Common Stock on the terms and for the purposes set forth in Section 3 hereof (the "***Option Shares***"). The Firm Shares and any Option Shares purchased pursuant to this Underwriting Agreement (this "***Agreement***") are herein collectively called the "***Securities***."

The Company hereby confirms its agreement with respect to the sale of the Securities to the several Underwriters, for whom Craig-Hallum Capital Group LLC and Benchmark Company, LLC are acting as representatives (the "***Representatives***" or "***you***"). To the extent there are no additional Underwriters named in Schedule I hereto other than you, the term Representatives as used herein shall mean you, as Underwriters.

1. ***Registration Statement and Prospectus.*** A registration statement on Form S-1 (File No. 333-235511) with respect to the Securities, including a preliminary form of prospectus, has been prepared by the Company in conformity with the requirements of the Securities Act of 1933, as amended (the "***Act***"), and the rules and regulations ("***Rules and Regulations***") of the U.S. Securities and Exchange Commission (the "***Commission***") thereunder and has been filed with the Commission. Such registration statement, including the amendments, exhibits and schedules thereto, as of the time it became effective, including the Rule 430A Information (as defined below), is referred to herein as the "***Registration Statement***." The Company will prepare and file a prospectus pursuant to Rule 424(b) of the Rules and Regulations that discloses the information previously omitted from the prospectus in the Registration Statement in reliance upon Rule 430A of the Rules and Regulations, which information will be deemed retroactively to be a part of the Registration Statement in accordance with Rule 430A of the Rules and Regulations ("***Rule 430A Information***"). If the Company has elected to rely upon Rule 462(b) of the Rules and Regulations to increase the size of the offering registered under the Act, the Company will prepare and file with the Commission a registration statement with respect to such increase pursuant to Rule 462(b) of the Rules and Regulations (such registration statement, including the contents of the Registration Statement incorporated by reference therein is the "***Rule 462(b) Registration Statement***"). References herein to the "***Registration Statement***" will be deemed to include the Rule 462(b) Registration Statement at and after the time of filing of the Rule 462(b) Registration Statement. "***Preliminary Prospectus***" means any prospectus included in the Registration Statement prior to the effective time of the Registration Statement, any prospectus filed with the Commission pursuant to Rule 424(a) under the Rules and Regulations and each prospectus that omits Rule 430A Information used after the effective time of the Registration Statement. "***Prospectus***" means the prospectus that discloses the public offering price and other final terms of the Securities and the offering and otherwise satisfies Section 10(a) of the Act. All references in this Agreement to the Registration Statement, any Preliminary Prospectus, the Prospectus or any amendment or supplement to any of the foregoing, is deemed to include the copy filed with the Commission pursuant to its Electronic Data Gathering, Analysis and Retrieval System or any successor system thereto ("***EDGAR***").

All references in this Agreement to financial statements and schedules and other information which is "described," "contained," "included" or "stated" in the Registration Statement, the Preliminary Prospectus or the Prospectus (or other references of like import) shall be deemed to mean and include all such financial statements and schedules and other information which is incorporated by reference in or otherwise deemed by the Rules and Regulations to be a part of or included in the Registration Statement, the Preliminary Prospectus or the Prospectus, as the case may be, and all references in this Agreement to amendments or supplements to the Registration Statement, the Preliminary Prospectus or the Prospectus shall be deemed to mean and include the subsequent filing of any document under the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), and which is deemed to be incorporated by reference therein or otherwise deemed by the Rules and Regulations to be a part thereof.

2. ***Representations and Warranties of the Company***.

(a) *Representations and Warranties of the Company*. The Company represents and warrants to, and agrees with, the several Underwriters as follows:[1]

(i) *Registration Statement and Prospectuses*. The Registration Statement and any post-effective amendment thereto has become effective under the Act. The Company has complied to the Commission's satisfaction with all requests of the Commission for additional or supplemental information. No stop order suspending the effectiveness of the Registration Statement or any part thereto or any post-effective amendment thereto has been issued, and no proceeding for that purpose has been initiated or, to the Company's knowledge, threatened by the Commission. No order preventing or suspending the use of any Preliminary Prospectus or the Prospectus (or any supplement thereto) has been issued by the Commission and no proceeding for that purpose has been initiated or is pending or, to the Company's knowledge, threatened by the Commission. As of the time each part of the Registration Statement (or any post-effective amendment thereto) became or becomes effective, such part conformed or will conform in all material respects to the requirements of the Act and the Rules and Regulations. Upon the filing or first use within the meaning of the Rules and Regulations, each Preliminary Prospectus and the Prospectus (or any supplement to either) conformed or will conform in all material respects to the requirements of the Act and the Rules and Regulations.

[1] NTD: Subject to ongoing due diligence.

(ii) *Accurate Disclosure*. Each Preliminary Prospectus, at the time of filing thereof or the time of first use within the meaning of the Rules and Regulations, did not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading. Neither the Registration Statement nor any amendment thereto, at the effective time of each part thereof, at the First Closing Date (as defined below) or at any Option Closing Date (as defined below), contained, contains or will contain an untrue statement of a material fact or omitted, omits or will omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. As of the Time of Sale (as defined below), neither (A) the Time of Sale Disclosure Package (as defined below) nor (B) any issuer free writing prospectus (as defined below), when considered together with the Time of Sale Disclosure Package, included an untrue statement of a material fact or omitted to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. Neither the Prospectus nor any supplement thereto, as of its issue date, at the time of any filing with the Commission pursuant to Rule 424(b) of the Rules and Regulations, at the First Closing Date or at any Option Closing Date, included, includes or will include an untrue statement of a material fact or omitted, omits or will omit to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The representations and warranties in this Section 2(a)(ii) shall not apply to statements in or omissions from any Preliminary Prospectus, the Registration Statement (or any amendment thereto), the Time of Sale Disclosure Package or the Prospectus (or any supplement thereto) made in reliance upon, and in conformity with, written information furnished to the Company by you, or by any Underwriter through you, specifically for use in the preparation of such document, it being understood and agreed that the only such information furnished by any Underwriter consists of the information described as such in Section 6(e).

"***Time of Sale Disclosure Package***" means the Preliminary Prospectus dated [●], 2020 and the information on Schedule III, all considered together.

Each reference to a "***free writing prospectus***" herein means a free writing prospectus as defined in Rule 405 of the Rules and Regulations.

"***Time of Sale***" means [●] (New York City time) on the date of this Agreement.

(iii) *No Other Offering Materials*. The Company has not distributed and will not distribute any prospectus or other offering material in connection with the offering and sale of the Securities other than any Preliminary Prospectus, the Time of Sale Disclosure Package or the Prospectus; provided, further, that the Company has not made and will not make any offer relating to the Securities that would constitute a free writing prospectus and, except as set forth on Schedule IV, the Company has not made and will not make any communication relating to the Securities that would constitute a Testing-the-Waters Communication (as defined below), except in accordance with the provisions of Section 2(a)(v) of this Agreement.

(iv) *Smaller Reporting Company*. From the time of initial filing of the Registration Statement to the Commission through the date hereof, the Company has been and is a "smaller reporting company," as defined in Rule 12b-2 under the Exchange Act.

(v) *Testing-the-Waters Materials*. The Company (i) has not alone engaged in any Testing-the-Waters Communications, other than Testing-the-Waters Communications with the prior consent of the Representatives with entities that are qualified institutional buyers within the meaning of Rule 144A under the Act or institutions that are accredited investors within the meaning of Rule 501 under the Act and (ii) has not authorized anyone other than the Representatives to engage in Testing-the-Waters Communications. The Company has not distributed any Written Testing-the-Waters Communications (as defined below) other than those listed on Schedule IV hereto. "***Testing-the-Waters Communication***" means any oral or written communication with potential investors undertaken in reliance on Section 5(d) under the Act. "***Written Testing-the-Waters Communication***" means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the Act. Any individual Written Testing-the-Waters Communication does not conflict with the information contained in the Registration Statement or the Time of Sale Disclosure Package, complied in all material respects with the Act, and when taken together with the Time of Sale Disclosure Package as of the Time of Sale, did not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(vi) *Financial Statements*. The financial statements of the Company, together with the related notes, set forth in the Registration Statement, the Time of Sale Disclosure Package and Prospectus comply in all material respects with the requirements of the Act and the Rules and Regulations and fairly present the financial condition of the Company and its consolidated subsidiary as of the dates indicated and the results of operations, cash flows and changes in stockholders' equity for the periods therein specified. The financial statements of the Company, together with the related notes, set forth in the Registration Statement, the Time of Sale Disclosure Package and Prospectus are in conformity with generally accepted accounting principles in the United States ("***GAAP***") consistently applied throughout the periods involved. The supporting schedules of the Company included in the Registration Statement present fairly the information required to be stated therein. All non-GAAP financial information, if any, included in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus complies with the requirements of Regulation G and Item 10 of Regulation S-K under the Act. Except as disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, there are no material off-balance sheet arrangements (as defined in Regulation S-K under the Act, Item 303(a)(4)(ii)) or any other relationships with unconsolidated entities or other persons, that may have a material current or, to the Company's knowledge, material future effect on the Company's financial condition, results of operations, liquidity, capital expenditures, capital resources or significant components of revenue or expenses. No other financial statements or schedules are required to be included in the Registration Statement, the Time of Sale Disclosure Package or the Prospectus. BD & Company, Inc., which has expressed its opinion with respect to the financial statements of the Company and related schedules filed as a part of the Registration Statement and included in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, is (x) an independent public accounting firm within the meaning of the Act and the Rules and Regulations, (y) a registered public accounting firm (as defined in Section 2(a)(12) of the Sarbanes-Oxley Act of 2002 (the "***Sarbanes-Oxley Act***")) and (z) not in violation of the auditor independence requirements of the Sarbanes-Oxley Act.

(vii) *Organization and Good Standing*. Each of the Company and its subsidiary have been duly organized and is validly existing as an entity in good standing under the laws of its jurisdiction of organization. Each of the Company and its subsidiary have full corporate power and authority to own its properties and conduct its business as currently being carried on and as described in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, and are duly qualified to do business as a foreign entity in good standing in each jurisdiction in which it owns or leases real property or in which the conduct of its business makes such qualification necessary and in which the failure to so qualify would have a material adverse effect upon the business, prospects, management, properties, operations, condition (financial or otherwise) or results of operations of the Company and its subsidiary, taken as a whole ("***Material Adverse Effect***").

(viii) *Absence of Certain Events*. Except as contemplated in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, subsequent to the respective dates as of which information is given in the Time of Sale Disclosure Package, neither the Company nor its subsidiary have incurred any material liabilities or obligations, direct or contingent, or entered into any material transactions, or declared or paid any dividends or made any distribution of any kind with respect to its capital stock; and there has not been any change in the capital stock (other than a change in the number of outstanding shares of Common Stock due to the issuance of shares upon the exercise of outstanding options or warrants or conversion of convertible securities), or any material change in the short-term or long-term debt (other than as a result of the conversion of convertible securities), or any issuance of options, warrants, convertible securities or other rights to purchase the capital stock, of the Company or its subsidiary, or any material adverse change in the general affairs, condition (financial or otherwise), business, prospects, management, properties, operations or results of operations of the Company and its subsidiary, taken as a whole ("***Material Adverse Change***") or any development which could reasonably be expected to result in any Material Adverse Change.

(ix) *Absence of Proceedings*. Except as set forth in the Time of Sale Disclosure Package and the Prospectus, there is not pending or, to the knowledge of the Company, threatened or contemplated, any action, suit or proceeding (a) to which the Company or its subsidiary are a party or (b) which has as the subject thereof any officer or director of the Company or its subsidiary, any employee benefit plan sponsored by the Company or its subsidiary or any property or assets owned or leased by the Company or its subsidiary before or by any court or Governmental Authority (as defined below), or any arbitrator, which, individually or in the aggregate, might result in any Material Adverse Change, or would materially and adversely affect the ability of the Company to perform its obligations under this Agreement or which are otherwise material in the context of the sale of the Securities. There are no current or, to the knowledge of the Company, pending, legal, governmental or regulatory actions, suits or proceedings (x) to which the Company or its subsidiary is subject or (y) which has as the subject thereof any officer or director of the Company or its subsidiary, any employee plan sponsored by the Company or its subsidiary or any property or assets owned or leased by the Company or its subsidiary, that are required to be described in the Registration Statement, Time of Sale Disclosure Package and Prospectus by the Act or by the Rules and Regulations and that have not been so described.

(x) *Authorization; No Conflicts; Authority*. This Agreement has been duly authorized, executed and delivered by the Company. This Agreement constitutes a valid, legal and binding obligation of the Company, enforceable in accordance with its terms, except as rights to indemnity hereunder may be limited by federal or state securities laws and except as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting the rights of creditors generally and subject to general principles of equity. The execution, delivery and performance of this Agreement and the consummation of the transactions herein contemplated will not (A) conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company or its subsidiary pursuant to any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or its subsidiary is a party or by which the Company or its subsidiary is bound or to which any of the property or assets of the Company or its subsidiary is subject, (B) result in any violation of the provisions of the Company's charter or bylaws or (C) result in the violation of any law or statute or any judgment, order, rule, regulation or decree of any court or arbitrator or supranational, international, national, federal, state, provincial, municipal, or local government or any political subdivision thereof (wherever located and whether foreign or domestic), any governmental, regulatory or administrative authority, agency, body, branch, instrumentality or commission, or other non-governmental regulatory authority or quasi-governmental authority (to the extent that the rules, regulations or orders of such organization or authority have the force of law), or any arbitrator, court, tribunal or other judicial or arbitral body of competent jurisdiction having jurisdiction over the Company or its subsidiary or any of their properties or assets (each, a "***Governmental Authority***"), except in the case of clause (A) as would not result in a Material Adverse Effect. No consent, approval, authorization or order of, or registration or filing with any Governmental Authority is required for the execution, delivery and performance of this Agreement or for the consummation of the transactions contemplated hereby, including the issuance or sale of the Securities by the Company, except such as may be required under the Act, the rules of the Financial Industry Regulatory Authority, Inc. (" ***FINRA***"), the Nasdaq Stock Market Rules or state securities or blue sky laws; and the Company has full power and authority to enter into this Agreement and to consummate the transactions contemplated hereby, including the authorization, issuance and sale of the Securities as contemplated by this Agreement.

(xi) *Capitalization; the Securities; Registration Rights*. All of the issued and outstanding shares of capital stock of the Company, including the outstanding shares of Common Stock, are duly authorized and validly issued, fully paid and nonassessable, have been issued in compliance with all federal and state and foreign securities laws, were not issued in violation of or subject to any preemptive rights or other rights to subscribe for or purchase securities that have not been waived in writing (a copy of which has been delivered to counsel to the Underwriters), and the holders thereof are not subject to personal liability by reason of being such holders; the Securities which may be sold hereunder by the Company have been duly authorized and, when issued, delivered and paid for in accordance with the terms of this Agreement, will have been validly issued and will be fully paid and nonassessable, and the holders thereof will not be subject to personal liability by reason of being such holders; and the capital stock of the Company, including the Common Stock, conforms to the description thereof in the Registration Statement, in the Time of Sale Disclosure Package and in the Prospectus. Except as otherwise stated in the Registration Statement, in the Time of Sale Disclosure Package and in the Prospectus, (A) there are no preemptive rights or other rights to subscribe for or to purchase that have not been waived in writing (a copy of which such waivers have been delivered to counsel to the Underwriters), or any restriction upon the voting or transfer of, any shares of Common Stock pursuant to the Company's charter, bylaws or any agreement or other instrument to which the Company or its subsidiary is a party or by which the Company or its subsidiary is bound, (B) none of the filing of the Registration Statement, the offering or the sale of the Securities as contemplated by this Agreement give rise to any rights for or relating to the registration of any shares of Common Stock or other securities of the Company (collectively "***Registration Rights***") that have not been waived in writing (a copy of which such waivers have been delivered to counsel to the Underwriters) and (C) any person to whom the Company has granted Registration Rights has agreed not to exercise such rights until after expiration of the Lock-Up Period (as defined below). All of the issued and outstanding shares of capital stock of the Company's subsidiary have been duly and validly authorized and issued and are fully paid and nonassessable, and, except as otherwise described in the Registration Statement, in the Time of Sale Disclosure Package and in the Prospectus, the Company owns of record and beneficially, free and clear of any security interests, claims, liens, proxies, equities or other encumbrances, all of the issued and outstanding shares of such stock. The Company has an authorized and outstanding capitalization as set forth in the Registration Statement, in the Time of Sale Disclosure Package and in the Prospectus under the caption "Description of our Securities." The Common Stock (including the Securities) conforms in all material respects to the description thereof contained in the Time of Sale Disclosure Package and the Prospectus.

(xii) *Stock Options*. Except as described in the Registration Statement, in the Time of Sale Disclosure Package and in the Prospectus, there are no options, warrants, agreements, contracts or other rights in existence to purchase or acquire from the Company or its subsidiary any shares of the capital stock of the Company or its subsidiary. The description of the Company's stock option, stock bonus and other stock plans or arrangements (the "***Company Stock Plans***"), and the options (the "***Options***") or other rights granted thereunder, set forth in the Time of Sale Disclosure Package and the Prospectus accurately and fairly presents the information required to be shown with respect to such plans, arrangements, options and rights. Each grant of an Option (A) was duly authorized no later than the date on which the grant of such Option was by its terms to be effective by all necessary corporate action, including, as applicable, approval by the board of directors of the Company (or a duly constituted and authorized committee thereof) and any required stockholder approval by the necessary number of votes or written consents, and the award agreement governing such grant (if any) was duly executed and delivered by each party thereto and (B) was made in accordance with the terms of the applicable Company Stock Plan, and all applicable laws and regulatory rules or requirements, including all applicable federal securities laws.

(xiii) *Compliance with Laws*. The Company and its subsidiary each hold, and are operating in compliance in all material respects with, all Permits required for the conduct of its business and all such Permits are valid and in full force and effect; and neither the Company nor its subsidiary have received notice of any revocation or modification of any such Permit or has reason to believe that any such Permit will not be renewed in the ordinary course; and the Company and its subsidiary are in compliance in all material respects with any federal, state, foreign, local, municipal or other law, statute, constitution, principle of common law, resolution, ordinance, code, edict, decree, rule, regulation, ruling, governmental order, binding governmental agreement, or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Authority and any orders, writs, injunctions, awards, judgments and decrees applicable to the Company or any of its Affiliates or to any of their respective assets, properties or businesses. "***Permits***" means all permits, licenses, franchises, approvals, orders, authorizations, registrations, certificates, variances, exemptions or similar rights obtained, or required to be obtained, from Governmental Authorities.

(xiv) *Ownership of Assets*. The Company and its subsidiary have good and marketable title to, or have valid rights to lease or otherwise use, all property (whether real or personal) described in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus as being owned, leased or used by them, in each case free and clear of all liens, claims, security interests, other encumbrances or defects except such as are described in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus. The property held under lease by the Company and its subsidiary is held by them under valid, subsisting and enforceable leases with only such exceptions with respect to any particular lease as do not interfere in any material respect with the conduct of the business of the Company or its subsidiary.

(xv) *Intellectual Property*.

(A) The Company and its subsidiary own or have the right to use pursuant to a valid and enforceable written license, all Intellectual Property (as defined below) for the conduct of the Company's and its subsidiary's business as such business is described in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus (the "***Company IP***"). "***Intellectual Property***" means all patents, patent applications, trade and service marks, trade and service mark registrations, trade names, copyrights, licenses, inventions, trade secrets, domain names, technology, know-how and other intellectual property.

(B) To the knowledge of the Company, there is no infringement, misappropriation or violation by third parties of any Company IP. There is no pending or, to the knowledge of the Company, threatened, action, suit, proceeding or claim by others challenging the Company IP, and the Company is unaware of any facts which would form a reasonable basis for any such claim. The Intellectual Property owned by the Company and, to the knowledge of the Company, the Intellectual Property licensed to the Company and its subsidiary, has not been adjudged invalid or unenforceable, in whole or in part, and there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others challenging the validity or scope of any Company IP, and the Company is unaware of any facts which would form a reasonable basis for any such claim. There is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others that the Company or its subsidiary infringes, misappropriates or otherwise violates any Intellectual Property or other proprietary rights of others, and neither the Company nor its subsidiary have received any written notice of such claim and the Company is unaware of any other fact which would form a reasonable basis for any such claim.

(C) To the Company's knowledge, no employee of the Company or its subsidiary is in or has ever been in material violation of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement or any restrictive covenant to or with a former employer where the basis of such violation relates to such employee's employment with the Company or its subsidiary or actions undertaken by the employee while employed with the Company or its subsidiary.

(D) The Company and its subsidiary have taken commercially reasonable security measures to protect the secrecy, confidentiality and value of all of their material Intellectual Property.

(E) All patent applications owned by the Company or its subsidiary and filed with the U.S. Patent and Trademark Office (the "***PTO***") or any foreign or international patent authority that have resulted in patents or currently pending applications that describe inventions necessary to conduct the business of the Company or its subsidiary as now conducted or as described in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus to be conducted (collectively, the "***Company Patent Applications***") have been or were duly and properly assigned and maintenance fees have been paid for the issued U.S. patents.

(xvi) *No Violations or Defaults*. Neither the Company nor its subsidiary are in violation of their respective charters, bylaws or other organizational documents, or in breach of or otherwise in default, and no event has occurred which, with notice or lapse of time or both, would constitute such a default in the performance of any material obligation, agreement or condition contained in any bond, debenture, note, indenture, loan agreement or any other material contract, lease or other instrument to which it is subject or by which any of them may be bound, or to which any of the material property or assets of the Company or its subsidiary is subject.

(xvii) *Taxes*. The Company and its subsidiary have timely filed all federal, state, local and foreign income and franchise tax returns required to be filed and are not in default in the payment of any taxes which were payable pursuant to said returns or any assessments with respect thereto, other than any which the Company or its subsidiary are contesting in good faith. There is no pending dispute with any taxing authority relating to any of such returns, and the Company has no knowledge of any proposed liability for any tax to be imposed upon the properties or assets of the Company or its subsidiary for which there is not an adequate reserve reflected in the Company's financial statements included in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus.

(xviii) *Exchange Listing and Exchange Act Registration*. The Securities have been approved for listing on the Nasdaq Capital Market upon official notice of issuance and, on the date the Registration Statement became effective, the Company's Registration Statement on Form 10, Form 8-A or other applicable form under the Exchange Act, became or was effective. Except as previously disclosed to counsel for the Underwriters or as set forth in the Time of Sale Disclosure Package and the Prospectus, there are no affiliations with members of FINRA among the Company's officers or directors or, to the knowledge of the Company, any five percent or greater stockholders of the Company or any beneficial owner of the Company's unregistered equity securities that were acquired during the 180-day period immediately preceding the initial filing date of the Registration Statement. The Company is currently in compliance in all material respects with the applicable requirements of the Nasdaq Capital Market for maintenance of inclusion of the Common Stock thereon.

(xix) *Ownership of Other Entities*. Other than the subsidiary of the Company listed in Exhibit 21.1 to the Registration Statement or as otherwise disclosed in the Registration Statement, Time of Sale Disclosure Package and Prospectus, the Company, directly or indirectly, owns no capital stock or other equity or ownership or proprietary interest in any corporation, partnership, association, trust or other entity.

(xx) *Internal Controls*. The Company and its subsidiary maintain a system of internal accounting controls sufficient to provide reasonable assurances that (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Except as disclosed in the Registration Statement, in the Time of Sale Disclosure Package and in the Prospectus, the Company's internal control over financial reporting is effective and none of the Company, its board of directors and its audit committee is aware of any "significant deficiencies" or "material weaknesses" (each as defined by the Public Company Accounting Oversight Board) in its internal control over financial reporting, or any fraud, whether or not material, that involves management or other employees of the Company or its subsidiary who have a significant role in the Company's internal controls; and since the end of the latest audited fiscal year, there has been no change in the Company's internal control over financial reporting (whether or not remediated) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. The Company's board of directors has, subject to the exceptions, cure periods and the phase-in periods specified in the applicable stock exchange rules (the "***Exchange Rules***"), validly appointed an audit committee to oversee internal accounting controls whose composition satisfies the applicable requirements of the Exchange Rules and the Company's board of directors and/or the audit committee has adopted a charter that satisfies the requirements of the Exchange Rules.

(xxi) *No Brokers or Finders*. Other than as contemplated by this Agreement, the Company has not incurred and will not incur any liability for any finder's or broker's fee or agent's commission in connection with the execution and delivery of this Agreement or the consummation of the transactions contemplated hereby.

(xxii) *Insurance*. The Company and its subsidiary carry, or are covered by, insurance from reputable insurers in such amounts and covering such risks as is adequate for the conduct of their business and the value of their properties and as is customary for companies engaged in similar businesses in similar industries; all policies of insurance and any fidelity or surety bonds insuring the Company or its subsidiary or their business, assets, employees, officers and directors are in full force and effect; the Company and its subsidiary are in compliance with the terms of such policies and instruments in all material respects; there are no claims by the Company or its subsidiary under any such policy or instrument as to which any insurance company is denying liability or defending under a reservation of rights clause; neither the Company nor its subsidiary have been refused any insurance coverage sought or applied for; and neither the Company nor its subsidiary have reason to believe that they will not be able to renew their existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not have a Material Adverse Effect.

(xxiii) *Investment Company Act.* The Company is not and, after giving effect to the offering and sale of the Securities, will not be an "investment company," as such term is defined in the Investment Company Act of 1940, as amended.

(xxiv) *Sarbanes-Oxley Act.* The Company is in compliance with all applicable provisions of the Sarbanes-Oxley Act and the rules and regulations of the Commission thereunder.

(xxv) *Disclosure Controls.* The Company has established and maintains disclosure controls and procedures (as defined in Rules 13a-14 and 15d-14 under the Exchange Act) and, except as disclosed in the Time of Sale Disclosure Package under the caption "*Risk Factors - We have identified material weaknesses in our internal control over financial reporting related to our control environment, which in turn results in a material weakness in our disclosure controls. If we do not remediate the material weaknesses in our internal control over financial reporting, or if we fail to establish and maintain effective internal control, we may not be able to accurately report our financial results, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our stock*," such controls and procedures are effective in ensuring that material information relating to the Company, including its subsidiary, is made known to the principal executive officer and the principal financial officer and such controls and procedures are effective to perform the functions for which they were established. The Company has utilized such controls and procedures in preparing and evaluating the disclosures in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus.

(xxvi) *Anti-Bribery and Anti-Money Laundering Laws*. Each of the Company, its subsidiary, its affiliates and any of their respective officers, directors, supervisors, managers, agents, or employees, has not violated, its participation in the offering will not violate, and the Company and its subsidiary have instituted and maintain policies and procedures designed to ensure continued compliance with, each of the following laws: (A) anti-bribery laws, including but not limited to, any applicable law, rule, or regulation of any locality, including but not limited to any law, rule, or regulation promulgated to implement the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, signed December 17, 1997, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.K. Bribery Act 2010, or any other law, rule or regulation of similar purposes and scope or (B) anti-money laundering laws, including but not limited to, applicable federal, state, international, foreign or other laws, regulations or government guidance regarding anti-money laundering, including, without limitation, Title 18 US. Code section 1956 and 1957, the Patriot Act, the Bank Secrecy Act, and international anti-money laundering principles or procedures by an intergovernmental group or organization, such as the Financial Action Task Force on Money Laundering, of which the United States is a member and with which designation the United States representative to the group or organization continues to concur, all as amended, and any executive order, directive, or regulation pursuant to the authority of any of the foregoing, or any orders or licenses issued thereunder. The Company has instituted, maintains and enforces policies and procedures designed to ensure compliance with anti-bribery laws.

(xxvii) *OFAC*.

(A) Neither the Company nor its subsidiary, nor any or their directors, officers or employees, nor, to the Company's knowledge, any agent, affiliate or representative of the Company or its subsidiary, is an individual or entity that is, or is owned or controlled by an individual or entity that is:

(1) the subject of any sanctions administered or enforced by the U.S. Department of Treasury's Office of Foreign Assets Control, the United Nations Security Council, the European Union, Her Majesty's Treasury, or other relevant sanctions authority (collectively, "***Sanctions***"), nor

(2) located, organized or resident in a country or territory that is the subject of Sanctions (including, without limitation, the Crimea Region of the Ukraine, Cuba, Iran, North Korea, Sudan and Syria).

(B) Neither the Company nor its subsidiary will, directly or indirectly, use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other individual or entity:

(1) to fund or facilitate any activities or business of or with any individual or entity or in any country or territory that, at the time of such funding or facilitation, is the subject of Sanctions; or

(2) in any other manner that will result in a violation of Sanctions by any individual or entity (including any individual or entity participating in the offering, whether as underwriter, advisor, investor or otherwise).

(C) For the past five years, neither the Company nor any of its subsidiaries has knowingly engaged in, and is not now knowingly engaged in, any dealings or transactions with any individual or entity, or in any country or territory, that at the time of the dealing or transaction is or was the subject of Sanctions.

(xxviii) *Compliance with Environmental Laws*. Except as disclosed in the Registration Statement, the Time of Disclosure Package and the Prospectus, neither the Company nor its subsidiary is in violation of any statute, rule, regulation, decision or order of any Governmental Authority or any court, domestic or foreign, relating to the use, disposal or release of hazardous or toxic substances or relating to the protection or restoration of the environment or human exposure to hazardous or toxic substances (collectively, "***Environmental Laws***"), owns or operates any real property contaminated with any substance that is subject to any Environmental Laws, is liable for any off-site disposal or contamination pursuant to any Environmental Laws, or is subject to any claim relating to any Environmental Laws, which violation, contamination, liability or claim would individually or in the aggregate, have a Material Adverse Effect; and the Company is not aware of any pending investigation which might lead to such a claim. Neither the Company nor its subsidiary anticipate incurring any material capital expenditures relating to compliance with Environmental Laws.

(xxix) *Compliance with Occupational Laws*. The Company and its subsidiary (A) is in compliance, in all material respects, with any and all applicable foreign, federal, state and local laws, rules, regulations, treaties, statutes and codes promulgated by any and all Governmental Authorities (including pursuant to the Occupational Health and Safety Act) relating to the protection of human health and safety in the workplace ("***Occupational Laws***"); (B) has received all material Permits required of it under applicable Occupational Laws to conduct its business as currently conducted; and (C) is in compliance, in all material respects, with all terms and conditions of such Permits. No action, proceeding, revocation proceeding, writ, injunction or claim is pending or, to the Company's knowledge, threatened against the Company or its subsidiary relating to Occupational Laws, and the Company does not have knowledge of any facts, circumstances or developments relating to its operations or cost accounting practices that could reasonably be expected to form the basis for or give rise to such actions, suits, investigations or proceedings.

(xxx) *ERISA and Employee Benefits Matters*. (A) To the knowledge of the Company, no "prohibited transaction" as defined under Section 406 of ERISA (as defined below) or Section 4975 of the Code (as defined below) and not exempt under ERISA Section 408 and the regulations and published interpretations thereunder has occurred with respect to any Employee Benefit Plan (as defined below). At no time has the Company or any ERISA Affiliate (as defined below) maintained, sponsored, participated in, contributed to or has or had any liability or obligation in respect of any Employee Benefit Plan subject to Part 3 of Subtitle B of Title I of ERISA, Title IV of ERISA, or Section 412 of the Code or any "multiemployer plan" as defined in Section 3(37) of ERISA or any multiple employer plan for which the Company or any ERISA Affiliate has incurred or could incur liability under Section 4063 or 4064 of ERISA. No Employee Benefit Plan provides or promises, or at any time provided or promised, retiree health, life insurance, or other retiree welfare benefits except as may be required by the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended, or similar state law. Each Employee Benefit Plan is and has been operated in material compliance with its terms and all applicable laws, including but not limited to ERISA and the Code and, to the knowledge of the Company, no event has occurred (including a "reportable event" as such term is defined in Section 4043 of ERISA) and no condition exists that would subject the Company or any ERISA Affiliate to any material tax, fine, lien, penalty or liability imposed by ERISA, the Code or other applicable law. Each Employee Benefit Plan intended to be qualified under Code Section 401(a) is so qualified and has a favorable determination or opinion letter from the IRS upon which it can rely, and any such determination or opinion letter remains in effect and has not been revoked; to the knowledge of the Company, nothing has occurred since the date of any such determination or opinion letter that is reasonably likely to adversely affect such qualification; and (B) neither the Company nor its subsidiary have any obligations under any collective bargaining agreement with any union and no organization efforts are underway with respect to employees of the Company or its subsidiary. As used in this Agreement, " ***Code***" means the Internal Revenue Code of 1986, as amended; "***Employee Benefit Plan***" means any "employee benefit plan" within the meaning of Section 3(3) of ERISA, including, without limitation, all stock purchase, stock option, stock-based severance, employment, change-in-control, medical, disability, fringe benefit, bonus, incentive, deferred compensation, employee loan and all other employee benefit plans, agreements, programs, policies or other arrangements, whether or not subject to ERISA, under which (x) any current or former employee, director or independent contractor of the Company or its subsidiaries has any present or future right to benefits and which are contributed to, sponsored by or maintained by the Company or its subsidiary or (y) the Company or its subsidiary has had or has any present or future obligation or liability; "***ERISA***" means the Employee Retirement Income Security Act of 1974, as amended; and "***ERISA Affiliate***" means any member of the Company's controlled group as defined in Code Section 414(b), (c), (m) or (o).

(xxxi) *Business Arrangements*. Except as disclosed in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus, neither the Company nor its subsidiary have granted any material rights to develop, manufacture, produce, assemble, distribute, license, market or sell its products to any other person and is not bound by any material agreement that affects the exclusive right of the Company or its subsidiary to develop, manufacture, produce, assemble, distribute, license, market or sell its products.

(xxxii) *Labor Matters*. No labor problem or dispute with the employees of the Company or its subsidiary exists or is threatened or imminent, and the Company is not aware of any existing or imminent labor disturbance by the employees of any of its or its subsidiary's principal suppliers, contractors or customers, that could have a Material Adverse Effect.

(xxxiii) *Disclosure of Legal Matters*. There are no statutes, regulations, legal or governmental proceedings or contracts or other documents required to be described in the Time of Sale Disclosure Package or in the Prospectus or included as exhibits to the Registration Statement that are not described or included as required.

(xxxiv) *Statistical Information*. Any third-party statistical and market-related data included in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus are based on or derived from sources that the Company believes to be reliable and accurate in all material respects, and the disclosures relating to such data are consistent with the sources from which they are derived.

(xxxv) *Forward-looking Statements*. No forward-looking statement (within the meaning of Section 27A of the Act and Section 21E of the Exchange Act) contained in the Registration Statement, the Time of Sale Disclosure Package or the Prospectus has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith.

(xxxvi) *Health Care and Regulatory Compliance*.

(A) Each of the Company, its subsidiary and its directors, officers, employees, and agents (while acting in such capacity) are, and at all times have been, in material compliance with all Health Care Laws. Neither the Company nor its subsidiary has received any notification, correspondence, or any other communication from any Governmental Authority of potential or actual non-compliance by, or liability of, the Company or its subsidiary under any Health Care Laws that would be reasonably expected to affect the Company, its subsidiary or their products. To Company's knowledge, no circumstances exist that would be reasonably likely to constitute a violation of any Health Care Law. "***Health Care Laws***" means the Federal Food, Drug, and Cosmetic Act ("***FDCA***"), Medicare (Title XVIII of the Social Security Act) and Medicaid (Title XIX of the Social Security Act), the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)), the Stark Anti-Self-Referral Law (42 U.S.C. §§ 1395nn), the Anti-Inducement Law (42 U.S.C. § 1320a-7a(a)(5)), the civil False Claims Act (31 U.S.C. §§ 3729 et seq.), the administrative False Claims Law (42 U.S.C. § 1320a-7b(a)), the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. § 1320d et seq.), as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. §§ 17921 et seq.), the exclusion laws (42 U.S.C. § 1320a-7), and any other law that regulates the design, development, testing, manufacturing, processing, storing, importing or exporting, licensing, labeling or packaging, advertising, distributing or marketing of pharmaceutical or medical device products, or that is related to bribery, kickbacks, privacy, patient or program charges, recordkeeping, claims process, documentation requirements, medical necessity, referrals, the hiring of employees or acquisition of services or supplies from those who have been excluded from government health care programs, quality, safety, licensure or any other aspect of providing health care services.

(B) There is no action, proceeding, revocation proceeding, writ, injunction or claim pending, received or, to the Company's knowledge, threatened against the Company or its subsidiary that relates to a violation of any Health Care Law or other law pertaining to governmental health care programs or which could result in the imposition of penalties against or the exclusion of the Company or its subsidiary from participation in any such health care program that would be reasonably expected to materially impact the current business of the Company. None of the Company, nor its subsidiary, nor, to the Company's knowledge, any of their respective officers, directors, employees, or agents has engaged in any activity which is reasonable cause for civil penalties or mandatory or permissive exclusion from any governmental health care program.

(C) Neither the Company nor its subsidiary, nor any of their respective directors, officers, managers, employees, distributors or agents has been (i) debarred, excluded, delisted or similarly punished under any law; or (ii) convicted of any crime, or to the knowledge of the Company engaged in any conduct, for which such a punishment is mandated or permitted.

(D) All applications, notifications, submissions, information, claims, reports and statistics and other data and conclusions derived therefrom, utilized as the basis for or submitted in connection with any and all requests for a Permit from the U.S. Food and Drug Administration ("***FDA***") or other Governmental Authority, when submitted to the FDA or other Governmental Authority were true, complete and correct in all material respects as of the date of submission and any necessary or required updates, changes, corrections or modification to such applications, submissions, information and data have been submitted to the FDA or other Governmental Authority.

(E) Since inception, neither the Company nor its Subsidiary has had any manufacturing site subject to a Governmental Authority (including FDA) shutdown or import or export prohibition, nor received any FDA Form 483 or other Governmental Authority notice of inspectional observations, "warning letters," "untitled letters" or similar correspondence or notice from the FDA or other Governmental Authority and alleging or asserting noncompliance with any applicable laws, Permits, and, to the knowledge of Company, neither the FDA nor any Governmental Authority is considering such action. All products have been manufactured in compliance with all applicable quality requirements in all material respects.

(F) All preclinical and clinical trials that have been or are being conducted by or on behalf of, or sponsored by, the Company, or in which the Company or its products have participated were and, if still pending, are being or have been conducted in compliance in all material respects with standard medical and scientific research procedures and the experimental protocols, procedures and controls pursuant to applicable Health Care Laws, including, but not limited to, the FDCA and its applicable implementing regulations at 21 C.F.R. Parts 50, 54, 56, 58, 312, 812 and all applicable laws governing performance evaluations and clinical trials. The Company has not received any written notices, correspondence or other communication from the FDA or any other Governmental Authority requiring the termination, suspension or material modification of any clinical trial conducted by or on behalf of the Company, or in which the Company has participated.

(G) Neither the Company nor its subsidiary is the subject of any pending or, to the knowledge of Company, threatened, investigation by the FDA pursuant to its "*Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities*" Final Policy set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto.

(H) There have been no recalls, field notifications, field corrections, market withdrawals or replacements, warnings, warning letters, "dear doctor" letters, medical device reports, vigilance reports, investigator notices, safety alerts or other notice of action relating to an alleged lack of safety, efficacy, or regulatory compliance of the Company, its subsidiary or their products ("***Safety Notices***"). There have been no material product complaints with respect to the products of the Company, and to the Company's knowledge, there are no facts that would be reasonably likely to result in (i) a Safety Notice with respect to the Company or its products, (ii) a change in the marketing classification or a material change in labeling of any the products of the Company; or (iii) a termination or suspension of marketing or testing of any the products of the Company.

(I) Each of the Company and its subsidiary has materially complied with all reporting requirements under applicable laws with respect to their products.

(J) All sales, marketing, and promotional materials and activities of Company and its subsidiary have been in compliance, in all material respects, with applicable laws.

(K) The Company is not a party to any corporate integrity agreement, deferred prosecution agreement, monitoring agreement, consent decree, settlement order, or similar agreements, or have any reporting obligations pursuant to any such agreement, plan or correction or other remedial measure entered into with any Governmental Authority.

(xxxvii) *No Rated Securities*. There are no debt securities or preferred stock of, or guaranteed by, the Company that are rated by a "nationally recognized statistical rating organization," as such term is defined in Section 3(a)(62) of the Exchange Act.

(xxxviii) *Related Party Transactions*. To the Company's knowledge, no transaction has occurred between or among the Company, on the one hand, and any of the Company's officers, directors or five percent or greater stockholders or any affiliate or affiliates of any such officer, director or five percent or greater stockholders that is required to be described that is not so described in the Registration Statement, the Time of Sale Disclosure Package and the Prospectus. The Company has not, directly or indirectly, extended or maintained credit, or arranged for the extension of credit, or renewed an extension of credit, in the form of a personal loan to or for any of its directors or executive officers in violation of applicable laws, including Section 402 of the Sarbanes-Oxley Act.

(xxxix) *Restrictions on Subsidiary Payments to the Company*. The subsidiary of the Company is not currently prohibited, directly or indirectly, from paying any dividends to the Company, from making any other distribution on such subsidiary's capital stock, from repaying to the Company any loans or advances to such subsidiary from the Company or from transferring any of such subsidiary's property or assets to the Company, except as described in or contemplated by the Registration Statement, the Time of Sale Disclosure Package and the Prospectus.

(b) *Effect of Certificates*. Any certificate signed by any officer of the Company and delivered to you or to counsel for the Underwriters shall be deemed a representation and warranty by the Company to the Underwriters as to the matters covered thereby.

3. ***Purchase, Sale and Delivery of Securities***.

(a) *Firm Shares*. On the basis of the representations, warranties and agreements herein contained, but subject to the terms and conditions herein set forth, the Company agrees to issue and sell the Firm Shares to the several Underwriters, and each Underwriter agrees, severally and not jointly, to purchase from the Company the number of Firm Shares set forth opposite the name of such Underwriter in Schedule I hereto. The purchase price for each Firm Share shall be $[●] per share. In making this Agreement, each Underwriter is contracting severally and not jointly. Except as provided in paragraph (d) of this Section 3, the agreement of each Underwriter is to purchase only the respective number of Firm Shares specified in Schedule I.

(b) *Option Shares*. On the basis of the representations, warranties and agreements herein contained, but subject to the terms and conditions herein set forth, the Company hereby grants to the several Underwriters an option to purchase all or any portion of the Option Shares at the same purchase price as the Firm Shares, made by the Underwriters in the sale and distribution of the Firm Shares. The option granted hereunder may be exercised in whole or in part at any time and from time to time within 30 days after the effective date of this Agreement upon notice (confirmed in writing) by the Representatives to the Company setting forth the aggregate number of Option Shares as to which the several Underwriters are exercising the option and the date and time, as determined by you, when the Option Shares are to be delivered, but in no event earlier than the First Closing Date (as defined below) nor (unless otherwise agreed by you and the Company) earlier than the second business day or later than the tenth business day after the date on which the option shall have been exercised. The number of Option Shares to be purchased by each Underwriter shall be the same percentage of the total number of Option Shares to be purchased by the several Underwriters as the number of Firm Shares to be purchased by such Underwriter is of the total number of Firm Shares to be purchased by the several Underwriters, as adjusted by the Representatives in such manner as the Representatives deem advisable to avoid fractional shares. No Option Shares shall be sold and delivered unless the Firm Shares previously have been, or simultaneously are, sold and delivered.

(c) *Payment and Delivery*.

(i) The Securities to be purchased by each Underwriter hereunder, in book-entry form in such authorized denominations and registered in such names as you may request upon at least forty-eight hours' prior notice to the Company, shall be delivered by or on behalf of the Company to you, through the facilities of the Depository Trust Company ("***DTC***"), for the account of such Underwriter, with any transfer taxes payable in connection with the transfer of the Securities to the Underwriters duly paid, against payment by or on behalf of such Underwriter of the purchase price therefor by wire transfer of Federal (same-day) funds to the account specified by the Company to you at least forty-eight hours in advance. The time and date of such delivery and payment shall be, with respect to the Firm Shares, 9:30 a.m., New York City time, on [●], 2020, or such other time and date as you and the Company may agree upon in writing, and, with respect to the Option Shares, 9:30 a.m., New York City time, on the date specified by you in each written notice given by you of the election to purchase such Option Shares, or such other time and date as you and the Company may agree upon in writing. Such time and date for delivery of the Firm Shares is herein called the "***First Closing Date***," each such time and date for delivery of the Option Shares, if not the First Closing Date, is herein called an "***Option Closing Date***," and each such time and date for delivery is herein called a "***Closing***" or a "***Closing Date***."

(ii) The documents to be delivered at each Closing by or on behalf of the parties hereto pursuant to Section 5 hereof, including the cross receipt for the Securities and any additional documents requested by the Underwriters pursuant to Section 5(n) hereof, will be delivered at the offices of the Company, and the Securities will be delivered to you, through the facilities of the DTC, for the account of such Underwriter, all at such Closing.

(d) *Purchase by Representatives on Behalf of Underwriters*. It is understood that you, individually and not as Representative of the several Underwriters, may (but shall not be obligated to) make payment to the Company, on behalf of any Underwriter for the Securities to be purchased by such Underwriter. Any such payment by you shall not relieve any such Underwriter of any of its obligations hereunder. Nothing herein contained shall constitute any of the Underwriters an unincorporated association or partner with the Company.

4. ***Covenants***. The Company covenants and agrees with the several Underwriters as follows:

(a) *Required Filings*. The Company will prepare and file a Prospectus with the Commission containing the Rule 430A Information omitted from the Preliminary Prospectus within the time period required by, and otherwise in accordance with the provisions of, Rules 424(b) and 430A of the Rules and Regulations. If the Company has elected to rely upon Rule 462(b) of the Rules and Regulations to increase the size of the offering registered under the Act and the Rule 462(b) Registration Statement has not yet been filed and become effective, the Company will prepare and file the Rule 462(b) Registration Statement with the Commission within the time period required by, and otherwise in accordance with the provisions of, Rule 462(b) of the Rules and Regulations and the Act. The Company will prepare and file with the Commission, promptly upon your request, any amendments or supplements to the Registration Statement or Prospectus that, in your opinion, may be necessary or advisable in connection with the distribution of the Securities by the Underwriters; and the Company will furnish you and counsel for the Underwriters a copy of any proposed amendment or supplement to the Registration Statement or Prospectus and will not file any amendment or supplement to the Registration Statement or Prospectus to which you shall reasonably object by notice to the Company after having been furnished a copy a reasonable time prior to the filing.

(b) *Notification of Certain Commission Actions*. The Company will advise you, promptly after it shall receive notice or obtain knowledge thereof, of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement, or any post-effective amendment thereto or preventing or suspending the use of any Preliminary Prospectus, the Time of Sale Disclosure Package, the Prospectus or any issuer free writing prospectus, of the suspension of the qualification of the Securities for offering or sale in any jurisdiction, or of the initiation or threatening of any proceeding for any such purpose; and the Company will promptly use its best efforts to prevent the issuance of any stop order or to obtain its withdrawal if such a stop order should be issued.

(c) *Continued Compliance with Securities Laws*.

(A) Within the time during which a prospectus (assuming the absence of Rule 172) relating to the Securities is required to be delivered under the Act by any Underwriter or any dealer, the Company will comply with all requirements imposed upon it by the Act, as now and hereafter amended, and by the Rules and Regulations, as from time to time in force, so far as necessary to permit the continuance of sales of or dealings in the Securities as contemplated by the provisions hereof, the Time of Sale Disclosure Package and the Prospectus. If during such period any event occurs as a result of which the Prospectus (or if the Prospectus is not yet available to prospective purchasers, the Time of Sale Disclosure Package) would include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances then existing, not misleading, or if during such period it is necessary to amend the Registration Statement or supplement the Prospectus (or if the Prospectus is not yet available to prospective investors, the Time of Sale Disclosure Package) to comply with the Act, the Company promptly will (x) notify you of such untrue statement or omission, (y) amend the Registration Statement or supplement the Prospectus (or, if the Prospectus is not yet available to prospective purchasers, the Time of Sale Disclosure Package) (at the expense of the Company) so as to correct such statement or omission or effect such compliance and (z) notify you when any amendment to the Registration Statement is filed or becomes effective or when any supplement to the Prospectus (or, if the Prospectus is not yet available to prospective purchasers, the Time of Sale Disclosure Package) is filed.

(B) If at any time following issuance of a Written Testing-the-Waters Communication there occurred or occurs an event or development as a result of which such Written Testing-the-Waters Communication conflicted or would conflict with the information contained in the Registration Statement, any Preliminary Prospectus or the Prospectus relating to the Securities or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at that subsequent time, not misleading, the Company (x) has promptly notified or promptly will notify the Representatives of such conflict, untrue statement or omission, (y) has promptly amended or will promptly amend or supplement, at its own expense, such Written Testing-the-Waters Communication to eliminate or correct such conflict, untrue statement or omission and (z) has notified or promptly will notify you when such amendment or supplement was or is filed with the Commission to the extent required to be filed by the Rules and Regulations.

(d) *Blue Sky Qualifications*. The Company shall take or cause to be taken all necessary action to qualify the Securities for sale under the securities laws of such domestic United States or foreign jurisdictions as you reasonably designate and to continue such qualifications in effect so long as required for the distribution of the Securities, except that the Company shall not be required in connection therewith to qualify as a foreign corporation or to execute a general consent to service of process in any state.

(e) *Provision of Documents*. The Company will furnish, at its own expense, to the Underwriters and counsel for the Underwriters copies of the Registration Statement (three of which will be signed and will include all consents and exhibits filed therewith), and to the Underwriters and any dealer each Preliminary Prospectus, the Time of Sale Disclosure Package, the Prospectus, and all amendments and supplements to such documents, in each case as soon as available and in such quantities as you may from time to time reasonably request.

(f) *Rule 158*. The Company will make generally available to its security holders as soon as practicable, but in no event later than 15 months after the end of the Company's current fiscal quarter, an earnings statement (which need not be audited) covering a 12-month period beginning after the effective date of the Registration Statement (which, for purposes of this paragraph, will be deemed to be the effective date of the Rule 462(b) Registration Statement, if applicable) that shall satisfy the provisions of Section 11(a) of the Act and Rule 158 of the Rules and Regulations.

(g) *Payment and Reimbursement of Expenses*. The Company, whether or not the transactions contemplated hereunder are consummated or this Agreement is terminated, will pay or cause to be paid (A) all expenses (including transfer taxes allocated to the respective transferees) incurred in connection with the delivery to the Underwriters of the Securities, (B) all expenses and fees (including, without limitation, fees and expenses of the Company's accountants and counsel) in connection with the preparation, printing, filing, delivery, and shipping of the Registration Statement (including the financial statements therein and all amendments, schedules, and exhibits thereto), the Securities, each Preliminary Prospectus, the Time of Sale Disclosure Package, the Prospectus, and any amendment thereof or supplement thereto, and the printing, delivery, and shipping of this Agreement and other underwriting documents, including Blue Sky Memoranda (covering the states and other applicable jurisdictions), (C) all filing fees and fees incurred in connection with the qualification of the Securities for offering and sale by the Underwriters or by dealers under the securities or blue sky laws of the states and other jurisdictions which you shall designate, (D) the fees and expenses of any transfer agent or registrar, (E) the reasonable out-of-pocket accountable fees and disbursements incurred by the Underwriters in connection with the offer, sale or marketing of the Securities and performance of the Underwriters' obligations hereunder, including all reasonable out-of-pocket accountable fees and disbursements of Underwriters' counsel, and for the avoidance of doubt, excluding any general overhead, salaries, supplies, or similar expenses of the Underwriters incurred in the normal conduct of business, (F) listing fees, if any, (G) all fees, expenses and disbursements relating to background checks of the Company's officers and directors, (H) the cost and expenses of the Company relating to investor presentations or any "road show" undertaken in connection with marketing of the Securities, including, without limitation, expenses associated with the preparation or dissemination of any electronic road show, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations with the prior approval of the Company, travel and lodging expenses of the representatives and officers of the Company and any such consultants, and the cost of any aircraft chartered in connection with the road show, and (I) all other costs and expenses of the Company incident to the performance of its obligations hereunder that are not otherwise specifically provided for herein. The expenses to be paid by the Company and reimbursed to the Underwriters under this Section 4(g) shall be capped at $135,000. If this Agreement is terminated by you pursuant to Section 8 hereof or if the sale of the Securities provided for herein is not consummated by reason of any failure, refusal or inability on the part of the Company to perform any agreement on its part to be performed, or because any other condition of the Underwriters' obligations hereunder required to be fulfilled by the Company is not fulfilled, the Company will reimburse the several Underwriters for all reasonable out-of-pocket accountable disbursements (including but not limited to fees and disbursements of counsel, printing expenses, travel expenses, postage, facsimile and telephone charges) incurred by the Underwriters in connection with their investigation, preparing to market and marketing the Securities or in contemplation of performing their obligations hereunder, it being understand that such amount shall be capped at $75,000.

(h) *Use of Proceeds*. The Company will apply the net proceeds from the sale of the Securities to be sold by it hereunder for the purposes set forth in the Time of Sale Disclosure Package and in the Prospectus and will file such reports with the Commission with respect to the sale of the Securities and the application of the proceeds therefrom as may be required in accordance with Rule 463 of the Rules and Regulations.

(i) *Company Lock-Up*. The Company will not, without the prior written consent of the Representatives, from the date of execution of this Agreement and continuing to and including the date 90 days after the date of the Prospectus (the "***Lock-Up Period***"), (A) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock or (B) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the Common Stock, whether any such transaction described in clause (A) or (B) above is to be settled by delivery of Common Stock or such other securities, in cash or otherwise, except to the Underwriters pursuant to this Agreement. Notwithstanding the foregoing, the Company may make, as referenced in the Registration Statement, the Time of Sale Disclosure Package and Prospectus, (w) issuances of shares of Common Stock to satisfy anti-dilution adjustment provisions for prior securities issuances, (z) issuances of shares of Common Stock pursuant to licensing agreements or similar agreements, and (aa) issuances of shares of Common Stock to satisfy the conversion of the Company's 2019 Senior Convertible Notes and line of credit agreements. In addition, the Company may also make (x) grants of options, shares of Common Stock and other awards to purchase or receive shares of Common Stock under the Company Stock Plans that are in effect as of or prior to the date hereof, or (y) issuances of shares of Common Stock upon the exercise of options or other awards granted under such Company Stock Plans. The Company agrees not to accelerate the vesting of any option or warrant or exercise any repurchase or expiry right in respect of any option or warrant, including the common share purchase warrants issued in connection with the Company's various private placements prior to the date hereof, prior to the expiration of the Lock-Up Period.

(j) *Stockholder Lock-Ups*. The Company has caused to be delivered to you prior to the date of this Agreement a letter, in the form ofExhibit A hereto (the "***Lock-Up Agreement***"), from each individual or entity listed on Schedule II. The Company will enforce the terms of each Lock-Up Agreement and issue stop-transfer instructions to its transfer agent and registrar for the Common Stock with respect to any transaction or contemplated transaction that would constitute a breach of or default under the applicable Lock-Up Agreement.

(k) *No Market Stabilization or Manipulation*. The Company has not taken and will not take, directly or indirectly, any action designed to or which might reasonably be expected to cause or result in, or which has constituted, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities, and has not effected any sales of Common Stock which are required to be disclosed in response to Item 701 of Regulation S-K under the Act which have not been so disclosed in the Registration Statement.

(l) *SEC Reports*. The Company will file on a timely basis with the Commission such periodic and special reports as required by the Rules and Regulations.

(m) *Free Writing Prospectuses*. The Company represents and agrees that, unless it obtains the prior written consent of the Representatives, and each Underwriter represents and agrees that, unless it obtains the prior written consent of the Company and the Representatives, it has not made and will not make any offer relating to the Securities that would constitute an issuer free writing prospectus or that would otherwise constitute a free writing prospectus. Each Underwriter severally represents and agrees that, (A) unless it obtains the prior written consent of the Company and the Representatives, it has not distributed, and will not distribute any Written Testing-the-Waters Communication other than those listed on Schedule IV, and (B) any Testing-the-Waters Communication undertaken by it was with entities that are qualified institutional buyers with the meaning of Rule 144A under the Act or institutions that are accredited investors within the meaning of Rule 501 under the Act.

5. ***Conditions of Underwriters' Obligations***. The obligations of the several Underwriters hereunder are subject to the accuracy, as of the date hereof and at each of the First Closing Date and any Option Closing Date (as if made at such Closing Date), of and compliance with all representations, warranties and agreements of the Company contained herein, to the performance by the Company of its obligations hereunder and to the following additional conditions:

(a) *Required Filings; Absence of Certain Commission Actions*. The Registration Statement shall have become effective not later than 5:30 p.m., New York City time, on the date of this Agreement, or such later time and date as you, as Representatives of the several Underwriters, shall approve and all filings required by Rules 424, 430A and 433 of the Rules and Regulations shall have been timely made (without reliance on Rule 424(b)(8) or Rule 164(b)); no stop order suspending the effectiveness of the Registration Statement or any part thereof or any amendment thereof, nor suspending or preventing the use of the Time of Sale Disclosure Package or the Prospectus shall have been issued; no proceedings for the issuance of such an order shall have been initiated or threatened; and any request of the Commission for additional information (to be included in the Registration Statement, the Time of Sale Disclosure Package, the Prospectus or otherwise) shall have been complied with to your satisfaction.

(b) *Continued Compliance with Securities Laws*. No Underwriter shall have advised the Company that (i) the Registration Statement or any amendment thereof or supplement thereto contains an untrue statement of a material fact which, in your opinion, is material or omits to state a material fact which, in your opinion, is required to be stated therein or necessary to make the statements therein not misleading, or (ii) the Time of Sale Disclosure Package or the Prospectus, or any amendment thereof or supplement thereto, contains an untrue statement of fact which, in your opinion, is material, or omits to state a fact which, in your opinion, is material and is required to be stated therein, or necessary to make the statements therein, in light of the circumstances under which they are made, not misleading.

(c) *Absence of Certain Events*. Except as contemplated in the Time of Sale Disclosure Package and in the Prospectus, subsequent to the respective dates as of which information is given in the Time of Sale Disclosure Package and the Prospectus, neither the Company nor its subsidiary shall have incurred any material liabilities or obligations, direct or contingent, or entered into any material transactions, or declared or paid any dividends or made any distribution of any kind with respect to its capital stock; and there shall not have been any change in the capital stock (subject to the requirements of Section 4(i) hereof, other than a change in the number of outstanding shares of Common Stock due to the issuance of shares upon the exercise of outstanding options or warrants or conversion of convertible securities), or any material change in the short-term or long-term debt of the Company (other than as a result of the conversion of convertible securities), or any issuance of options, warrants, convertible securities or other rights to purchase the capital stock of the Company or its subsidiary, or any Material Adverse Change or any development involving a prospective Material Adverse Change (whether or not arising in the ordinary course of business), that, in your judgment, makes it impractical or inadvisable to offer or deliver the Securities on the terms and in the manner contemplated in the Time of Sale Disclosure Package and in the Prospectus.

(d) *Opinions of Company Counsel*. On each Closing Date, there shall have been furnished to you, as Representatives of the several Underwriters, the opinion and negative assurance statement of Foley & Lardner LLP, counsel for the Company, dated as of such Closing Date and addressed to you in form and substance reasonably satisfactory to the Representatives.

(e) *Opinion of Company Intellectual Property Counsel*. On each Closing Date, there shall have been furnished to you, as Representatives of the several Underwriters, the opinion of Foley & Lardner LLP, intellectual property counsel for the Company, dated as of such Closing Date and addressed to you in form and substance reasonably satisfactory to the Representatives.

(f) *Opinion of Underwriters' Counsel*. On each Closing Date, there shall have been furnished to you, as Representatives of the several Underwriters, such opinion or opinions and negative assurance statement of Faegre Drinker Biddle & Reath LLP, counsel for the Underwriters, dated as of such Closing Date and addressed to you, with respect to such matters as you reasonably may request, and such counsel shall have received such papers and information as they request to enable them to pass upon such matters.

(g) *Comfort Letters*. On the date hereof, on the effective date of any post-effective amendment to the Registration Statement filed after the date hereof and on each Closing Date, you, as Representatives of the several Underwriters, shall have received a letter from BD & Company, Inc., each dated as of such date and addressed to you, in form and substance satisfactory to you.

(h) *Officers' Certificate*. On each Closing Date, there shall have been furnished to you, as Representatives of the several Underwriters, a certificate, dated as of such Closing Date and addressed to you, signed by the chief executive officer and by the chief financial officer of the Company, to the effect that:

(i) the representations and warranties of the Company in this Agreement are true and correct as if made at and as of such Closing Date, and the Company has complied with all the agreements and satisfied all the conditions on its part to be performed or satisfied at or prior to such Closing Date;

(ii) no stop order or other order suspending the effectiveness of the Registration Statement or any part thereof or any amendment thereof or the qualification of the Securities for offering or sale, nor suspending or preventing the use of the Time of Sale Disclosure Package, the Prospectus or any issuer free writing prospectus, has been issued, and no proceeding for that purpose has been instituted or, to the best of their knowledge, is contemplated by the Commission or any state or regulatory body; and

(iii) affirms the accuracy of the matters set forth in subsection (c) of this Section 5.

(i) *Lock-Up Agreement*. The Representatives shall have received all of the Lock-Up Agreements referenced in Section 4 and the Lock-Up Agreements shall remain in full force and effect.

(j) *Officer's Certificate*. On the date hereof and on each Closing Date, the Company shall have furnished to you, as Representatives of the several Underwriters, a certificate, dated as of such date, signed on behalf of the Company by its Chief Executive Officer, regarding certain regulatory disclosure in the Preliminary Prospectus and the Prospectus, respectively, in form and substance satisfactory to you.

(k) *FINRA No Objections*. FINRA shall have raised no objection to the fairness and reasonableness of the underwriting terms and arrangements.

(l) *Exchange Listing*. The Securities to be delivered on such Closing Date will have been approved for listing on the Nasdaq Capital Market.

(m) *Other Documents*. The Company shall have furnished to you, as Representatives of the several Underwriters, and counsel for the Underwriters such additional documents, certificates and evidence as you or they may have reasonably requested.

All such opinions, certificates, letters and other documents will be in compliance with the provisions hereof only if they are satisfactory in form and substance to you, as Representatives of the several Underwriters, and counsel for the Underwriters. The Company will furnish you with such conformed copies of such opinions, certificates, letters and other documents as you shall reasonably request.

6. ***Indemnification and Contribution***.

(a) *Indemnification by the Company*. The Company agrees to indemnify and hold harmless each Underwriter, its affiliates, directors and officers and each person, if any, who controls such Underwriter within the meaning of Section 15 of the Act or Section 20 of the Exchange Act, from and against any losses, claims, damages or liabilities, joint or several, to which such Underwriter may become subject, under the Act or otherwise (including in settlement of any litigation if such settlement is effected with the written consent of the Company), insofar as such losses, claims, damages or liabilities (or actions in respect thereof) (i) arise out of or are based upon an untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, including the 430A Information and any other information deemed to be a part of the Registration Statement at the time of effectiveness and at any subsequent time pursuant to the Rules and Regulations, if applicable, any Preliminary Prospectus, the Time of Sale Disclosure Package, the Prospectus, or any amendment or supplement thereto, any issuer free writing prospectus, any issuer information that the Company has filed or is required to file pursuant to Rule 433(d) of the Rules and Regulations, any Written Testing-the-Waters Communication, or any road show as defined in Rule 433(h) under the Act (a "***road show***"), or (ii) arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, and will reimburse each Underwriter for any legal or other expenses reasonably incurred by it in connection with investigating or defending against such loss, claim, damage, liability or action as such expenses are incurred; *provided, however*, that the Company will not be liable in any such case to the extent that any such loss, claim, damage, liability or action arises out of or is based upon an untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with written information furnished to the Company by you, or by any Underwriter through you, specifically for use in the preparation thereof; it being understood and agreed that the only information furnished by an Underwriter consists of the information described as such in Section 6(e).

(b) *Indemnification by the Underwriters*. Each Underwriter will, severally and not jointly, indemnify and hold harmless the Company, its affiliates, directors and officers and each person, if any, who controls the Company within the meaning of Section 15 of the Act and Section 20 of the Exchange Act, from and against any losses, claims, damages or liabilities to which the Company may become subject, under the Act or otherwise (including in settlement of any litigation, if such settlement is effected with the written consent of such Underwriter), insofar as such losses, claims, damages or liabilities (or actions in respect thereof) (i) arise out of or are based upon an untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, any Preliminary Prospectus, the Time of Sale Disclosure Package, the Prospectus, or any amendment or supplement thereto, any issuer free writing prospectus, any issuer information that the Company has filed or is required to file pursuant to Rule 433(d) of the Rules and Regulations, any Written Testing-the-Waters Communication, or any road show, or (ii) arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was made in conformity with written information furnished to the Company by you, or by such Underwriter through you, specifically for use in the preparation thereof (it being understood and agreed that the only information furnished by an Underwriter consists of the information described as such in Section 6(e)), and will reimburse the Company for any legal or other expenses reasonably incurred and documented by the Company in connection with investigating or defending against any such loss, claim, damage, liability or action as such expenses are incurred.

(c) *Notice and Procedures*. Promptly after receipt by an indemnified party under subsection (a) or (b) above of notice of the commencement of any action, such indemnified party shall, if a claim in respect thereof is to be made against the indemnifying party under such subsection, notify the indemnifying party in writing of the commencement thereof; but the omission so to notify the indemnifying party shall not relieve the indemnifying party from any liability that it may have to any indemnified party except to the extent such indemnifying party has been materially prejudiced by such failure (through the forfeiture of substantive rights or defenses). In case any such action shall be brought against any indemnified party, and it shall notify the indemnifying party of the commencement thereof, the indemnifying party shall be entitled to participate in, and, to the extent that it shall wish, jointly with any other indemnifying party similarly notified, to assume the defense thereof, with counsel satisfactory to such indemnified party, and after notice from the indemnifying party to such indemnified party of the indemnifying party's election so to assume the defense thereof, the indemnifying party shall not be liable to such indemnified party under such subsection for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof other than reasonable costs of investigation; provided, however, that if, in your sole judgment, it is advisable for the Underwriters to be represented as a group by separate counsel, you shall have the right to employ a single counsel (in addition to local counsel) to represent all Underwriters who may be subject to liability arising from any claim in respect of which indemnity may be sought by the Underwriters under subsection (a) above, in which event the reasonable fees and expenses of such separate counsel shall be borne by the indemnifying party or parties and reimbursed to the Underwriters as incurred. An indemnifying party shall not be obligated under any settlement agreement relating to any action under this Section 6 to which it has not agreed in writing. In addition, no indemnifying party shall, without the prior written consent of the indemnified party (which consent shall not be unreasonably withheld or delayed) effect any settlement of any pending or threatened proceeding unless such settlement includes an unconditional release of such indemnified party for all liability on claims that are the subject matter of such proceeding and does not include a statement as to, or an admission of, fault, culpability or a failure to act by or on behalf of an indemnified party. Notwithstanding the foregoing, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel pursuant to this Section 6(c), such indemnifying party agrees that it shall be liable for any settlement effected without its written consent if (i) such settlement is entered into more than 45 days after receipt by such indemnifying party of the aforesaid request and (ii) such indemnifying party shall not have reimbursed such indemnified party in accordance with such request prior to the date of such settlement.

(d) *Contribution; Limitations on Liability; Non-Exclusive Remedy*. If the indemnification provided for in this Section 6 is unavailable or insufficient to hold harmless an indemnified party under subsection (a) or (b) above, then each indemnifying party shall contribute to the amount paid or payable by such indemnified party as a result of the losses, claims, damages or liabilities referred to in subsection (a) or (b), (i) in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and the Underwriters on the other from the offering of the Securities or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company on the one hand and the Underwriters on the other in connection with the statements or omissions that resulted in such losses, claims, damages or liabilities, as well as any other relevant equitable considerations. The relative benefits received by the Company on the one hand and the Underwriters on the other shall be deemed to be in the same proportion as the total net proceeds from the offering (before deducting expenses) received by the Company bear to the total underwriting discounts and commissions received by the Underwriters, in each case as set forth in the table on the cover page of the Prospectus. The relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company or the Underwriters and the parties' relevant intent, knowledge, access to information and opportunity to correct or prevent such untrue statement or omission. The Company and the Underwriters agree that it would not be just and equitable if contributions pursuant to this subsection (d) were to be determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation which does not take account of the equitable considerations referred to in the first sentence of this subsection (d). The amount paid by an indemnified party as a result of the losses, claims, damages or liabilities referred to in the first sentence of this subsection (d) shall be deemed to include any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending against any action or claim which is the subject of this subsection (d). Notwithstanding the provisions of this subsection (d), no Underwriter shall be required to contribute any amount in excess of the amount by which the total underwriting discounts and commissions received by such Underwriter with respect to the Securities exceeds the amount of any damages that such Underwriter has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The Underwriters' obligations in this subsection (d) to contribute are several in proportion to their respective underwriting obligations and not joint. The remedies provided for in this Section 6 are not exclusive and shall not limit any rights or remedies that might otherwise be available to any indemnified party at law or in equity.

(e) *Information Provided by the Underwriters.* The Underwriters severally confirm that the statements with respect to the public offering of the Securities by the Underwriters set forth in the second and fourteenth paragraphs under the caption "Underwriting" in the Time of Sale Disclosure Package and in the Prospectus are correct and the Company acknowledges such statements constitute the only information concerning the Underwriters furnished in writing to the Company by or on behalf of the Underwriters specifically for inclusion in the Registration Statement, any Preliminary Prospectus, the Time of Sale Disclosure Package, the Prospectus or any issuer free writing prospectus.

7. ***Representations and Agreements to Survive Delivery.*** All representations, warranties, and agreements of the Company herein or in certificates delivered pursuant hereto, and the agreements of the several Underwriters and the Company contained in Section 6 hereof, shall remain operative and in full force and effect regardless of any investigation made by or on behalf of any Underwriter or any controlling person thereof, or the Company or any of its officers, directors, or controlling persons, and shall survive delivery of, and payment for, the Securities to and by the Underwriters hereunder and any termination of this Agreement.

8. ***Termination***.

(a) *Right to Terminate*. You shall have the right to terminate this Agreement by giving notice as hereinafter specified at any time at or prior to the First Closing Date, and the option referred to in Section 3(b), if exercised, may be cancelled at any time prior to the Option Closing Date, if (i) the Company shall have failed, refused or been unable, at or prior to such Closing Date, to perform any agreement on its part to be performed hereunder, (ii) any other condition of the Underwriters' obligations hereunder is not fulfilled, (iii) trading on the Nasdaq Stock Market shall have been wholly suspended, (iv) minimum or maximum prices for trading shall have been fixed, or maximum ranges for prices for securities shall have been required on the Nasdaq Stock Market by such Exchange or by order of the Commission or any other Governmental Authority, (v) a banking moratorium shall have been declared by federal or state authorities, or (vi) there shall have occurred any outbreak or escalation of hostilities or any change in financial markets or any calamity or crisis that, in your judgment, is material and adverse and makes it impractical or inadvisable to proceed with the completion of the sale of and payment for the Securities. Any such termination shall be without liability of any party to any other party except that the provisions of Section 4(g) and Section 6 hereof shall at all times be effective.

(b) *Notice of Termination.* If you elect to terminate this Agreement as provided in this Section, the Company shall be notified promptly by you by telephone, confirmed by letter.

9. ***Default by the Company.***

(a) *Default by the Company*. If the Company shall fail at the First Closing Date to sell and deliver the Securities which it is obligated to sell hereunder, then this Agreement shall terminate without any liability on the part of any Underwriter.

(b) *No Relief from Liability*. No action taken pursuant to this Section shall relieve the Company from liability, if any, in respect of any default hereunder.

10. ***Defaulting Underwriter***. If on the Closing Date or any Option Closing Date, if any, any Underwriter shall fail to purchase and pay for the portion of the Firm Shares or Option Shares, as the case may be, which such Underwriter has agreed to purchase and pay for on such date (otherwise than by reason of any default on the part of the Company), the Representatives, or if either Representative is the defaulting Underwriter, the non-defaulting Underwriters, shall use their reasonable efforts to procure within 36 hours thereafter one or more of the other Underwriters, or any others, to purchase from the Company such amounts as may be agreed upon and upon the terms set forth herein, the Firm Shares or Option Shares , as the case may be, which the defaulting Underwriter or Underwriters failed to purchase. If during such 36 hours the Representatives shall not have procured such other Underwriters, or any others, to purchase the Firm Shares or Option Shares, as the case may be, agreed to be purchased by the defaulting Underwriter or Underwriters, then (a) if the aggregate number of Firm Shares or Option Shares, as the case may be, with respect to which such default shall occur does not exceed 10% of the Firm Shares or Option Shares, as the case may be, to be purchased on such Closing Date, the other Underwriters shall be obligated, severally, in proportion to the respective numbers of Firm Shares or Option Shares, as the case may be, which they are obligated to purchase hereunder, to purchase the Firm Shares or Option Shares, as the case may be, which such defaulting Underwriter or Underwriters failed to purchase, or (b) if the aggregate number of Firm Shares or Option Shares, as the case may be, with respect to which such default shall occur exceeds 10% of the Firm Shares or Option Shares, as the case may be, covered hereby, the Company or the Representatives will have the right to terminate this Agreement without liability on the part of the non-defaulting Underwriters or of the Company except to the extent provided in Section 6 hereof. In the event of a default by any Underwriter or Underwriters, as set forth in this Section 10, the applicable Closing Date may be postponed for such period, not exceeding seven days, as the Representatives, or if either Representative is the defaulting Underwriter, the non-defaulting Underwriters, may determine in order that the required changes in the Prospectus or in any other documents or arrangements may be effected. The term "Underwriter" includes any person substituted for a defaulting Underwriter. Any action taken under this Section shall not relieve any defaulting Underwriter from liability in respect of any default of such Underwriter under this Agreement.

11. ***Notices***. Except as otherwise provided herein, all communications hereunder shall be in writing and, if to the Underwriters, shall be mailed via overnight delivery service or hand delivered via courier, to the Representatives c/o Craig-Hallum Capital Group LLC, 222 South Ninth Street, Suite 350, Minneapolis, Minnesota 55402, Attention: Investment Banking, and Benchmark Company, LLC, 150 E. 58th Street, 17th Floor, New York, New York 10155, with a copy to Faegre Drinker Biddle & Reath LLP, 2200 Wells Fargo Center, 90 South Seventh Street, Minneapolis, Minnesota 55402, Attention: Jonathan Zimmerman; and (ii) if to the Company, shall be mailed or delivered to it at 7380 Coca Cola Drive, Suite 106, Hanover, MD 21076, Attention: Dr. David Young, with a copy to Foley & Lardner LLP, One Independent Drive, Suite 1300, Jacksonville, FL 32202, Attention: Michael Kirwan. Any party to this Agreement may change such address for notices by sending to the parties to this Agreement written notice of a new address for such purpose.

12. ***Persons Entitled to Benefit of Agreement***. This Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective successors and assigns and the controlling persons, officers and directors referred to in Section 6. Nothing in this Agreement is intended or shall be construed to give to any other person, firm or corporation any legal or equitable remedy or claim under or in respect of this Agreement or any provision herein contained. The term "successors and assigns" as herein used shall not include any purchaser, as such purchaser, of any of the Securities from any of the several Underwriters.

13. ***Absence of Fiduciary Relationship***. The Company acknowledges and agrees that: (a) the Representatives have been retained solely to act as underwriters in connection with the sale of the Securities and that no fiduciary, advisory or agency relationship between the Company and either Representatives has been created in respect of any of the transactions contemplated by this Agreement, irrespective of whether the Representatives have advised or are advising the Company on other matters; (b) the price and other terms of the Securities set forth in this Agreement were established by the Company following discussions and arms-length negotiations with the Representatives and the Company is capable of evaluating and understanding and understands and accepts the terms, risks and conditions of the transactions contemplated by this Agreement; (c) it has been advised that the Representatives and their affiliates are engaged in a broad range of transactions which may involve interests that differ from those of the Company and that the Representatives have no obligation to disclose such interests and transactions to the Company by virtue of any fiduciary, advisory or agency relationship; (d) it has been advised that the you are acting, in respect of the transactions contemplated by this Agreement, solely for the benefit of the Underwriters, and not on behalf of the Company; (e) it waives to the fullest extent permitted by law, any claims it may have against the Underwriters for breach of fiduciary duty or alleged breach of fiduciary duty in respect of any of the transactions contemplated by this Agreement and agrees that the Underwriters shall have no liability (whether direct or indirect) to the Company in respect of such a fiduciary duty claim on behalf of or in right of the Company, including stockholders, employees or creditors of the Company.

14. ***Governing Law; Waiver of Jury Trial***. This Agreement shall be governed by and construed in accordance with the laws of the State of New York. The Company (on its behalf and, to the extent permitted by applicable law, on behalf of its stockholders and affiliates) and each of the Underwriters hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

15. ***Counterparts***. This Agreement may be executed in one or more counterparts and, if executed in more than one counterpart, the executed counterparts shall each be deemed to be an original and all such counterparts shall together constitute one and the same instrument.

16. ***General Provisions***. This Agreement constitutes the entire agreement of the parties to this Agreement and supersedes all prior written or oral and all contemporaneous oral agreements, understandings and negotiations with respect to the subject matter hereof, including the engagement letter dated July 24, 2020, by and between the Company and Craig-Hallum Capital Group LLC, except as to the provisions contained in Sections 5 and 6 thereof and Sections A, C, E, F, G, I and K of Annex II thereto, which shall survive and remain in full force and effect. This Agreement may not be amended or modified unless in writing by all of the parties hereto, and no condition herein (express or implied) may be waived unless waived in writing by each party whom the condition is meant to benefit. The Section headings herein are for the convenience of the parties only and shall not affect the construction or interpretation of this Agreement. The invalidity or unenforceability of any Section, paragraph or provision of this Agreement shall not affect the validity or enforceability of any other Section, paragraph or provision hereof. If any Section, paragraph or provision of this Agreement is for any reason determined to be invalid or unenforceable, there shall be deemed to be made such minor changes (and only such minor changes) as are necessary to make it valid and enforceable.

[*The remainder of this page has intentionally been left blank.*]

Please sign and return to the Company the enclosed duplicates of this letter whereupon this letter will become a binding agreement between the Company and the several Underwriters in accordance with its terms.

Very truly yours,

**Processa Pharmaceuticals, Inc.**

By: _____
Name:
Title:

Confirmed as of the date first above mentioned,
for themselves and as Representatives of the several
Underwriters named in Schedule I hereto.

**Craig-Hallum Capital Group LLC**

By: _____
Name:
Title:

**Benchmark Company, LLC**

By: _____
Name:
Title:

**SCHEDULE I**

| Underwriter | Number of Firm Shares (1) |
|---|---|
| Craig-Hallum Capital Group LLC | [●] |
| Benchmark Company, LLC | [●] |
| National Securities Corporation | [●] |
| Total | [●] |

(1) The Underwriters may purchase up to an additional [●] Option Shares, to the extent the option described in Section 3(b) of the Agreement is exercised, in the proportions and in the manner described in the Agreement.

**SCHEDULE II**

**List of Individuals and Entities Executing Lock-Up Agreements**

David Young
Patrick Lin
Sian Bigora
James Stanker
Wendy Guy
Justin Yorke
Virgil Thompson
Geraldine Pannu
Young-Plaisance Revoc. Trust
CorLyst, LLC
CoNCERT Pharmaceuticals, Inc.

**SCHEDULE III**

**Pricing Information**

Firm Shares: [●]

Option Shares: [●]

Price to the public: $[●] per share

Price to the Underwriters: $[●] per share

**SCHEDULE IV**

**Written Testing-the-Waters Communications**

None

**EXHIBIT A**

**Form of Lock-Up Agreement**

Date: _____

CRAIG-HALLUM CAPITAL GROUP LLC and
BENCHMARK COMPANY, LLC
As Representatives of the several
Underwriters named in Schedule I to the Underwriting Agreement

c/o Craig-Hallum Capital Group LLC
222 South Ninth Street, Suite 350
Minneapolis, Minnesota 55402

c/o Benchmark Company, LLC
150 E 58th Street, 17th Floor
New York, NY 10155

Ladies and Gentlemen:

As an inducement to Craig-Hallum Capital Group LLC and Benchmark Company, LLC to execute an underwriting agreement (the "***Underwriting Agreement***") in their capacity as representatives for the several underwriters named in Schedule I thereto (the "***Representatives***") providing for a public offering (the "***Offering***") of common stock, $0.0001 par value per share (the "***Common Shares***") of Processa Pharmaceuticals, Inc., a Delaware corporation, and any successor (by merger or otherwise) thereto (the "***Company***"), the undersigned hereby agrees that without, in each case, the prior written consent of the Representatives during the period specified in the second succeeding paragraph (the "***Lock-Up Period***"), the undersigned will not: (1) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, make any short sale or otherwise transfer or dispose of, directly or indirectly, any Common Shares or any securities convertible into, exercisable or exchangeable for or that represent the right to receive Common Shares (including without limitation, Common Shares which may be deemed to be beneficially owned by the undersigned in accordance with the rules and regulations of the U.S. Securities and Exchange Commission (the "***SEC***") and securities which may be issued upon exercise of a stock option, warrant or other convertible security) whether now owned or hereafter acquired (the "***Undersigned's Securities***"); (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the Undersigned's Securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Common Shares or other securities, in cash or otherwise; (3) make any demand for or exercise any right with respect to, the registration of any Common Shares or any security convertible into or exercisable or exchangeable for Common Shares; or (4) publicly disclose the intention to do any of the foregoing.

The undersigned agrees that the foregoing restrictions preclude the undersigned from engaging in any hedging or other transaction which is designed to or which reasonably could be expected to lead to or result in a sale or disposition of the Undersigned's Securities even if such securities would be disposed of by someone other than the undersigned. Such prohibited hedging or other transactions would include without limitation any short sale or any purchase, sale or grant of any right (including without limitation any put or call option) with respect to any of the Undersigned's Securities or with respect to any security that includes, relates to or derives any significant part of its value from such securities.

The Lock-Up Period will commence on the date of this Lock-Up Agreement and continue until and include the date ninety (90) days after the date of the final prospectus used to sell the Common Shares in the Offering pursuant to the Underwriting Agreement.

Notwithstanding the foregoing, the undersigned may transfer the Undersigned's Securities (i) as a *bona fide* gift or gifts, (ii) to any trust for the direct or indirect benefit of the undersigned or the immediate family of the undersigned, (iii) if the undersigned is a corporation, partnership, limited liability company, trust or other business entity (1) to another corporation, partnership, limited liability company, trust or other business entity that is a direct or indirect affiliate (as defined in Rule 405 promulgated under the Securities Act of 1933, as amended) of the undersigned or (2) as distributions of Common Shares or any security convertible into or exercisable for Common Shares to limited partners, limited liability company members or stockholders of the undersigned, (iv) if the undersigned is a trust, to the beneficiary of such trust, (v) by testate succession or intestate succession, (vi) the transfer of the Undersigned's Securities that occurs by operation of law pursuant to a qualified domestic order in connection with a divorce settlement or other court order, or (vii) pursuant to the Underwriting Agreement; *provided*, in the case of clauses (i) through (vi), that (x) such transfer shall not involve a disposition for value, (y) the transferee agrees in writing with the Representatives to be bound by the terms of this Lock-Up Agreement, and (z) no filing by any party under Section 16(a) of the U.S. Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), shall be required or shall be made voluntarily in connection with such transfer. For purposes of this Lock-Up Agreement, "immediate family" shall mean any relationship by blood, marriage or adoption, not more remote than first cousin.

In addition, the foregoing restrictions shall not apply to (i) the exercise of stock options granted pursuant to the Company's equity incentive plans;*provided* that such restrictions shall apply to any of the Undersigned's Securities issued upon such exercise, or (ii) the establishment of any contract, instruction or plan (a "***Plan***") that satisfies all of the requirements of Rule 10b5-1(c)(1)(i)(B) under the Exchange Act; *provided* that no sales of the Undersigned's Securities shall be made pursuant to such a Plan prior to the expiration of the Lock-Up Period, and such a Plan may only be established if no public announcement of the establishment or existence thereof and no filing with the SEC or other regulatory authority in respect thereof or transactions thereunder or contemplated thereby, by the undersigned, the Company or any other person, shall be required, and no such announcement or filing is made voluntarily, by the undersigned, the Company or any other person, prior to the expiration of the Lock-Up Period.

In addition, the undersigned may transfer the Undersigned's Securities in respect of tax withholding payments due upon the vesting of restricted stock grants pursuant to the Company's equity incentive plans, provided that any filing required to be made with the SEC or other publicity made regarding the same will indicate that such transactions relate to such tax withholding payments.

In furtherance of the foregoing, the Company and its transfer agent and registrar are hereby authorized to decline to make any transfer of Common Shares if such transfer would constitute a violation or breach of this Lock-Up Agreement.

The undersigned hereby represents and warrants that the undersigned has full power and authority to enter into this Lock-Up Agreement and that upon request, the undersigned will execute any additional documents necessary to ensure the validity or enforcement of this Lock-Up Agreement. All authority herein conferred or agreed to be conferred and any obligations of the undersigned shall be binding upon the successors, assigns, heirs or personal representatives of the undersigned.

The undersigned understands that the undersigned shall be released from all obligations under this Lock-Up Agreement if (i) the Company notifies the Representatives that it does not intend to proceed with the Offering, (ii) the Underwriting Agreement does not become effective, or if the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the Common to be sold thereunder, or (iii) the Offering is not completed by October 31, 2020.

The undersigned understands that the Representatives are entering into the Underwriting Agreement and proceeding with the Offering in reliance upon this Lock-Up Agreement.

This Lock-Up Agreement shall be governed by, and construed in accordance with, the laws of the State of New York.

[*The remainder of this page has intentionally been left blank.*]

Very truly yours,

Printed Name of Holder

Signature

Printed Name and Title of Person Signing
(*if signing as custodian, trustee or on behalf of an entity*)

# ACQUISITION AGREEMENT

**By and Among**

**HEATWURX, INC.,**
**a Delaware corporation**

**PROCESSA THERAPEUTICS, LLC**
**a Delaware limited liability company**

**and**

**PROMET THERAPEUTICS, LLC**
**a Delaware limited liability company**
**dated as of**

**October 2, 2017**

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**ACQUISITION AGREEMENT**

THIS ACQUISITION AGREEMENT, dated as of October 2, 2017 (this "Agreement"), is by and among HEATWURX, INC., a Delaware corporation ("HUWX"), PROCESSA THERAPEUTICS, LLC a Delaware Limited Liability Company wholly owned by HUWX ("SUB") and PROMET THERAPEUTICS LLC, a Delaware limited liability company (the "Company").

WHEREAS, The Company desires to sell to HUWX and HUWX desires to purchase from the Company, all of the properties, rights and assets owned by the Company, directly or indirectly, in whole or in part, of every type and description, real, personal or mixed, tangible and intangible, wherever located and whether or not reflected on the books of the Company (the "Contributed Assets"), including, without limitation, all technology, intellectual property, patent and patent pending technology, all rights to exploit, distribute, and derive revenue from the foregoing, and any materials or media relating to the foregoing solely in exchange for HUWX's issuance to the Company of HUWX Common Stock.

WHEREAS, the Company, upon the terms and subject to the conditions of this Agreement and in accordance with Delaware Law, desires to make a capital contribution of the Contributed Assets to HUWX solely in exchange for HUWX Common Stock (as defined herein) (the "Acquisition");

WHEREAS, the respective boards of directors of HUWX and the Company have determined that the Acquisition is fair to, and in the best interests of, it and its stockholders and have approved and adopted this Agreement and the transactions contemplated hereby;

WHEREAS, for federal, state and local income tax purposes, it is intended that the transfer of the Contributed Assets, constituting the Acquisition, to HUWX and the issuance of the HUWX Common Stock qualify as a tax-free contribution of property pursuant to the provisions of Section 351 of the United States Internal Revenue Code of 1986, as amended (the "Code");

WHEREAS, HUWX, Sub, and Company desire to make certain representations, warranties and agreements in connection with the Acquisition and also to prescribe various conditions to the Acquisition.

NOW, THEREFORE, in consideration of the foregoing and the respective representations, warranties, covenants and agreements set forth in this Agreement, the parties hereto agree as follows:

ARTICLE I

DEFINITIONS

1.01. Definitions. Certain capitalized and other terms used in this Agreement are defined in Exhibit A hereto and are used herein with the meanings ascribed to them therein.

1.02. Rules of Construction. Unless the context otherwise requires, as used in this Agreement: (a) an accounting term not otherwise defined has the meaning ascribed to it in accordance with GAAP; (b) "or" is not exclusive; (c) "including" means "including, without limitation;" (d) words in the plural include the singular; (e) the terms "hereof," "herein," "hereby," "hereto" and derivative or similar words refer to this entire Agreement; and (f) the terms "Article" or "Section" refer to the specified Article of Section of this Agreement.

ARTICLE II

THE ACQUISITION

2.01 The Acquisition. Upon the terms and subject to the conditions set forth in this Agreement, and in accordance with Delaware Law, at the Effective Time (as defined in Section 2.03 of this Agreement), the Company shall transfer the Contributed Assets to HUWX, which will in turn promptly transfer the Contributed Assets to SUB, which is intended to be a disregarded entity for federal income tax purposes pursuant to the Plan, whereby the Contributed Assets shall continue within HUWX but owned by the SUB (the "Operating Company").

2.02. Purchase and Sale of Assets. At the Closing, upon the satisfaction or waiver of all conditions precedent: (a) the Company shall sell, transfer, convey, assign and deliver the Contributed Assets to HUWX, free and clear of any and all Liens, and (b) HUWX shall issue the Issued Shares to the Company, fully paid and non-assessable and free and clear of all Liens. Notwithstanding anything to the contrary, HUWX shall assume all obligations and liabilities with respect to the Contributed Assets The Company's delivery to HUWX of all right, title and interest in and to the Contributed Assets, shall be deemed to occur upon HUWX's delivery to the Company of a certificate evidencing the HUWX Common Stock, without the need of any further act by any Party. Notwithstanding the foregoing, at HUWX's request, the Company shall promptly execute one or more further Contracts to the extent HUWX deems such execution necessary or appropriate to effectuate the intent of this Agreement.

2.03. Closing; Closing Date; Effective Time. The consummation of the Acquisition and the closing of the transactions contemplated by this Agreement (the "Closing") shall take place at the offices of Law Offices of Aaron A. Grunfeld, 11111 Santa Monica Boulevard, Suite 1840, Los Angeles California 90025, as soon as practicable (but in any event within two business days) after the satisfaction or, if permissible, waiver of the conditions set forth in Article VIII, or at such other date, time and place as HUWX and the Company may agree in writing (the date of the Closing being the "Closing Date" and also known as the "Effective Time").

2.04. Effect of the Acquisition. At the Effective Time, the effect of the Acquisition shall be as provided in the applicable provisions of Delaware Law. Without limiting the generality of the foregoing, and subject thereto, at the Effective Time, all the property, rights, privileges, powers and franchises of the Company shall continue with, or vest in, as the case may be, HUWX and the Operating Company, and all debts, liabilities and duties of the Company shall continue to be, or become, as the case may be, the debts, liabilities and duties of the Operating Company.

2.05. Certificate of Incorporation; Bylaws. At the Effective Time, the Certificate of Formation and Bylaws of the SUB shall be the Certificate of Formation of the Operating Company, in each case, as in effect immediately prior to the Effective Time and shall thereafter continue to be the Certificate of Formation of the Operating Company until amended as provided therein and pursuant to Delaware Law.

2.06. Directors and Officers. The directors and officers of the Company immediately prior to the Effective Time shall enter into employment agreements on the terms and conditions set forth in such employment agreements and shall serve in their respective offices of the Operating Company from and after the Effective Time, in each case until their respective successors are duly elected or appointed and qualified or until their resignation or removal, provided that at least one director designated by HUWX, Justin Yorke, shall also continue as a director of HUWX and of the Operating Company for one Year following the Effective Date, until his successor is duly elected or appointed and qualified by HUWX shareholder vote.

## ARTICLE III

## ISSUANCE OF SECURITIES

3.01. Acquisition Consideration; Issuance of Securities. At the Effective Time, by virtue of the Acquisition, and in exchange for the Contributed Assets,:

(a) HUWX shall issue to the Company, immediately prior to the Effective Time 222,217,112 shares of Common Stock of HUWX ("HUWX Common Stock") as the Acquisition Consideration for the Contributed Assets; provided, however, that in no event shall the aggregate number of shares of HUWX Common Stock issued for the Contributed Assets exceed 90% of the outstanding shares of HUWX as determined on a fully diluted basis; provided, however, that in all cases the percentage of HUWX Common Stock issued to the Company for the Contributed Assets shall constitute "control" as defined and set forth and defined in Code sections 351 and 368(c), respectively.

(b) The shares of HUWX Common Stock issued and outstanding immediately prior to the Effective Time shall be unaffected by the Acquisition and such shares shall remain issued and outstanding.

3.02. Issuance of Certificates for HUWX Common Stock.

(a) As soon as practicable after the Effective Time, the Company shall be entitled to receive a certificate representing the number of whole shares of HUWX Common Stock that the Company has a right to receive in accordance with Section 3.01 (or at HUWX's discretion a book-entry confirmation of such HUWX Common Stock ownership), and a cash payment in lieu of fractional shares of HUWX Common Stock, if any, in accordance with Section 3.02(c).

(b) All shares of HUWX Common Stock issued in accordance with the terms hereof, including any cash paid in accordance with Section 3.02(c), shall be deemed to have been issued and paid in full satisfaction of all rights pertaining to the Contributed Assets.

(c) No fraction of a share of HUWX Common Stock will be issued as a result of the Acquisition. In lieu of any such fractional shares that otherwise would have been issued in the Acquisition, HUWX will pay the Company an amount in cash (without interest and rounded to the nearest cent) determined by multiplying (a) the highest bid price on date of Closing by (b) the fractional interest of a share of HUWX Common Stock to the Company would otherwise be entitled (after taking into account the value of Contributed Assets at the Effective Time).

(d) HUWX shall be entitled to deduct and withhold from the consideration otherwise payable pursuant to this Agreement to the Company such amounts as HUWX (or any affiliate thereof) is required to deduct and withhold with respect to the making of such payment under the Code, or any provision of state, local or foreign Tax Law. To the extent that amounts are so withheld by HUWX, such withheld amounts shall be treated for all purposes of this Agreement as having been paid to the Company in respect of which such deduction and withholding was made by HUWX (or any affiliate thereof).

(e) The certificates evidencing shares of HUWX Common Stock (or at HUWX's discretion the book-entry confirmation of such HUWX Common Stock ownership) delivered pursuant to this Section 3.02 will bear a legend substantially in the form set forth below and containing such other information as HUWX may deem necessary or appropriate:

> THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), AND MAY NOT BE SOLD OR TRANSFERRED IN THE ABSENCE OF AN EFFECTIVE REGISTRATION STATEMENT UNDER THE ACT OR AN EXEMPTION FROM REGISTRATION THEREUNDER.

## ARTICLE IV

## REPRESENTATIONS AND WARRANTIES OF THE COMPANY

The Company hereby represents and warrants to HUWX that:

4.01. Organization and Standing. The Company is a limited liability company duly organized and existing under, and by virtue of, the laws of the State of Delaware and is in good standing under such laws. The Company has all requisite corporate power and authority to own and operate its properties and assets, and to carry on its business. The Company is duly qualified to transact business and is in good standing in each jurisdiction in which the failure to so qualify would have a Company Material Adverse Effect.

4.02. Certificate of Formation and LLC Agreement. The Company has heretofore made available to HUWX a complete and correct copy of the Certificate of Formation and the Amended and Restated Company Agreement, as amended to date, of the Company (the "Company LLC Agreement"). The Company is not in violation in any material respect of any of the provisions of its Certificate of Formation or the Company LLC Agreement.

4.03. Corporate Power. The Company has, and will have at the Closing Date, all requisite legal and corporate power and authority to execute and deliver this Agreement and to carry out and perform its obligations under the terms of this Agreement.

4.04. Reserved.

4.05. Authorization. All corporate action on the part of the Company, its directors and Unitholders necessary for the authorization, execution, delivery and performance of this Agreement and the performance of all of the Company's obligations hereunder has been taken or will be taken prior to the Closing Date. This Agreement constitutes a valid and binding obligation of the Company, enforceable in accordance with its terms, except (i) as the same may be limited by bankruptcy, insolvency or other laws relating to or affecting creditors' rights generally or by general equitable principles and (ii) as limited by laws relating to the availability of specific performance, injunctive relief, or other equitable remedies.

4.06. No Conflict; Required Filings and Consents.

(a) Assuming that the Approvals, filings and notifications described in Section 4.06(b) have been obtained or made, as the case may be, the execution and delivery of this Agreement by the Company does not, and the consummation of the transactions contemplated hereby will not (i) conflict with or violate the Certificate of Formation or the Company LLC Agreement, in each case as amended or restated, of the Company, (ii) conflict with or violate any Laws applicable to the Company or by which any of its assets or properties is bound or subject, or (iii) result in any breach of or constitute a default (or an event that with notice or lapse of time or both would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation of, or require payment under, or result in the creation of a lien or encumbrance on any of the properties or assets of the Company pursuant to, any note, bond, mortgage, indenture, contract, agreement, lease, license, permit, franchise or other instrument or obligation to which the Company is a party or by or to which the Company or any of its assets or properties is bound or subject, except for any such conflicts or violations described in clause (ii) or breaches, defaults, events, rights of termination, amendment, acceleration or cancellation, payment obligations or liens or encumbrances described in clause (iii) that would not reasonably be expected to have a Company Material Adverse Effect.

(b) The execution and delivery of this Agreement by the Company does not, and the consummation of the transactions contemplated hereby will not, require the Company to obtain any Approvals of or from, or to make any filing with or notification to, any Governmental Entity or third Person, except (i) as disclosed in Section 4.06(b) of the Company Disclosure Letter, (ii) for the filing and recordation of appropriate Acquisition documents as required by Delaware Law, and (iii) where the failure to obtain such Approvals, or to make such filings or notifications, would not reasonably be expected to have a Company Material Adverse Effect.

4.07. Financial Statements. The Company has delivered to HUWX its audited balance sheet as of the years ended December 31, 2015 and 2016 and its reviewed balance sheet as of June 30, 2017 and its audited statements of operations for the period from January 1, 2015 and 2016 through December 31, 2015 and 2016 and for the period from January 1, 2017 through June 30, 2017 (the "Company Financial Statements"). The Company Financial Statements are complete and correct in all material respects and have been prepared in accordance with GAAP applied on a consistent basis throughout the periods indicated. The Company Financial Statements accurately set out and describe the financial condition and operating results of the Company as of the dates, and during the periods, indicated therein.

4.08. Absence of Changes. Since June 30, 2015, except as described in Section 4.08 of the Company Disclosure Letter and this Agreement:

(a) the Company has not entered into any transaction which was not in the ordinary course of business;

(b) there has been no event or occurrence that would have a Company Material Adverse Effect;

(c) there has been no damage to, destruction of or loss of physical property (whether or not covered by insurance) materially adversely affecting the business or operations of the Company;

(d) the Company has not declared, set aside or paid any dividend or made any distribution on its capital stock, or directly or indirectly redeemed, purchased or otherwise acquired any of its capital stock;

(e) the Company has not increased the compensation of any of its officers, directors or agents, or the rate of pay of its employees as a group;

(f) there has been no resignation or termination of employment of any key officer or employee of the Company, the Company does not have a present intention to terminate the employment of any of the foregoing, and the Company has no Knowledge of the impending resignation or termination of employment of any such officer or employee;

(g) there has been no labor dispute involving the Company or its employees and none is pending or, to the Company's Knowledge, threatened;

(h) there has not been any change in the contingent obligations of the Company, by way of guaranty, endorsement, indemnity, warranty or otherwise;

(i) there have not been any loans, advances or guarantees made by the Company to any of its employees, officers or directors; and

(j) to the Company's Knowledge, there has been no other event or condition of any character pertaining to and materially adversely affecting the assets or business of the Company.

4.09. Liabilities/Solvency. The Company has no liabilities or obligations, absolute or contingent (individually or in the aggregate), except (i) the liabilities and obligations set forth in the Company Financial Statements, (ii) liabilities and obligations which have been incurred subsequent to [June] 30, 2017in the ordinary course of business which have not been in the aggregate, materially adverse, (iii) liabilities and obligations under the lease for its principal lab, and (iv) liabilities and obligations under licensing, sales, procurement and other contracts and arrangements entered into in the normal course of business. The Company is able to meet all of its payment obligations as they come due. The fair market value of the Company's assets exceeds the fair market value of its obligations, whether contingent or otherwise.

4.10. Title to Properties and Assets; Liens. The Company holds good and merchantable title to the Contributed Assets free and clear of all mortgages, liens, loans and encumbrances, except such encumbrances and liens which arise in the ordinary course of business and do not materially impair the Company's ownership or use of such properties or assets, and on the Closing Date, upon the issuance to the Company of the HUWX Common Stock, will have conveyed to HUWX, and HUWX shall have, good and merchantable title to the Contributed Assets, free and clear of all mortgages, liens, loans and encumbrances, except as disclosed herein. . With respect to the properties and assets it leases, the Company, and to the Company's knowledge, the counterparty is in compliance with such leases and the Company holds a valid leasehold interest free of any liens, claims or encumbrances. The Company does not own any real property.

4.11. Patents and Other Intangible Assets.

(a) The Company owns or has the right or license to use all patents, trademarks, service marks, service names, trade names, trade secrets and copyrights used in the conduct of its business as now conducted, free and clear of all claims, mortgages, liens, loans, and encumbrances, except such encumbrances and liens which arise in the ordinary course of business and do not materially impair the Company's ownership or use of such intellectual property rights. All of the patents, trademarks, service marks and copyrights that the Company owns or has the right or license to use are listed or described in Section 4.11 of the Company Disclosure Letter.

(b) The Company has no actual knowledge, without any investigation, that the Company is infringing upon or misappropriating any valid intellectual property rights of any Person (including without limitation, former employers of all current and former employees, consultants, officers, directors and stockholders of the Company), including the right to the name "Promet", and its web site address [www.promettherapeutics.com]. Without any special investigation for purposes of this Agreement, the Company, in its reasoned judgment, has determined that making, using or selling any products or methods set forth in Section 4.11 of the Company Disclosure Letter will not constitute an infringement or misappropriation by the Company of the kind described in the preceding sentence.

(c) Except as set forth inSection 4.11 of the Company Disclosure Letter, the Company is not obligated or under any liability whatsoever to make any payments by way of royalties, fees or otherwise to any owner of, licensor of, or other claimant to, any patent, trademark, trade name, copyright or other intellectual property right, with respect to the use thereof or in connection with the conduct of its business or otherwise.

(d) The Term sheet dated _____ as amended to date, between the Company and Concert Pharmaceuticals, Inc.is in full force and effect, and no default or event which with the lapse of time or the giving of notice would constitute a default, exists thereunder.

4.12. Litigation. There are no actions, suits, proceedings or investigations pending or, to the Company's Knowledge, threatened against the Company or its properties before any Governmental Entity. The Company is not subject to any continuing order, writ, injunction, consent decree or settlement agreement of, or similar written agreement with, or, to the Company's Knowledge, continuing investigation by, any Court or Governmental Entity.

4.13. Employees. To the Company's Knowledge, no employee of the Company is in violation of any term of any employment contract, intellectual property disclosure agreement or any other contract or agreement relating to the relationship of such employee with the Company or any other party because of the nature of the business conducted or to be conducted by the Company. The Company is in compliance in all material respects with the applicable provisions of ERISA, and no "reportable event," as such term is defined in Section 4043 of ERISA, has occurred with respect to any plan subject to Title IV of ERISA or any other plan to which the Company is required to contribute on behalf of its employees. Schedule 4.13 of the Company Disclosure Letter contains a list of the name of each officer and each full-time employee of Company employed by the Company at the date hereof and such person's position. Since [June 30, 2017], except as set forth on Schedule 4.13 of the Company Disclosure Letter, there has been no change of, or agreement to change, any terms of employment, including without limitation, salary, wage rates or other compensation, of any officer or employee of Company. The Company will use its commercially reasonable best efforts to induce all employees of Company to continue their respective employment following the Closing Date. For each employee hired by Company after January 1, 2017, the Company has verified appropriate documents and has a verified and signed INS Form I-9 for each such employee, if required. All such forms are in Company's possession and shall be turned over to HUWX for each employee accepting employment with HUWX as of the Closing. Company has not received any information that would lead it to believe that a material number of the employees of Company will or may cease to be employees of Company, or will refuse offers of employment from HUWX, because of the consummation of the Acquisition s to which it is a party.

4.14. Certain Transactions. Except as set forth inSection 4.14 of the Company Disclosure Letter, the Company is not indebted, directly or indirectly, to any of its officers, directors or stockholders or to their respective spouses or children, in any amount whatsoever; none of said officers, directors or, to the Company's Knowledge, stockholders, or any members of their immediate families, are indebted to the Company or have any direct or indirect ownership interest in any firm, corporation or entity with which the Company is affiliated or with which the Company has a business relationship, or any firm or corporation which competes with the Company except that officers, directors and/or stockholders of the Company may own less than 1% of the stock of publicly traded companies which may compete with the Company. No officer, director or stockholder, or any member of their immediate families, is, directly or indirectly, interested in any material contract with the Company. The Company is not a guarantor or indemnitor of any indebtedness of any other person, firm or corporation.

4.15. Material Contracts and Obligations. Included in Section 4.15 of the Company Disclosure Letter is a list of all agreements, contracts, indebtedness, liabilities and other obligations to which the Company is a party or by which it is bound that are material to the conduct and operations of its business and properties, specifically including those which provide for payments in any fiscal year to or by the Company in excess of $10,000, which obligate the Company to share, license or develop any product or technology, which purports to restrict or limit the ability of the Company from freely engaging in any line of business anywhere in the world or competing with any other Person, which provides for any joint venture or partnership involving the Company, or which involve transactions or proposed transactions between the Company and its officers, directors, affiliates or any affiliate thereof. Copies of such agreements and contracts and documentation evidencing such liabilities and other obligations have been made available for inspection by HUWX and its counsel. All of such agreements and contracts are valid, binding obligations of the Company and are in full force and effect in all material respects, assuming due execution by the other parties to such agreements and contracts. The Company has no Knowledge of any breach or anticipated breach by any other parties to any contract, agreement or instrument included in Section 4.15 of the Company Disclosure Letter.

4.16. Private Placements. All securities issued by the Company prior to the date hereof have been issued in transactions exempt from registration under the Securities Act and all applicable state securities or "blue sky" Laws, and the Company has not violated the Securities Act or any applicable state securities or "blue sky" Laws in connection with the issuance of any such securities.

4.17. Brokers or Finders; Other Offers. Except as set forth in Section 4.17 of the Company Disclosure Letter the Company has not incurred and will not incur, directly or indirectly, as a result of any action taken by the Company, any liability for brokerage or finders' fees or agents' commissions or any similar charges in connection with this Agreement.

4.18. Tax Return and Payments.

(a) All tax returns and reports of or with respect to any Tax ("Tax Returns") that are required to be filed by or with respect to the Company on or before the Effective Time have been or will be duly and timely filed,

(b) all items of income, gain, loss, deduction and credit or other items ("Tax Items") required to be included in each such Tax Return have been so included and all such Tax Items and any other information provided in each such Tax Return are true, correct and complete, subject to Company's right to amend such Tax Returns to correct any errors or oversights therein that would not have an adverse effect on HUWX,

(c) all Taxes owed by the Company that are or have become due reflected on such returns and reports have been timely paid in full,

(d) there are no mortgages, pledges, liens, encumbrances, charges or other security interests on any of the assets of the Company that arose in connection with any failure (or alleged failure) to pay any Tax,

(e) there is no claim against the Company for Taxes due and payable, and no assessment, deficiency or adjustment has been asserted, proposed or, to the Knowledge of the Company, threatened with respect to any Tax Return of or with respect to the Company,

(f) no claim has ever been made by a Taxing authority in a jurisdiction where the Company does not file Tax Returns that it is or may be subject to taxation in that jurisdiction,

(g) there is not in force any waiver or agreement for any extension of time for the assessment or payment of any Tax of or with respect to the Company,

(h) the total amounts set up as liabilities for current and deferred Taxes in the Company Financial Statements are sufficient to cover the payment of all Taxes, whether or not assessed or disputed, which are, or are hereafter found to be, or to have been, due by or with respect to the Company up to and through the periods covered thereby,

(i) the Company has not entered into any Tax allocation, sharing or indemnity agreement under which the Company could become liable to another Person as a result of the imposition of Tax upon such Person, or the assessment or collection of Tax,

(j) except for liens for current Taxes not yet due and payable, no liens for Taxes exist upon the assets of any of the Company, and

(k) the Company has not entered into any agreement or arrangement with any Taxing authority that requires the Company to take any action or to refrain from taking any action.

(l) the Company has complied in all material respects with all applicable Laws, rules and regulations relating to the payment and withholding of Taxes (including withholding of Taxes pursuant to Sections 1441 and 1442 of the Code or similar provisions under any foreign Laws).

(m) the Company is not required to include in income any adjustment pursuant to Section 481(a) of the Code by reason of any voluntary change in accounting method (nor has any Governmental Entity proposed in writing any such adjustment or change of accounting method).

(n) no audits are presently pending with regard to any Taxes or Tax Returns of the Company and a list of all Audits commenced or completed with respect to the Company with respect to taxable periods ending after December 31, 2013 is set forth in Section 4.18 of the Company Disclosure Letter. No written notification has been received by the Company that such an Audit is pending or threatened with respect to any Taxes due from or with respect to or attributable to the Company or any Tax Return filed by or with respect to the Company.

(o) All Tax deficiencies that have been claimed, proposed or asserted against the Company have been fully paid or finally settled, and no issue has been raised in any examination by any taxing authority that, by application of similar principles, could reasonably be expected to result in the proposal or assertion of a Tax deficiency for another year not so examined.

(p) There are no outstanding requests, agreements, consents or waivers to extend the statutory period of limitations applicable to the assessment of any Taxes or deficiencies against the Company.

(q) No power of attorney has been granted by or with respect to the Company with respect to any matter relating to Taxes.

(r) the Company is not a party to any agreement, plan, contract or arrangement (whether oral or in writing) that could result, separately or in the aggregate, in the payment of any "excess parachute payments" within the meaning of Section 280G of the Code.

(s) All transactions that could give rise to an understatement of the federal income tax liability of the Company within the meaning of Section 6662(d) of the Code are adequately disclosed on Tax Returns in accordance with Section 6662(d)(2)(B) of the Code if there is or was no substantial authority for the treatment giving rise to such understatement.

(t) the Company is not and has not been a U.S. real property holding company (as defined in Section 897(c)(2) of the Code) during the applicable period specified in Section 897(c)(1)(A)(ii) of the Code.

(u) Other than any Tax Returns that have not yet been required to be filed, the Company has made available to Buyer true, correct and complete copies of the United States federal income Tax Return and any material state, local or foreign Tax Return for the Company for any jurisdiction for each of the taxable periods ended December 31, 2010 through December 31, 2012.

(v) The net operating loss and credit carryovers, if any, available to the Company, and their expiration dates, are set forth in the Disclosure Schedule.

(w) the Company has delivered or made available to Buyer complete and accurate copies of each of (i) all Audit reports, letter rulings, technical advice memoranda and similar documents issued by a Governmental Entity relating to United States Taxes due from the Company, and (ii) all closing agreements entered into by the Company with any Taxing Authority existing on the date hereof.

(x) No taxing authority is asserting or, to the Company's knowledge, threatening to assert a claim against the Company under or as a result of Section 482 of the Code or any similar provision Law.

(y) the Company has not distributed stock of another entity, or has had its stock distributed by another entity, in a transaction that was purported or intended to be governed in whole or in part by Section 355 or Section 361 of the Code.

(z) the Company has not engaged in any reportable transactions that were required to be disclosed pursuant to Section 1.6011-4 of the Code.

4.19. Environmental and Safety Laws. The Company is not in violation of any applicable statute, Law or Regulation relating to the environment or occupational health and safety, which violation would have a Company Material Adverse Effect, nor are any material expenditures required in order to comply with any such existing statute, Law or Regulation.

4.20. Compliance with Laws; Permits. To the Company's Knowledge, the Company is not in violation of any applicable statute, Regulation, order or restriction of any Governmental Entity in respect of the conduct of its business or the ownership of its properties, which violation would have a Company Material Adverse Effect. The Company has all franchises, permits, licenses and any similar authority necessary for the conduct of its business as now being conducted by it, the lack of which would have a Company Material Adverse Effect, and believes it can obtain without undue burden or expense, any similar authority for the conduct of its business as presently planned to be conducted. The Company is not in default in any material respect under any of such franchises, permits, licenses or other similar authority.

4.21. Absence of Certain Events. To Company's knowledge, and except as may be otherwise disclosed on Schedule 4.21 or by another written attachment hereto, no executive officer, director or managing member or an officer of equivalent rank of the Company has been within the past five (5) years, (i) a party to any bankruptcy petition against such person or against any business of which such person was affiliated; (ii) convicted in a criminal proceeding or subject to a pending criminal proceeding (excluding traffic violations and other minor offenses; (iii) subject to any order, judgment or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting their involvement in any type of business, securities or banking activities; or (iv) found by a court of competent jurisdiction in a civil action by the Securities and Exchange Commission or the Commodity Futures Trading Commission, to have violated a federal or state securities or commodities law and which judgment has not been reversed, suspended or vacated.

4.22. Certain Payments. Except as otherwise disclosed herein or in Schedule 4.22 annexed hereto, to Company's knowledge, neither Company nor any of its officers, employees or agents, nor any other person acting on behalf of Company, has directly or indirectly, within the past five (5) years, given or agreed to give any gift or similar benefit to any person who is, or may be in a position to help or hinder Company's business, or assist it in connection with any actual or proposed transaction, which (i) might be reasonably expected to subject it to any material damage or penalty in any action or to have a Company Material Adverse Effect on Company or its business, assets, properties, financial condition or results of operations (a "Material Adverse Effect"), (ii) if not given in the past, might have reasonably been expected to have had a Material Adverse Effect, or (iii) if not continued in the future, might be reasonably expected to have a Material Adverse Effect or to subject Company to material suit or penalty in any action.

## ARTICLE V

## REPRESENTATIONS AND WARRANTIES OF HUWX

HUWX hereby represents and warrants to the Company that:

5.01. Organization and Standing. HUWX is a corporation duly organized and existing under, and by virtue of, the laws of the State of Delaware and is in good standing under such laws. HUWX has all requisite corporate power and authority to own and operate its properties and assets, and to carry on its business. HUWX is duly qualified to transact business and is in good standing in each jurisdiction in which the failure to so qualify would have a HUWX Material Adverse Effect.

5.02. Charter and Bylaws. HUWX has heretofore made available to the Company a complete and correct copy of the Certificate of Incorporation and Bylaws, as amended or restated. HUWX is not in violation of any of the provisions of its Certificate of Incorporation or any material provision of its Bylaws.

5.03. Corporate Power. HUWX have, and will have at the Closing Date, all requisite legal and corporate power and authority to execute and deliver this Agreement and to carry out and perform its obligations under the terms of this Agreement. HUWX has, and will have at the Closing Date, all requisite legal and corporate power and authority to issue the Acquisition Shares and pay the other Acquisition Consideration hereunder.

5.04. Capitalization.

(a) The authorized capital of HUWX as of the Effective Time will consist of:

(i) 350,000,000 shares of HUWX Common Stock, 24,690,790 shares of which will be issued and outstanding, excluding HUWX Common Stock representing the Acquisition Consideration and 10,000,000shares of "blank check" preferred stock of which no shares will be issued and outstanding as of the Effective Time.

(ii) HUWX has reserved no shares of HUWX Common Stock for issuance to officers, directors, employees, consultants and advisors of HUWX pursuant to the HUWX Stock Plan.

(b) Except as described in this Section 5.04 or in Section 5.04(b) of the HUWX Disclosure Letter, as of the date of this Agreement, no shares of capital stock or other equity securities of HUWX are issued or outstanding or reserved for any purpose. Each of the outstanding shares of capital stock of HUWX as of the date hereof is duly authorized, validly issued, and fully paid and nonassessable, and has not been issued in violation of any preemptive or similar rights created by statute, the Certificate of Incorporation or Bylaws of HUWX, or any agreement to which HUWX is a party or bound. Except as set forth on Schedule 5.04 of the HUWX Disclosure Letter, there is no outstanding subscription, contract, convertible or exchangeable security, option, warrant, call or other right obligating HUWX to issue, sell, exchange, or otherwise dispose of, or to purchase, redeem or otherwise acquire, shares of, or securities convertible into or exchangeable for, capital stock of HUWX. Notwithstanding anything of the foregoing, prior to the Closing, all of the existing debt of HUWX, in the approximate amount of $2,482,263, shall have been converted into 12,953,902 shares of common stock of HUWX (the "HUWX Note Conversion"). At or prior to the Closing any accrued, but unpaid dividends payable to holders of outstanding shares of HUWX Preferred Stock shall have been paid in kind or otherwise satisfied and the 178,924 shares of Series D HUWX Preferred Stock currently outstanding , shall convert into 719,500 shares of common stock of HUWX (the "HUWX Preferred Stock Conversion"). After giving effect to the HUWX Note Conversion and HUWX Preferred Stock Conversion, HUWX shall be deemed to have 24,690,790 shares of common stock issued and outstanding at the Closing (the "Pre-Acquisition Total").At the Effective Time giving effect to the Pre-Acquisition Total and the Acquisition Consideration an aggregate of 246, 907,902 shares of common stock shall be issued and outstanding. The percentages set forth herein are calculated prior to giving effect to the Sale of HUWX's Assets and the Placement (each as defined below).

(c) Except as set forth in Section 5.04(a)(ii) above or in Section 5.04(c) of the HUWX Disclosure Letter, there are no outstanding securities, options, warrants or other rights (including registration rights), agreements or commitments of any character to which HUWX is a party relating to the issued or unissued capital stock or other equity interests of HUWX or obligating HUWX to grant, issue, deliver or sell, or cause to be granted, issued, delivered or sold, any shares of the capital stock or other equity interests of HUWX, by sale, lease, license or otherwise. Except as set forth in Section 5.04(c) of the HUWX Disclosure Letter, there are no voting trusts, proxies or other agreements or understandings to which HUWX is a party or by which HUWX is bound with respect to the voting of any shares of capital stock or equity interests of HUWX. HUWX has agreed to issue certain convertible promissory notes as set forth in Section 5.04(c) of the HUWX Disclosure Letter.

5.05. Authorization. All corporate action on the part of HUWX, its directors and stockholders necessary for the authorization, execution, delivery and performance of this Agreement, the authorization, issuance and delivery of the Acquisition Shares and the performance of all of HUWX's obligations hereunder has been taken or will be taken prior to the Closing Date. This Agreement constitutes a valid and binding obligation of HUWX, enforceable in accordance with its terms, except (i) as the same may be limited by bankruptcy, insolvency or other laws relating to or affecting creditors' rights generally or by general equitable principles and (ii) as limited by laws relating to the availability of specific performance, injunctive relief, or other equitable remedies. The Acquisition Shares, when issued in compliance with the provisions of this Agreement, will be validly issued, fully paid and nonassessable and will have the rights, preferences and privileges described in HUWX's charter and the Acquisition Shares will be free of any liens or encumbrances, other than any liens or encumbrances created by or imposed upon the holders thereof through no action of HUWX; provided, however, that the Acquisition Shares will be subject to restrictions on transfer under state and/or federal securities laws. The issuance of the Acquisition Shares is not subject to any preemptive rights or rights of first refusal.

5.06. No Conflict; Required Filings and Consents.

(a) Assuming that the Approvals, filings and notifications described in Section 5.06(b) have been obtained or made, as the case may be, the execution and delivery of this Agreement by HUWX does not, and the consummation of the transactions contemplated hereby will not (i) conflict with or violate the charter or bylaws, in each case as amended or restated, of HUWX, (ii) conflict with or violate any Laws applicable to HUWX or by which any of its assets or properties is bound or subject, or (iii) result in any breach of or constitute a default (or an event that with notice or lapse of time or both would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation of, or require payment under, or result in the creation of a lien or encumbrance on any of the properties or assets of HUWX pursuant to, any note, bond, mortgage, indenture, contract, agreement, lease, license, permit, franchise or other instrument or obligation to which HUWX is a party or by or to which HUWX or any of its assets or properties is bound or subject, except for any such conflicts or violations described in clause (ii) or breaches, defaults, events, rights of termination, amendment, acceleration or cancellation, payment obligations or liens or encumbrances described in clause (iii) that would not reasonably be expected to have a HUWX Material Adverse Effect.

(b) The execution and delivery of this Agreement by HUWX does not, and the consummation of the transactions contemplated hereby will not, require HUWX to obtain any Approvals of or from, or to make any filing with or notification to, any Governmental Entity or third Person, except (i) as disclosed in Section 5.06(b) of the HUWX Disclosure Letter, (ii) for applicable requirements, if any, of the Securities Act, "blue sky" Laws and the filing and recordation of appropriate Acquisition documents as required by Delaware Law, and (iii) where the failure to obtain such Approvals, or to make such filings or notifications, would not have a HUWX Material Adverse Effect.

5.07. SEC Reports and Financial Statements. HUWX delivered to Company prior to the execution of this Agreement by direction to the SEC's EDGAR website a true and complete copy of each form, report, schedule, registration statement, definitive proxy statement and other document (together with all amendments thereof and supplements thereto) filed or to be filed by HUWX or any of its Subsidiaries with the SEC for the two fiscal years ended December 31, 2015 and December 31, 2016 and shall have delivered to the Company prior to the Effective Time the quarterly reports due for the six months ended June 30,2017 (as such documents have since the time of their filing been amended or supplemented, the "HUWX SEC Reports"), which are all the documents (other than preliminary material) that HUWX and its Subsidiaries were required to file with the SEC since the dates hereinabove set forth. As of their respective dates, the HUWX SEC Reports (i) complied as to form in all material respects with the requirements of the Securities Act or the Exchange Act, as the case may be, and (ii) did not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The audited consolidated financial statements and unaudited interim consolidated financial statements (including, in each case, the notes, if any, thereto) included in the HUWX SEC Reports (the "HUWX Financial Statements") complied as to form in all material respects with the published rules and regulations of the SEC with respect thereto, were prepared in accordance with generally accepted accounting principles applied on a consistent basis during the periods involved (except as may be indicated therein or in the notes thereto and except with respect to unaudited statements as permitted by Form 10-Q of the SEC) and fairly present (subject, in the case of the unaudited interim financial statements, to normal, recurring year-end audit adjustments which are not expected to be, individually or in the aggregate, materially adverse to HUWX and its Subsidiaries taken as a whole) the consolidated financial position of HUWX and its consolidated Subsidiaries as at the respective dates thereof and the consolidated results of their operations and cash flows for the respective periods then ended. Each Subsidiary of HUWX is treated as a consolidated Subsidiary of HUWX in the HUWX Financial Statements for all periods covered thereby.

5.08. Title to Properties and Assets; Liens. HUWX owns its properties and assets, free and clear of all mortgages, liens, loans and encumbrances, except such encumbrances and liens which arise in the ordinary course of business and do not materially impair HUWX's ownership or use of such properties or assets. With respect to the properties and assets it leases, HUWX, and to HUWX's Knowledge, the counterparty is in compliance with such leases and HUWX holds a valid leasehold interest free of any liens, claims or encumbrances.

5.09. Patents and Other Intangible Assets.

(a) HUWX owns or has the right or license to use all patents, trademarks, service marks, service names, trade names, trade secrets and copyrights used in the conduct of its business as now conducted, free and clear of all claims, mortgages, liens, loans, and encumbrances, except such encumbrances and liens which arise in the ordinary course of business and do not materially impair HUWX's ownership or use of such intellectual property rights. All of the material patents, trademarks, service marks and copyrights that HUWX owns or has the right or license to use are listed or described in Section 5.09 of the HUWX Disclosure Letter.

(b) Except as set forth in Section 5.09 of the HUWX Disclosure Letter, HUWX has no actual knowledge, without any investigation, that HUWX is infringing upon or misappropriating any valid intellectual property rights of any Person or entity (including without limitation, former employers of all current and former employees, consultants, officers, directors and stockholders of HUWX). Without any special investigation for purposes of this Agreement, HUWX, in its reasoned judgment, has determined that making, using or selling any products or methods set forth in Section 5.09 of the HUWX Disclosure Letter will not constitute an infringement or misappropriation by HUWX of the kind described in the preceding sentence.

(c) Except as set forth in Section 5.09 of the HUWX Disclosure Letter, HUWX is not obligated or under any liability whatsoever to make any payments by way of royalties, fees or otherwise to any owner of, licensor of, or other claimant to, any patent, trademark, trade name, copyright or other intellectual property right, with respect to the use thereof or in connection with the conduct of its business or otherwise.

(d) HUWX has obtained from all employees and consultants of HUWX an invention assignment and confidentiality agreement (or substantially similar agreement), copies of which were previously made available to the Company.

5.10. Litigation. There are no actions, suits, proceedings or investigations pending or, to HUWX's Knowledge, threatened against HUWX or its properties before any Governmental Entity. HUWX is not subject to any continuing order, writ, injunction, consent decree or settlement agreement of, or similar written agreement with, or, to HUWX's Knowledge, continuing investigation by, any Court or Governmental Entity.

5.11. Employees. To HUWX's Knowledge, no employee of HUWX is in violation of any term of any employment contract, intellectual property disclosure agreement or any other contract or agreement relating to the relationship of such employee with HUWX or any other party because of the nature of the business conducted or to be conducted by HUWX. HUWX is in compliance in all material respects with the applicable provisions of ERISA, and no "reportable event," as such term is defined in Section 4043 of ERISA, has occurred with respect to any plan subject to Title IV of ERISA or any other plan to which HUWX is required to contribute on behalf of its employees.

5.12. Certain Transactions. Except as set forth in Section 5.12 of the HUWX Disclosure Letter, HUWX is not indebted, directly or indirectly, to any of its officers, directors or stockholders or to their respective spouses or children, in any amount whatsoever; none of said officers, directors or, to HUWX's Knowledge, stockholders, or any members of their immediate families, are indebted to HUWX or have any direct or indirect ownership interest in any firm, corporation or entity with which HUWX is affiliated or with which HUWX has a business relationship, or any firm or corporation which competes with HUWX except that officers, directors and/or stockholders of HUWX may own less than 1% of the stock of publicly traded companies which may compete with HUWX. No officer, director or stockholder, or any member of their immediate families, is, directly or indirectly, interested in any material contract with HUWX. HUWX is not a guarantor or indemnitor of any indebtedness of any other person, firm or corporation.

5.13. Private Placement. All securities issued by HUWX prior to the date hereof have been issued in transactions exempt from registration under the Securities Act and all applicable state securities or "blue sky" Laws, or issued in transactions that resulted in the securities being registered under the Securities Act and HUWX has not violated the Securities Act or any applicable state securities or "blue sky" Laws in connection with the issuances of any such securities.

5.14. Brokers or Finders; Other Offers. Except as may be set forth on Section 5.14 of the HUWX Disclosure Letter HUWX has not incurred and will not incur, directly or indirectly, as a result of any action taken by HUWX, any liability for brokerage or finders' fees or agents' commissions in connection with this Agreement.

5.15. Environmental and Safety Laws. HUWX is not in violation of any applicable statute, Law or Regulation relating to the environment or occupational health and safety, which violation would have a HUWX Material Adverse Effect, nor are any material expenditures required in order to comply with any such existing statute, Law or Regulation.

5.16. Compliance with Laws; Permits. HUWX is not in violation of any applicable statute, Regulation, order or restriction of any Governmental Entity in respect of the conduct of its business or the ownership of its properties, which violation would have a HUWX Material Adverse Effect. HUWX has all franchises, permits, licenses and any similar authority necessary for the conduct of its business as now being conducted by it, the lack of which would have a HUWX Material Adverse Effect, and believes it can obtain without undue burden or expense, any similar authority for the conduct of its business as presently planned to be conducted. HUWX is not in default in any material respect under any of such franchises, permits, licenses or other similar authority.

5.17. Specific Tax Representations.

(a) HUWX has no plan or intention to reacquire any of the HUWX Common Stock to be issued under or in connection with the Transactions;

(b) HUWX has no plans or intentions to sell or otherwise dispose of any of the assets of the Company, except for dispositions made in the ordinary course of business or as otherwise disclosed to the Company in connection with a proposed disposition of certain intellectual property associated with the prior operations of HUWX;

(c) Following the transactions contemplated by this Agreement, HUWX will use all of the assets of the Company in the business of HUWX;

(d) HUWX does not own directly or indirectly, nor has it owned during the past five (5) years, directly or indirectly, any Membership Units or other equity of the Company;

(e) HUWX is not an investment company within the meaning of section 351(e) of the Code;

(f) The HUWX Common Stock to be issued in the transactions contemplated by the Agreement has the current right to vote in the election of corporate directors of HUWX.

(g) Other than the cash to be issued in lieu of fractional shares under Section 3.02(c) of this Agreement, the only consideration to be issued in exchange for the Contributed Assets of the Company on the Closing Date will be HUWX Common Stock;

(h) HUWX currently is and as of the Closing Date will be classified as a corporation for U.S Federal income tax purposes;

(i) HUWX will pay its own expenses, if any, incurred in connection with the Acquisition.

## ARTICLE VI

## COVENANTS

6.01. Affirmative Covenants of HUWX and the Company. Each of HUWX and the Company hereby covenants and agrees that, prior to the Effective Time, unless otherwise expressly contemplated by this Agreement or consented to in writing by the other, it will:

(a) operate its business in all material respects in the usual and ordinary course consistent with past practices;

(b) use its reasonable best efforts to preserve substantially intact its business organization, maintain its material rights and franchises, retain the services of its respective officers and key employees and maintain its relationships and goodwill with its customers and suppliers;

(c) maintain and keep its material properties and assets in as good repair and condition as at present, ordinary wear and tear excepted, and maintain supplies and inventories in quantities consistent with its customary business practice; and

(d) with respect to the Company, use its reasonable best efforts to keep in full force and effect insurance and bonds comparable in amount and scope of coverage to that currently maintained.

6.02. Negative Covenants of the Company. Except as expressly contemplated by this Agreement or otherwise consented to in writing by HUWX, from the date of this Agreement until the Effective Time, the Company will not do any of the foregoing:

(a) (i) increase the compensation payable to or to become payable to any director, officer or employee; (ii) grant any severance or termination pay to, or enter into or amend any employment or severance agreement with, any director, officer or employee; (iii) establish, adopt or enter into any employee benefit plan or arrangement; or (iv) amend, or take any other actions with respect to, any employee benefit plan or the Company Stock Plan, except as expressly contemplated by or stated within this Agreement;

(b) declare or pay any dividend on, or make any other distribution in respect of, outstanding shares of capital stock or other equity interests of the Company;

(c) (i) except as expressly contemplated in this Agreement, redeem, purchase or otherwise acquire any shares of its capital stock or other equity interests or any securities or obligations convertible into or exchangeable for any shares of its capital stock or other equity interests, or any options, warrants or conversion or other rights to acquire any shares of its capital stock or other equity interests or any such securities or obligations; (ii) effect any reorganization or recapitalization; or (iii) split, combine or reclassify any of its capital stock or other equity interests or issue or authorize or propose the issuance of any other securities in respect of, in lieu of or in substitution for, shares of its capital stock or other equity interests;

(d) (i) issue, deliver, award, grant or sell, or authorize or propose the issuance, delivery, award, grant or sale (including the grant of any security interests, liens, claims, pledges, limitations in voting rights, charges or other encumbrances) of, any units or shares of any class of its capital stock or other equity interests (including shares held in treasury), any securities convertible into or exercisable or exchangeable for any such units, shares or interests, or any rights, warrants or options to acquire any such units, shares or interests; (ii) amend or otherwise modify the terms of any such rights, warrants or options the effect of which shall be to make such terms more favorable to the holders thereof; (iii) take any action to optionally accelerate the exercisability of any such rights, options or warrants;

(e) acquire or agree to acquire, by merging or consolidating with, by purchasing an equity interest in or a portion of the assets of, or by any other manner, any other Person or division thereof, or otherwise acquire or agree to acquire any assets of any other Person (other than the purchase of assets from suppliers or vendors in the ordinary course of business and consistent with past practice);

(f) sell, lease (as lessor), exchange, mortgage, pledge, transfer or otherwise dispose of, or agree to sell, lease (as lessor), exchange, mortgage, pledge, transfer or otherwise dispose of, any of its assets, except for dispositions of inventories and of assets in the ordinary course of business and consistent with past practice;

(g) release any third party from its obligations, or grant any consent, under any existing standstill provision under any confidentiality or other agreement, or fail to enforce any such agreement upon the request of HUWX;

(h) adopt or propose to adopt any amendments to its operating agreement or certificate of formation; change any of its methods of accounting in effect at September 30, 2015, except as required by Law or GAAP, or (ii) settle or compromise any claim, action, suit, litigation, proceeding, arbitration, investigation, audit or controversy relating to Taxes;

(i) incur any obligation for borrowed money or purchase money indebtedness, whether or not evidenced by a note, bond, debenture or similar instrument, other than such obligations that are owed to HUWX from time to time;

(j) enter into any arrangement, agreement or contract with any third Person which provides for an exclusive arrangement with that third Person or is substantially more restrictive on Company or substantially less advantageous to the Company than arrangements, agreements or contracts existing on the date hereof;

(k) enter into, renew, amend or waive in any material manner, or terminate or give notice of a proposed renewal or material amendment, waiver or termination of, any contract, arrangement or agreement to which the Company is a party;

(l) take or cause to be taken any action that could reasonably be expected to materially delay, or materially and adversely affect, the consummation of the transactions contemplated hereby;

(m) enter into or amend in any material manner any contract, agreement or commitment with any officer, director, employee or stockholder of the Company or with any affiliate or associate of any of the foregoing;

(n) pay, satisfy, discharge or settle any claims, liabilities or obligations (absolute, accrued, contingent or otherwise), other than pursuant to mandatory terms of any contract in effect on the date hereof, involving payments by the Company in excess of $1,000 individually or in the aggregate;

(o) make any loans, advances or capital contributions to, or investments in any Person;

(p) enter into any new line of business;

(q) make any capital expenditures in excess of $1,000 individually or in the aggregate; or

(r) agree in writing or otherwise to do any of the foregoing.

6.03. Negative Covenants of HUWX. Except as expressly contemplated by this Agreement or otherwise consented to in writing by the Company, from the date of this Agreement until the Effective Time, HUWX will not do any of the following:

(a) declare or pay any dividend on, or make any other distribution in respect of, outstanding shares of capital stock or other equity interests of HUWX;

(b) sell, lease (as lessor), exchange, mortgage, pledge, transfer or otherwise dispose of, or agree to sell, lease (as lessor), exchange, mortgage, pledge, transfer or otherwise dispose of, any of its material assets or any material assets of any of its subsidiaries, except for dispositions of inventories and of assets in the ordinary course of business and consistent with past practice;

(c) take or cause to be taken any action that could reasonably be expected to materially delay, or materially and adversely affect, the consummation of the transactions contemplated hereby;

(d) undertake any action or make any election that would deprive the ability of the Acquisition to qualify as a tax-free contribution of property to the Company pursuant to the provisions of section 351 of the Code, or

(e) agree in writing or otherwise to do any of the foregoing.

6.04. No Solicitation.

(a) From the date of this Agreement until the earlier of the Effective Time or the termination of this Agreement pursuant to Section 9.01, the Company agrees that it will not, and will not authorize or permit any of its officers, directors, employees, accountants, consultants, legal counsel, agents and other representatives ("Representatives") to, directly or indirectly, (i) initiate, solicit, encourage or otherwise facilitate any inquiries regarding or the making or implementation of any Acquisition Proposal, (ii) engage in any discussions or negotiations with, or provide any information or data to, any Person relating to or that may reasonably be expected to lead to an Acquisition Proposal or otherwise facilitate any effort or attempt to make or implement an Acquisition Proposal, (iii) approve or recommend or propose publicly to approve or recommend any Acquisition Proposal or (iv) enter into any agreement, arrangement or understanding contemplating or relating to any Acquisition Proposal or requiring the Company to abandon, terminate or fail to consummate the Acquisition or any other transactions contemplated by this Agreement.

(b) From and after the date of this Agreement, the Company shall as promptly as possible after receipt (and in any event within 24 hours) notify HUWX in writing of any inquiries, proposals or offers, or any discussions or negotiations sought to be initiated or continued with, it or its Representatives relating to, constituting or which could reasonably be expected to lead to an Acquisition Proposal or any request for information relating to the Company contemplating, relating to or which could reasonably be expected to lead to any Acquisition Proposal. Such notice will include the name of such Person and the material terms and conditions of any proposal, inquiry, offer or request, and the Company will as soon as possible provide such other details of the Acquisition Proposal, inquiry, offer or request as HUWX may reasonably request. The Company will keep HUWX fully informed on a prompt basis (and in any event within 24 hours) of the status and terms, including any material changes or adjustments made to or proposed to be made to the terms, of any such inquiry, proposal, offer or request. If the Company or its Representatives receives a request for information from a Person who has made an unsolicited bona fide written Acquisition Proposal and the Company is permitted, as contemplated under Section 6.04(b), to provide such Person with information, the Company will provide to HUWX a copy of the confidentiality agreement with such Person promptly upon its execution and provide to HUWX a list of, and copies of, the information provided to such Person concurrently with delivery to such Person and immediately provide HUWX with access to all information to which such Person was provided access.

(c) The Company will immediately cease and cause to be terminated all existing activities, discussions or negotiations by it and the other Persons referred to in Section 6.04(a) with any Person other than HUWX conducted heretofore with respect to any Acquisition Proposal. The Company also agrees, if it has not already done so, to promptly request each Person, if any, that has heretofore executed a confidentiality agreement within the 12 months prior to the date hereof in connection with any Acquisition Proposal to return or destroy all confidential information heretofore furnished to such Person by or on behalf of it or its Subsidiaries and take commercially reasonable actions necessary to enforce the provisions of any continuing confidentiality, standstill or similar agreement. The Company will take such action as is necessary to inform promptly the Persons referred to in Section 6.04(a) of the provisions of this Section 6.04 and will be responsible for any breach of this Section 6.04 by such Persons.

6.05. Notices of Certain Events; Consultation.

(a) The Company shall as promptly as reasonably practicable notify HUWX of: (i) any notice or other communication of which the Company has Knowledge from any Person alleging that the consent of such Person (or another Person) is or may be required in connection with the transactions contemplated by this Agreement; (ii) any notice or other communication of which the Company has Knowledge from any Governmental Entity in connection with the transactions contemplated by this Agreement; (iii) any actions, suits, claims, investigations or proceedings commenced or, or to the Knowledge of the Company, threatened against, relating to or involving or otherwise affecting the Company that, if pending on the date of this Agreement, would have been required to have been disclosed pursuant to Section 4.08 or which relate to the consummation of the transactions contemplated by this Agreement; and (iv) any fact or occurrence between the date of this Agreement and the Effective Time of which it has Knowledge which makes any of its representations contained in this Agreement untrue in any material respect or causes any material breach of its obligations under this Agreement.

(b) HUWX shall as promptly as reasonably practicable notify the Company of: (i) any notice or other communication of which HUWX has Knowledge from any Person alleging that the consent of such Person (or other Person) is or may be required in connection with the transactions contemplated by this Agreement; (ii) any notice or other communication of which HUWX has Knowledge from any Governmental Entity in connection with the transactions contemplated by this Agreement; and (iii) any fact or occurrence between the date of this Agreement and the Effective Time of which it becomes aware which makes any of its representations contained in this Agreement untrue in any material respect or causes any material breach of its obligations under this Agreement.

6.06. No Reverse Split. Except as contemplated by the parties in connection with the Acquisition, the Operating Company and HUWX following the Acquisition shall effect the Reverse Split but shall not allow or effect any other reverse split or combination of securities of HUWX for period of not less than twelve months following the Effective Time.

6.07. Access and Information.

(a) Each of HUWX and the Company shall (i) afford to the other party and such other party's Representatives reasonable access at reasonable times, upon reasonable prior notice, to its officers, employees, agents, properties, offices and other facilities and to the books and records thereof and (ii) furnish promptly to the other party and its Representatives such information concerning its business, properties, contracts, records and personnel (including, without limitation, financial, operating and other data and information) as may be reasonably requested, from time to time, by such other party.

(b) Notwithstanding the foregoing provisions of this Section 6.07, neither party shall be required to grant access or furnish information to the other party to the extent that such access or the furnishing of such information is prohibited by Law. No investigation by the parties hereto made heretofore or hereafter shall affect the representations and warranties of the parties which are herein contained and each such representation and warranty shall survive such investigation.

(c) The information received pursuant to Section 6.07(a) that is non-public shall be deemed to be confidential information for purposes of this Agreement.

6.08. Lock-up Agreement by the Company. Indirect beneficial owners of HUWX Common Stock identified by HUWX, including officers and directors of the Company (and after the Closing, officers of the Operating Company and Directors of HUWX) shall have delivered at Closing a signed agreement with HUWX whereby they agree to lock up shares of HUWX common stock owned by the Company, a total of [ ] shares of the Acquisition Shares, for a period of not less than 365 days commencing from the date of closing of the Placement and subject to leak-out and release provisions to be delivered at Closing..

ARTICLE VII

ADDITIONAL AGREEMENTS

7.01. Meetings of Stockholders.

(a) As promptly as practicable after the execution of this Agreement, HUWX and the Company shall prepare an information statement (the "Information Statement") containing such information regarding the Acquisition, the transactions contemplated by this Agreement and the issuance of the Acquisition Shares as necessary to satisfy the requirements of Rule 502 of Regulation D under the Securities Act. The information supplied by the Company and HUWX for inclusion in the Information Statement shall not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein not misleading. If at any time prior to the Effective Time any event or circumstance relating to the Company or HUWX, or any of their respective officers or directors, should be discovered by the Company or HUWX that should be set forth in a supplement to the Information Statement, the Company or HUWX, as the case may be, shall promptly inform the other party thereof in writing.

(b) The Company will, as promptly as possible have taken all actions necessary in accordance with state and federal securities Laws, Delaware Law and its Certificate of Formation and Company LLC Agreement to either (i) call, give notice of, convene and hold a meeting of the Company's Unitholders to be held on the earliest possible date or (ii) prepare and distribute a written consent of Unitholders in lieu of a meeting of the Company's Unitholders, in either case to consider and vote on approval of this Agreement and the Acquisition (the "Company Unitholders' Meeting"), and the Company will consult with HUWX in connection therewith. Subject to Section 7.01(b), the Board of Directors of the Company will recommend to the Unitholders of the Company the approval of this Agreement and the Acquisition and the Company will use its reasonable best efforts to solicit from the Unitholders of the Company proxies or consents in favor of the approval of this Agreement and the Acquisition and to secure the Required Company Vote. The Company will, in connection with the delivery of notice of the Company Unitholders' Meeting, deliver the Information Statement to its Unitholders entitled to notice of and to vote at the Company Unitholders' Meeting. Subject to the foregoing and Sections 7.01(c), as applicable, the Information Statement shall include the recommendation of the Company's Board of Directors in favor of approval of the Acquisition and adoption and approval of this Agreement and the recommendation of HUWX's Board of Directors in favor of approval of the Acquisition and adoption and approval of this Agreement and the issuance of the Acquisition Shares pursuant to the Acquisition.

(c) Unless this Agreement is terminated in accordance with Article IX, the obligation of the Company to convene and hold the Company Unitholders' Meeting will not be limited or otherwise effected by any Change of Recommendation. Without limiting the generality of the foregoing, the Company agrees that its obligations pursuant to the immediately preceding sentence will not be effected by the commencement, public proposal, public disclosure or communication to the Company of any Acquisition Proposal or interest in an Acquisition Proposal or any Change of Recommendation. The Company's Board of Directors will not, in connection with any Change of Recommendation, take any action to withdraw the approval of the Board of Directors of the Company of this Agreement or the Acquisition.

7.02. Appropriate Action; Consents; Filings.

(a) The Company and HUWX shall each use their reasonable best efforts to (i) take, or cause to be taken, all appropriate action, and do, or cause to be done, all things necessary, proper or advisable under applicable Law or otherwise to consummate and make effective the transactions contemplated by this Agreement, (ii) obtain from any Governmental Entities any consents, licenses, permits, waivers, approvals, authorizations or orders required to be obtained or make any filings with or notifications or submissions to any Governmental Entity (other than described in the following clause (iii)) required to be made by the Company or HUWX in connection with the authorization, execution and delivery of this Agreement and the consummation of the transactions contemplated hereby, including, without limitation, the Acquisition, (iii) make all necessary filings, and thereafter make any other required submissions, with respect to this Agreement and the Acquisition, required under (A) the Securities Act and any other applicable federal or state securities Laws,

and (B) any other applicable Law; provided that the Company and HUWX shall cooperate with each other in connection with the making of all such filings and submissions. Each of the Company and HUWX, upon request, shall furnish to the other and to any Governmental Entity all information concerning itself and its subsidiaries, directors, officers and stockholders and such other matters as may be reasonably necessary, advisable or required for any application or other filing or submission to be made pursuant to the rules and regulations of any applicable Law in connection with the transactions contemplated by this Agreement.

(b) The Company and HUWX agree to cooperate with respect to and agree to use their reasonable best efforts to contest and resist, any action, including legislative, administrative or judicial action, and to have vacated, lifted, reversed or overturned any decree, judgment, injunction or other order (whether temporary, preliminary or permanent) of any Court or other Governmental Entity that is in effect and that restricts, prevents or prohibits the consummation of the Acquisition or any other transactions contemplated by this Agreement.

(c)(i) Each of the Company and HUWX shall give any notices to third Persons, and use their reasonable best efforts to obtain any third Persons consents (A) necessary, proper or advisable to consummate the transactions contemplated by this Agreement, (B) otherwise required under any contracts, licenses, leases or other agreements in connection with the consummation of the transactions contemplated hereby or (C) required to prevent a Company Material Adverse Effect or a HUWX Material Adverse Effect from occurring after the Effective Time.

(ii) In the event that any party shall fail to obtain any third Person consent described in subsection (c)(i) above, such party shall use its reasonable best efforts, and shall take any such actions reasonably requested by the other parties, to limit the adverse effect upon the Company and HUWX and their respective businesses resulting, or which could reasonably be expected to result after the Effective Time, from the failure to obtain such consent.

(d) Nothing in this Agreement shall require HUWX to agree to, or permit the Company to agree to, the imposition of conditions, the payment of any amounts or any requirement of divestiture to obtain any Approval, and in no event shall any party take, or be required to take, any action that would or could reasonably be expected to have a Company Material Adverse Effect or a HUWX Material Adverse Effect.

(e) Each of the Company and HUWX shall promptly notify the other of (i) any material change in its current or future business, financial condition or results of operations, (ii) any complaints, investigations or hearings (or communications indicating that the same may be contemplated) of any Court or Governmental Entities with respect to the transactions contemplated hereby or its business, (iii) the institution or the threat of material litigation involving it, or (iv) any event or condition that might reasonably be expected to cause any of its representations, warranties, covenants or agreements set forth herein not to be true and correct at the Effective Time. As used in the preceding sentence, "material litigation" means any case, arbitration or adversary proceeding or other matter which would have been required to be disclosed on the Company Disclosure Letter pursuant to Section 7.02 of the HUWX Disclosure Letter pursuant to Section 5.10, as the case may be, if in existence on the date hereof, or in respect of which the legal fees and other costs to the Company might reasonably be expected to exceed $50,000 over the life of the matter.

7.03. Tax Treatment. The parties hereto intend that the Acquisition shall qualify as a tax-free contribution of property solely for shares within the meaning of Section 351(a) of the Code and that this Agreement shall accordingly constitute an asset contribution agreement for the purposes of Section 351 of the Code and the Treasury Regulations promulgated thereunder. Each party hereto shall use its reasonable best efforts to cause the Acquisition to qualify, and shall not take, and shall use its reasonable best efforts to prevent any affiliate of such party from taking, any actions that could prevent the Acquisition from qualifying, as a tax-free contribution of property to HUWX under the provisions of Section 351(a) of the Code.

7.04. Public Announcements. HUWX shall be responsible for issuing any press release or otherwise making any public statements with respect to the Acquisition.

7.05. Employees. HUWX shall have the right, but not the obligation, to make offers of employment and enter into employment or consulting arrangements with any employee or consultant of the Company. Any such employment or consulting arrangement shall be effective at the Effective Time. HUWX is also expressly authorized to offer awards under the HUWX Stock Plan to officers, directors, employees, agent and consultants of the Company in HUWX's sole and absolute discretion.

7.06. Indemnification.

(a) Indemnity Agreement of Company. Subject to the provisions and limitations of this Section 7.06, the Company, for itself, its successors and assigns, agrees to indemnify and hold harmless each of HUWX and Sub and its or their respective officers, directors, representatives, and agents from and against:

(i) Failure to Perform Obligations. Any Event of Loss or Loss (each as defined below) arising as a result of Company's failure to perform or discharge any of its duties or obligations to be performed by Company hereunder prior to the Closing Date; and

(ii) Breach of Representations, Warranties or Covenants. Any Event of Loss or Loss arising from any breach of a representation, warranty or covenant of Company set forth in this Agreement.

(b) Indemnity Agreement of HUWX and Sub. Subject to the provisions and limitations of this Section 7.06, each of HUWX and Sub, for itself, its successors and assigns, agrees to indemnify and save harmless Company from and against:

(i) Failure to Perform Obligations. Any Event of Loss or Loss arising as a result of HUWX's or Sub's failure to discharge or perform any duties or obligations to be performed by HUWX or Sub hereunder prior to the Closing Date; and

(ii) Breach of Representations, Warranties or Covenants. Any Event of Loss or Loss arising from any breach of a representation, warranty or covenant of HUWX or Sub set forth in this Agreement.

(c) Definition of "Loss". Any party to this Agreement against whom or which indemnification may be sought pursuant to this Section 7.06 shall be herein called an "Indemnifying Party," and any person entitled to indemnification pursuant to this Section 7.06 shall be herein called an "Indemnified Party." The occurrence of an event which may result in a loss, cost, expense or liability of an Indemnified Party hereunder as to which the Indemnifying Party shall have received notice from the Indemnified Party shall be herein called an "Event of Loss," and the amount of any loss, cost, expense or liability of any kind whatsoever (including legal fees and disbursements incurred in connection therewith) incurred by an Indemnified Party shall be herein called a "Loss;" provided, however, that for purposes of computing the amount of Loss incurred by any Indemnified Party, there shall be deducted an amount equal to the amount of any insurance proceeds (other than self-insurance) directly or indirectly received by such Indemnified Party in connection with such Loss or the circumstances giving rise thereto.

Upon payment by an Indemnified Party of any Loss, the Indemnifying Party shall discharge its obligation to indemnify the Indemnified Party against such Loss by paying to the Indemnified Party an amount that, on an after-tax basis reflecting the hypothetical tax consequences, if any, of the receipt of such amount, shall be equal to the hypothetical after-tax amount of such Loss by taking into account the hypothetical tax consequences, if any, to the Indemnified Party of the payment of such Loss. For purposes of this Section 7.06, references to "after-tax basis," "hypothetical" tax consequences and "hypothetical" after-tax amount refer to calculations of foreign, federal, state and local tax at the maximum statutory rate (or rates, in the case of an item of income or deduction taxable or deductible for purposes of more than one tax) applicable to the Indemnified Party for the relevant year, after taking into account, for example, the effect of deductions available for other taxes such as state and local income taxes, which effect would similarly be calculated on the basis of the maximum statutory rate (or rates) of the tax (or taxes) for which such deduction was available.

(d) Insurance Proceeds Received After Indemnification. Each party agrees that, if it receives any payments from the other party hereto with respect to any Loss pursuant to this Section 7.06 and subsequently such party receives any amount of insurance proceeds (other than from self-insurance) in connection with any such Loss or the circumstances giving rise thereto, such party agrees to promptly deliver or cause to be delivered the amount of such insurance proceeds to the party that made such indemnification payments pursuant to this Section 7.06; provided, however, a party shall not be required to pay (or cause to be paid) to the other party an amount of insurance proceeds in excess of the payment in respect of the related Loss paid by the Indemnifying Party.

(e) Deductible Amount and Time Period. An Indemnifying Party shall not be required to make any indemnification payments hereunder for which such Indemnifying Party would otherwise be liable under this Section 7.06 until (and then only to the extent that) the total of all amounts to which, but for the provisions of this sentence, the Indemnified Party would be entitled pursuant to this Section 7.06 with respect to all Losses actually exceeds $25,000; provided, however, that the limitations on liability set forth in this sentence shall not be applicable to (i) any claim against an Indemnifying Party alleging fraudulent misrepresentation or (ii) any payments to be made by the Indemnifying Party pursuant to any provision of this Agreement (other than those set forth in this Section 7.06) or any provision of the instruments of assumption referred to herein.

Notwithstanding anything in this Section 7.06 to the contrary, the Indemnifying Party shall have (i) no liability for any Loss arising out of claims of a person not a party or an affiliate of a party to this Agreement as to which the Indemnifying Party shall not have received notice within six years from the Closing Date and (ii) no liability for any Loss arising out of claims under this Agreement (other than those referred to in clause (i) of this sentence) as to which the Indemnifying Party shall not have received notice within four years from the Closing Date.

(f) Defense of Claims. In case any legal action shall be commenced or threatened (provided that in the case of a threatened legal action the Indemnified Party believes in good faith that an indemnifiable Loss is likely to occur) against an Indemnified Party which could result in a Loss, the Indemnified Party shall promptly notify the Indemnifying Party in writing. After receipt of any such notice, the Indemnifying Party shall have the right, exercisable by written notice of exercise to the Indemnified Party promptly after receipt of the notice provided for in the next preceding sentence, (A) to participate in and (B) assume (and control) the defense of such action, at its own expense and with its own counsel, provided such counsel is satisfactory to the Indemnified Party. If the Indemnifying Party elects to assume the defense of such action, the Indemnifying Party shall keep the Indemnified Party informed of all material developments and events relating to such action. The Indemnified Party shall have the right to participate in (but not control) the defense of any such action, but the fees and expenses of counsel for the Indemnified Party shall be at its own expense except as set forth in the following sentence. The Indemnifying Party shall bear the reasonable fees and expenses of counsel retained by the Indemnified Party if (i) the Indemnified Party shall have retained such counsel due to actual or potential conflicting interests between the Indemnified Party and the Indemnifying Party, (ii) the Indemnifying Party shall not elect to assume the defense of the action, (iii) the Indemnifying Party shall not have employed counsel satisfactory to the Indemnified Party to represent the Indemnifying Party in connection with its assumption of the defense of the action within a reasonable time after notice pursuant to the first sentence of this paragraph is delivered to the effect that such action has been commenced or is threatened, or (iv) the Indemnifying Party has authorized the employment of counsel for the Indemnified Party to handle the defense of the action at the expense of the Indemnifying Party. In no event will the Indemnifying Party be liable for any settlement or admission of liability with respect to any action without its prior written consent, which shall not be unreasonably withheld, but if settled with such consent, the Indemnifying Party shall be liable therefor, subject to the limitations set forth in this Section 7.06. The Indemnifying Party may not settle any liability or claim subject to indemnification pursuant to this Section 7.06 without the consent of the Indemnified Party and on any basis that does not provide for a full release of the Indemnified Party. Any participation in, or assumption of the defense of, any action by an Indemnifying Party shall be without prejudice to the right of the Indemnifying Party, and shall not be construed as a waiver of its right to deny the obligation to indemnify the Indemnified Party. The giving of notice, as above provided, of a loss, damage, cost or expense claimed to be indemnifiable hereunder, to exercise the right, as the same is provided (and limited) herein, to participate in and assume control of the defense against such claim, shall be a prerequisite to any obligation to indemnify; provided, however, that the Indemnified Party's rights pursuant to this Section 7.06 shall not be forfeited by reason of a failure to give such notice or to cooperate in the defense to the extent such failure does not have a material and adverse effect on the defense of such matter. Notwithstanding any of the above, HUWX shall have control of any action arising from a tax claim to the extent such claim is reflected on HUWX's tax returns.

(g) Payment of Loss; Subrogation. Any Loss for which an Indemnified Party is entitled to payment hereunder shall be paid by the Indemnifying Party upon written demand by the Indemnified Party. The Indemnifying Party shall be subrogated to any claims or rights of the Indemnified Party as against any other persons with respect to any Loss paid by the Indemnifying Party under this Section 7.06. The Indemnified Party shall cooperate with the Indemnifying Party to a reasonable extent, at the Indemnifying Party's expense, in the assertion by the Indemnifying Party of any such claims against such other persons.

(h) Notice of Event of Loss. Each party agrees that it will give notice to the other party hereunder promptly, but in no event later than 30 days, after the receipt by one of its responsible officers of knowledge of a state of facts which, if not corrected, would be an Event of Loss hereunder. Each party shall make available to the other party and its counsel and accountants, at reasonable times and for reasonable periods, during normal business hours, all books and records of such party relating to any such possible Event of Loss, and each party will render to the other such assistance as it may reasonably require of the other in order to insure prompt and adequate prosecution of the defense of any suit, claim or proceeding based upon such state of facts.

(i) Indemnification by John P. McGrain. Supplemental to the foregoing, John P. McGrain shall indemnify and hold the post-Closing HUWX harmless from all liabilities, causes of action and claims that exceed $25,000 arising out of the operations of HUWX since its formation through the Closing, (the "McGrain Indemnification"). The amount of the McGrain Indemnification (i) shall not exceed $500,000 in the aggregate, and (ii) will lapse and be no longer effective on the earlier of (a) 180 days following the Closing or (b) the completion of the underwritten public offering of the securities of the post-Acquisition HUWX. In the event HUWX's pre-Closing assets are sold post-Closing, or if they are sold pre-closing but are not given effect to permit HUWX a greater post-Closing percentage and additional shares in the Transaction then before seeking indemnification for any loss from John P. McGrain pursuant to this Section 7.06, HUWX shall first credit and offset against any such claim the proceeds received by HUWX from the sale of HUWX's pre-Closing assets.

## ARTICLE VIII

## CONDITIONS

8.01. Conditions to Obligations of Each Party. The respective obligations of each party to effect the Acquisition and the other transactions contemplated hereby shall be subject to the satisfaction at or prior to the Closing Date of the following conditions:

(a) No Order. No Governmental Entity of competent jurisdiction shall have enacted, issued, promulgated, enforced or entered any statute, Regulation, executive order, decree, injunction or other order (whether temporary, preliminary or permanent) that is in effect and has the effect of making the Acquisition or the other transactions contemplated hereby illegal or otherwise prohibiting consummation of the Acquisition or the other transactions contemplated hereby.

(b) Government Consents. The applicable waiting period under any Approvals of any Governmental Entity the failure to obtain would constitute a criminal offense, or individually or in the aggregate would be reasonably expected to have a Company Material Adverse Effect or a HUWX Material Adverse Effect after the Effective Time, shall have been obtained.

8.02. Additional Conditions to Obligations of HUWX. The obligations of HUWX to effect the Acquisition and the other transactions contemplated hereby are also subject to the satisfaction at or prior to the Closing Date of the following conditions:

(a) Representations and Warranties. Each of the representations and warranties of the Company contained in this Agreement (which for purposes of this subparagraph (a) shall be read as though none of them contained any Company Material Adverse Effect or other materiality qualifications), except for the representations and warranties contained in Sections 4.01, 4.02, 4.03, 4.04 and 4.05, shall be true and correct in all respects on the date of this Agreement and as of the Closing Date as though made on and as of such date (except to the extent such representations and warranties specifically relate to a specified date, in which case

such representations and warranties shall be true and correct as of such specified date) except where the failure of such representations and warranties in the aggregate to be true and correct in all respects has not had, and would not reasonably be expected to have, a Company Material Adverse Effect. Each of the representations and warranties of the Company set forth in Sections 4.01, 4.02, 4.03, 4.04 and 4.05 of this Agreement shall be true and correct in all respects on the date of this Agreement and on the Closing Date as if made on and as of such date (except for such representations and warranties made as of a specified date, which shall be true and correct in all respects as of such specified date).

(b) Agreements and Covenants. The Company shall have performed or complied in all material respects with all agreements and covenants required by this Agreement to be performed or complied with by it on or prior to the Closing Date.

(c) No Material Adverse Effect. No Company Material Adverse Effect shall have occurred since the date hereof and be continuing.

(d) Compliance Certificate. HUWX shall have received a certificate of the Chief Executive Officer of the Company, dated the Closing Date, confirming that the conditions in Sections 8.02(a), (b) and (c) have been satisfied.

(e) No Pending Action. There shall not be any action taken, any Law, Regulation or order enacted (whether temporary, preliminary or permanent), issued, promulgated, enforced, entered or deemed applicable by any Governmental Entity or pending or threatened any Action by any Governmental Entity or other Person, (i) challenging or seeking to make illegal, to delay materially or otherwise directly or indirectly to restrain or prohibit the consummation of the Acquisition, (ii) seeking to obtain material damages in connection with the transactions contemplated by this Agreement or (iii) imposing any condition or restriction that in the judgment of HUWX, acting reasonably, would be materially burdensome to the future operations or business of HUWX or the Operating Company after the Effective Time.

(f) Consent, Waiver and Investment Agreement. Company Unitholders representing the Required Company Vote shall have executed and delivered a Consent, Waiver and Investment Agreement in form and substance satisfactory to the Company and HUWX.

(g) Unitholder Approval. This Agreement and the Acquisition shall have been approved and adopted by the Required Company Vote.

8.03. Additional Conditions to Obligations of the Company. The obligations of the Company to effect the Acquisition and the other transactions contemplated hereby are also subject to the satisfaction at or prior to the Closing Date of the following conditions:

(a) Representations and Warranties. Each of the representations and warranties of HUWX contained in this Agreement (which for purposes of this subparagraph (a) shall be read as though none of them contained any HUWX Material Adverse Effect or other materiality qualification), except for the representations and warranties contained in Sections 5.01, 5.02, 5.03, 5.04 and 5.05, shall be true and correct in all respects on the date of this Agreement and as of the Closing Date as though made on and as of such date (except to the extent such representations and warranties specifically relate to a specified date, in which case such representations and warranties shall be true and correct as of such specified date) except where the failure of such representations and warranties in the aggregate to be true and correct in all respects has not had, and would not reasonably be expected to have, a HUWX Material Adverse Effect. Each of the representations and warranties of HUWX set forth in Sections 5.01, 5.02, 5.03, 5.04 and 5.05 of this Agreement shall be true and correct in all respects on the date of this Agreement and on the Closing Date as if made on and as of such date (except for such representations and warranties made as of a specified date, which shall be true and correct in all respects as of such specified date).

(b) Agreements and Covenants. HUWX shall have performed or complied in all material respects with all agreements and covenants required by this Agreement to be performed or complied with by them on or prior to the Closing Date.

(c) No Material Adverse Effect. No HUWX Material Adverse Effect shall have occurred since the date hereof and be continuing.

( d ) Compliance Certificate. The Company shall have received a certificate of the President of HUWX, dated the Closing Date, confirming that the conditions in Sections 8.03(a), (b) and (c) have been satisfied.

(e) Stockholder Approval. This Agreement and the Acquisition shall have been approved and adopted by stockholders of HUWX.

ARTICLE IX

TERMINATION, AMENDMENT AND WAIVER

9 . 0 1 . Termination. This Agreement may be terminated at any time prior to the Effective Time, whether before or after approval by the stockholders of the Company or HUWX of the Acquisition:

(a) by mutual written consent of the Company and HUWX;

(b) by HUWX, upon a breach of any representation, warranty, covenant or agreement on the part of the Company set forth in this Agreement, or if any representation or warranty of the Company shall have become untrue, in either case only if the conditions set forth in Section 8.02(a), (b) or (c) of this Agreement, as the case may be, would be incapable of being satisfied; provided, that such breach or untruth has not been cured within 30 days following the earlier of receipt by HUWX of written notice of such breach or untruth from the Company or receipt by the Company of written notice of such breach or untruth from HUWX;

(c) by the Company, upon a breach of any representation, warranty, covenant or agreement on the part of HUWX set forth in this Agreement, or if any representation or warranty of HUWX shall have become untrue, in either case only if the conditions set forth in Section 8.03(a), (b) or (c) of this Agreement, as the case may be, would be incapable of being satisfied; provided, that such breach or untruth has not been cured within 30 days following the earlier of receipt by the Company of written notice of such breach or untruth from HUWX or receipt by HUWX of written notice of such breach or untruth from the Company;

(d) by either HUWX or the Company, if there shall be any Law, order, injunction or decree which is final and non-appealable preventing the consummation of the Acquisition;

(e) by either HUWX or the Company, if the Acquisition shall not have been consummated before the 45th day after the date of this Agreement; provided, however, that the right to terminate this Agreement under this Section 9.01(e) shall not be available to any party whose failure or whose affiliates' failure to perform any material covenant, agreement or obligation hereunder has been the cause of, or resulted in, the failure of the Acquisition to occur on or before such date;

(f) by either HUWX or the Company if this Agreement and the Acquisition shall not be adopted and approved by the Required Company Vote;

(g) by either HUWX or the Company if this Agreement and the Acquisition shall not be adopted and approved by the requisite vote of the stockholders of HUWX;

(h) by HUWX, if the Board of Directors of the Company (A) shall fail to recommend or shall withdraw, modify or change in any manner adverse to HUWX its approval or recommendation of this Agreement and the Acquisition, (B) shall approve, recommend or publicly announce its intention to enter into any Acquisition Proposal, (C) shall have breached any of its obligations under Section 6.04, (D) shall fail to reaffirm its approval or recommendation of this Agreement and the Acquisition as promptly as practicable (but in any event within five business days) after receipt of any written request to do so from HUWX, (E) shall not have sent to its stockholders pursuant to Rule 14e-2 promulgated under the Securities Act a statement disclosing that the Board of Directors of the Company recommends rejection of any tender or exchange offer relating to its

securities that has been commenced by a Person unaffiliated with HUWX within ten business days after such tender or exchange offer is first published, sent or given, (F) shall exempt any Person other than HUWX from the ability to acquire or vote shares or (G) shall resolve to take any of the actions specified in clause (A), (B) or (F) of this Section 9.01(h); or

(i) by the Company, if the Board of Directors of the Company shall have made a Change of Recommendation in accordance with Section 7.01(b).

9.02. Effect of Termination. Except as provided in Section 9.05 or Section 10.01 of this Agreement, in the event of the termination of this Agreement pursuant to Section 9.01, this Agreement shall forthwith become void, there shall be no liability on the part of HUWX or the Company or their respective officers, directors, or stockholders and all rights and obligations of any party hereto shall cease, except that nothing herein shall relieve any party of any liability for any willful breach of such party's representations or warranties contained in this Agreement. No termination of this Agreement shall affect the obligations of the parties under the Confidentiality Agreement.

9.03. Amendment. This Agreement may be amended by the parties hereto by action taken by or on behalf of their respective Boards of Directors at any time prior to the Effective Time; provided, however, that, after approval of the Acquisition by the Unitholders of the Company, no amendment, which under applicable Law may not be made without the approval of the Unitholders of the Company, may be made without such approval. This Agreement may not be amended except by an instrument in writing signed by the parties hereto.

9.04. Waiver. At any time prior to the Effective Time, any party hereto may (a) extend the time for the performance of any of the obligations or other acts of the other party hereto, (b) waive any inaccuracies in the representations and warranties of the other party contained herein or in any document delivered pursuant hereto and (c) waive compliance by the other party with any of the agreements or conditions contained herein. Any such extension or waiver shall be valid only if set forth in an instrument in writing signed by the party or parties to be bound thereby.

9.05. Fees, Expenses and Other Payments. Except as provided in Section 9.02 of this Agreement, all expenses incurred by the parties hereto shall be borne solely and entirely by the party which has incurred such expenses whether or not the Acquisition is consummated.

## ARTICLE X

## GENERAL PROVISIONS

10.01. Effectiveness of Representations, Warranties and Agreements.

(a) Except as set forth in Section 10.01(b) of this Agreement, the representations, warranties and agreements of each party hereto shall remain operative and in full force and effect regardless of any investigation made by or on behalf of any other party hereto, any person controlling any such party or any of their officers, directors, representatives or agents, whether prior to or after the execution of this Agreement.

(b) The representations and warranties in this Agreement shall terminate at the Effective Time or upon the termination of this Agreement pursuant to Article IX. This Section 10.01(b) shall not limit any covenant or agreement of the parties hereto which by its terms contemplates performance after the Effective Time or after termination of this Agreement.

10.02. Notices. All notices and other communications given or made pursuant hereto shall be in writing and shall be deemed to have been duly given upon receipt, if delivered personally, mailed by registered or certified mail (postage prepaid, return receipt requested) to the parties at the following addresses (or at such other address for a party as shall be specified by like changes of address) or sent by electronic transmission to the e-mail address specified below:

If to HUWX, to:

Heatwurx Inc.
530 South Lake Avenue, Suite 615
Pasadena, California 91101
Attention: John P. McGrain
E-mail:

with a copy to (which copy shall not constitute notice hereunder):

Law offices of Aaron A. Grunfeld
11111 Santa Monica Boulevard
Suite 1840
Attention: Aaron A. Grunfeld
Email: agrunfeld@grunfeldlaw.com

If to Company:

Promet Therapeutics, LLC.
7380 Coca Cola Drive
Hanover, Maryland 21076
Attention: David Young Ph.D.
E-mail: David.Young@promettherapeutics.com

With a copy (which copy shall not constitute notice) to:
Matheau J. W. Stout, Esq.
Attorney At Law
400 East Pratt Street
8th Floor
Baltimore, Maryland 21202
E-mail: mstout@otclawyers.com

10.03. Headings. The headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement. Section references herein are, unless the context otherwise requires, references to sections of this Agreement.

10.04. Severability. If any term or other provision of this Agreement is invalid, illegal or incapable of being enforced by any rule of Law or public policy, all other conditions and provisions of this Agreement shall nevertheless remain in full force and effect so long as the economic or legal substance of the transactions contemplated hereby is not affected in any manner materially adverse to any party. Upon such determination that any term or other provision is invalid, illegal or incapable of being enforced, the parties hereto shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in an acceptable manner to the end that transactions contemplated hereby are fulfilled to the extent possible.

10.05. Entire Agreement. This Agreement (together with the Exhibits, the Company Disclosure Letter and the HUWX Disclosure Letter) and the Confidentiality Agreement constitute the entire agreement of the parties, and supersede all prior agreements and undertakings, both written and oral, among the parties or between any of them, with respect to the subject matter hereof. The Company agrees that nothing contained in this Agreement, or the transactions contemplated hereby or thereby, shall be deemed to violate the Confidentiality Agreement.

10.06. Assignment. This Agreement shall not be assigned by any party prior to the Effective Time by operation of Law or otherwise.

10.07. Parties in Interest. This Agreement shall be binding upon and inure solely to the benefit of each party hereto, and nothing in this Agreement, express or implied, is intended to or shall confer upon any other person any right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

10.08. Specific Performance. The parties hereby acknowledge and agree that the failure of any party to perform its agreements and covenants hereunder, including its failure to take all actions as are necessary on its part to the consummation of the Acquisition, will cause irreparable injury to the other parties for which damages, even if available, will not be an adequate remedy. Accordingly, each party hereby consents to the issuance of injunctive relief by any court of competent jurisdiction to compel performance of such party's obligations and to the granting by any court of the remedy of specific performance of its obligations hereunder.

10.09. Failure or Indulgence Not Waiver; Remedies Cumulative. No failure or delay on the part of any party hereto in the exercise of any right hereunder shall impair such right or be construed to be a waiver of, or acquiescence in, any breach of any representation, warranty or agreement herein, nor shall any single or partial exercise of any such right preclude other or further exercise thereof or of any other right. All rights and remedies existing under this Agreement are cumulative to, and not exclusive to, and not exclusive of, any rights or remedies otherwise available.

10.10. Governing Law; Consent Jurisdiction; Venue.

(a) This Agreement, and the rights and obligations of the parties hereto, shall be governed by and construed in accordance with the laws of the State of Delaware, regardless of the Laws that might otherwise govern under applicable principles of conflicts of Law.

(b) Each of the parties hereto irrevocably submits to the exclusive jurisdiction of the state courts of Delaware and to the jurisdiction of the United States District Court for Delaware, for the purpose of any action or proceeding arising out of or relating to this Agreement and each of the parties hereto irrevocably agrees that all claims in respect to such action or proceeding may be heard and determined exclusively in any Delaware state or federal court.. Each of the parties hereto agrees that a final judgment in any action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by Law.

(c) Each of the parties hereto irrevocably consents to the service of any summons and complaint and any other process in any other action or proceeding relating to the Acquisition, on behalf of itself or its property, by the personal delivery of copies of such process to such party. Nothing in this Section 10.10 shall affect the right of any party hereto to service legal process in any other manner permitted by Law.

10.11. Waiver of Trial by Jury. EACH PARTY ACKNOWLEDGES AND AGREES THAT ANY CONTROVERSY WHICH MAY ARISE UNDER THIS AGREEMENT IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES, AND THEREFORE EACH SUCH PARTY HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT SUCH PARTY MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LITIGATION DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT, OR THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT.

10.12. Counterparts. This Agreement may be executed in multiple counterparts, and by the different parties hereto in separate counterparts, each of which when executed shall be deemed to be an original but all of which taken together shall constitute one and the same agreement.

* * * * *

[Signature Page Follows]

IN WITNESS WHEREOF, each of the parties hereto has caused this Agreement to be executed as of the date first written above by their respective officers thereunto duly authorized.

HEATWURX, INC.

By: /s/ John P. McGrain
Name: John P. McGrain
Title: Interim President and Chief Executive Officer

PROMET THERAPEUTICS LLC

By: /s/ David Young
Name: David Young
Title: Chief Executive Officer

PROCESSA THERAPEUTICS, LLC

By: /s/ David Young
Name: David Young
Title: David Young

**EXHIBIT A**

**Definitions**

*"Acquisition Proposal"* means any contract, proposal, offer or other indication of interest (whether or not in writing and whether or not delivered to the stockholders of the Company generally) relating to any of the following (other than the transactions contemplated by this Agreement or the Acquisition): (a) any merger, amalgamation, arrangement, share exchange, take-over bid, tender offer, recapitalization, consolidation or other business combination directly or indirectly involving the Company, (b) any acquisition of any business that constitutes 25% or more of the Company's net revenues, net income or stockholders' equity, or assets representing 25% of the book value of the assets of the Company (or any license, lease, long-term supply agreement, exchange, mortgage, pledge or other arrangement having a similar economic effect) in each case in a single transaction or a series of related transactions, (c) any acquisition of beneficial ownership (as defined under Section 13(d) of the Exchange Act) of 25% or more of the capital stock of the Company, or (d) any public announcement of an intention to, do any of the foregoing;

"*Affiliate*" means a person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, another person;

"*Approvals*" means any consent, license, permit, approval, waiver, authorization or order;

*"Beneficial Owner"* a person shall be deemed a "*beneficial owner*" of or to have "beneficial ownership" of capital stock in accordance with the interpretation of the term "beneficial ownership" as defined in Rule 13d-3 under the Exchange Act, as in effect on the date hereof; provided that a person shall be deemed to be the beneficial owner of, and to have beneficial ownership of, capital stock that such person or any affiliate of such person has the right to acquire (whether such right is exercisable immediately or only after the passage of time) pursuant to any agreement, arrangement or understanding or upon the exercise of conversion rights, exchange rights, warrants or options, or otherwise;

"*Business day*" means any day other than a day on which banks in the State of Delaware are authorized or obligated to be closed;

"*Certificates*" shall have the meaning set forth in Section 3.01(e);

"*Change of Recommendation*" shall have the meaning set forth in Section 7.01(c);

"*Change of Recommendation Notice Date*" shall have the meaning set forth in Section 7.01(c);

"*Claim*" shall have the meaning set forth in Section 7.08;

"*Closing*" shall have the meaning set forth in Section 2.02;

"*Closing Date*" shall have the meaning set forth in Section 2.02;

*"Code"* shall mean the Internal Revenue Code of 1986, as amended, and the rules and regulations promulgated thereunder;

*"Company Disclosure Letter"* shall mean a letter of even date herewith delivered by the Company to HUWX prior to the execution of the Agreement and certified by a duly authorized officer of the Company, which identifies exceptions to the Company's representations and warranties contained in Article IV by specific Section and subsection references;

"*Company Financial Statements*" shall have the meaning set forth in Section 4.07;

*"Company Material Adverse Effect"* shall mean any change, effect, event, circumstance or occurrence with respect to the business, condition (financial or otherwise), results of operations, properties, assets, liabilities or obligations of the Company, that is, or could be, material and adverse to the current or future business, condition (financial or otherwise), results of operations, properties, assets, liabilities or obligations of the Company or could prevent or materially delay or impair the Company's ability to perform its obligations under this Agreement;

"*Company Unitholders*" or "*Unitholders*" means the holders of the Common Units of the Company;

"*Company Unitholders' Meeting*" shall have the meaning set forth in Section 7.01(b);

"*Contributed Assets*" shall have the meaning set forth in the Preamble..

"*Control*" (including the terms "controlled," "controlled by" and "under common control with") means the possession, directly or indirectly or as trustee or executor, of the power to direct or cause the direction of the management or policies of a person, whether through the ownership of stock or as trustee or executor, by contract or credit arrangement or otherwise;

*"Court"* shall mean any court or arbitration tribunal of the United States, any foreign country or any domestic or foreign state, and any political subdivision thereof, and shall include the European Court of Justice;

"*Delaware Law*" shall mean the General Corporation Law of the State of Delaware;

"*Effective Time*" shall have the meaning set forth in Section 2.02;

"*ERISA*" shall mean the Employee Retirement Income Security Act of 1974, as amended from time to time, and the Regulations promulgated thereunder;

*"Exchange* Act*"* shall mean the Securities Exchange Act of 1934, as amended, and the Regulations promulgated thereunder;

"*Existing IP Assets*" shall have the meaning set forth in Section 3.04(a).

*"GAAP"* shall mean generally accepted accounting principles in the United States as in effect from time to time;

*"Governmental Entity"* shall mean any governmental agency or authority (including a Court) of the United States, any foreign country, or any domestic or foreign state, and any political subdivision thereof, and shall include any multinational authority having governmental or quasi-governmental powers;

"*Indemnified Parties*" shall have the meaning set forth in Section 7.08;

"*Information Statement*" shall have the meaning set forth in Section 7.01(a);

"*Knowledge*" means the actual knowledge of any officer or director of a Person after reasonable inquiry of the management personnel employed by such Person;

*"Law"* shall mean all laws, statutes and ordinances of the United States, any state of the United States, any foreign country, any foreign state and any political subdivision thereof, including all decisions of Courts having the effect of law in each such jurisdiction;

"*Acquisition*" shall have the meaning set forth in Section 2.01;

"*Acquisition Consideration*" shall have the meaning set forth in Section 3.01(d);

"*Acquisition Shares*" shall have the meaning set forth in Section 3.01(d);

"*HUWX Audited Financial Statements*" shall have the meaning set forth in Section 5.07;

"*HUWX Common Stock*" shall mean the common stock, par value $0.001 per share, of HUWX;

"*HUWX Disclosure Letter*" shall mean a letter of even date herewith delivered by HUWX to the Company prior to the execution of the Agreement and certified by a duly authorized officer of HUWX, which identifies exceptions to HUWX's representations and warranties contained in Article V by specific Section and subsection references;

"*HUWX Financial Statements*" shall have the meaning set forth in Section 5.07;

*"HUWX Material Adverse Effect"* shall mean any change, effect, event, circumstance or occurrence with respect to the business, condition (financial or otherwise), results of operations, properties, assets, liabilities or obligations of HUWX, that is, or could be, material and adverse to the current or future business, condition (financial or otherwise), results of operations, properties, assets, liabilities or obligations of HUWX or could prevent or materially delay or impair HUWX's ability to perform its obligations under this Agreement;

"*HUWX Options*" shall have the meaning set forth in Section 5.04(a)(iii);

"*HUWX Stock Plan*" shall mean the Long-Term Incentive Plan previously adopted by the Board of Directors and approved by HUWX's stockholders as currently in effect;

"*HUWX Stockholders' Meeting*" shall have the meaning set forth in Section 7.01(e);

"*HUWX Unaudited Financial Statements*" shall have the meaning set forth in Section 5.07;

"*Person*" means an individual, corporation, partnership, limited liability company, joint stock company, association, trust, estate, unincorporated organization, other entity or group (as defined in Section 13(d) of the Exchange Act);

"*Plan*" shall mean the agreement for the contribution of assets to HUWX adopted by HUWX prior to the date of this Agreement under which the Company plans to transfer property to HUWX pursuant to a tax-free capital contribution under the provisions of Section 351 of the Code under this Agreement, solely in exchange for HUWX Common Stock except to the extent cash is issued by HUWX to compensate the Company for fractional units payable to such Unitholders.

*"Regulation"* shall mean any rule or regulation of any Governmental Entity having the effect of Law or of any rule or regulation of any self-regulatory organization;

"*Representatives*" shall have the meaning set forth in Section 6.04;

"*Required Company Vote*" shall mean the (i) affirmative vote of the holders of at least a majority of the issued and outstanding Series A Preferred Units and Common Units, voting together, to approve this Agreement and the Acquisition, and (ii) the affirmative vote of the holders of a majority of the issued and outstanding Series A Preferred Units, voting together as a separate class.

*"Securities Act"* shall mean the Securities Act of 1933, as amended, and the Regulations promulgated thereunder;

"*subsidiary*" or "*subsidiaries*" of any Person, means any entity, whether incorporated or unincorporated, of which at least a majority of the securities or ownership interests having by their terms ordinary voting power to elect a majority of the board of directors or other persons performing similar functions is directly or indirectly owned or controlled by such party or by one or more of its respective subsidiaries or by such party and any one or more of its respective subsidiaries;

"*Operating Company*" shall have the meaning set forth in Section 2.01;

"*Tax*" or "*Taxes*" means any and all taxes, charges, fees, levies, assessments, duties or other amounts payable to any federal, state, local or foreign taxing authority or agency, including, without limitation, (A) income, franchise, profits, gross receipts, minimum, alternative minimum, estimated, ad valorem, value added, sales, use, service, real or personal property, capital stock, license, payroll, withholding, disability, employment, social security, workers compensation, unemployment compensation, utility, severance, excise, stamp, windfall profits, transfer and gains taxes, (B) customs, duties, imposts, charges, levies or other similar assessments of any kind, and (C) interest, penalties and additions to Tax imposed with respect thereto;

"*Tax Items*" shall have the meaning set forth in Section 4.19; and

"*Tax Returns*" shall have the meaning set forth in Section 4.19.

"*Units*" shall collectively mean the Common Units and any other outstanding Units of the Company.

**Exhibit 3.1**

**FOURTH AMENDED AND REST A TED CERTIFICATE OF INCORPORATION**

**OF**

**HEATWURX, INC.**

Heatwurx, Inc, (hereinafter called the "Corporation"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware, does hereby certify as follows:

1. The name of the corporation is Heatwurx, Inc. The date of the filing of its original Certificate of Incorporation with the Secretary of State of the State of Delaware was March 29, 2011. The Certificate of Incorporation was restated on April 15, 2011, October 25, 2011, and July 24, 2012, was amended on June 28, 2011, and June 21, 2013.

2. This Fourth Amended and Restated Certificate of Incorporation was duly adopted by the board of directors and the stockholders of the Corporation in accordance with the applicable provisions of Sections 141,228,242 and 245 of the General Corporation Law of the State of Delaware.

3. This Fourth Amended and Restated Certificate of Incorporation amends and restates the current Restated Certificate of Incorporation, and the text of the Restated Certificate of Incorporation is hereby amended and restated to read as herein set forth in full:

FIRST: The name of the Corporation is: Heatwurx, Inc.

SECOND: The address of the Corporation's registered office in the State of Delaware is 160 Greentree Drive, Suite 101, City of Dover, County of Kent, Delaware 19904. The name of its registered agent at such address is National Registered Agents, Inc.

THIRD: The nature of the business or purposes to be conducted or promoted by the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of Delaware.

FOURTH: The total number of shares of all classes of stock which the Corporation shall have authority to issue is (i) 350,000,000 shares of Common Stock, $0.0001 par value per share ("Common Stock") and (ii) 10,000,000 shares of Preferred Stock, $0.000 I par value per share ("Preferred Stock").

The following is a statement of the designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation.

A. COMMON STOCK.

1. General. The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights ofthe holders of the Preferred Stock of any series as may be designated by the Board of Directors upon any issuance of the Preferred Stock of any series.

2. Voting. The holders of the Common Stock shall have voting rights at all meetings of stockholders, each such holder being entitled to one vote for each share thereof held by such holder; provided, however, that, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Certificate of Incorporation (which, as used herein, shall mean the certificate of incorporation of the Corporation, as amended from time to time, including the terms of any certificate of designations of any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon pursuant to this Certificate of Incorporation. There shall be no cumulative voting.

**State of Delaware**
**Secretary of State**
**Division of Corporations**
**Delivered 10:51 AM 09/27/2017**
**FILED 10:51 AM 09/27/2017**
**SR 20176357090 - File Number 4961094**

The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(bX2) of the General Corporation Law of the State of Delaware.

3. Dividends. Dividends may be declared and paid on the Common Stock from funds lawfully available therefor as and when determined by the Board of Directors and subject to any preferential dividend or other rights of any then outstanding Preferred Stock.

4. Liquidation. Upon the dissolution or liquidation of the Corporation, whether voluntary or involuntary, holders of Common Stock will be entitled to receive all assets of the Corporation available for distribution to its stockholders, subject to any preferential or other rights of any then outstanding Preferred Stock.

B. PREFERRED STOCK.

Preferred Stock may be issued from time to time in one or more series, each of such series to have such terms as stated or expressed herein and in the resolution or resolutions providing for the issue of such series adopted by the Board of Directors of the Corporation as hereinafter provided. Any shares of Preferred Stock which may be redeemed, purchased or acquired by the Corporation may be reissued except as otherwise provided by law.

Authority is hereby expressly granted to the Board of Directors from time to time to issue the Preferred Stock in one or more series, and in connection with the creation of any such series, by adopting, a resolution or resolutions providing for the issuance of the shares thereof and by filing a certificate of designations relating thereto in accordance with the General Corporation Law of the State of Delaware, to determine and fix the number of shares of such series and such voting powers, full or limited, or no voting powers, and such designations, preferences and relative participating, optional or other special rights, and qualifications, limitations or restrictions thereof, including without limitation thereof, dividend rights, conversion rights, redemption privileges and liquidation preferences, as shall be stated and expressed in such resolutions, as to the full extent now or hereafter permitted by the General Corporation Law of the State of Delaware. Without limiting the generality of the foregoing, the resolutions providing for issuance of any series of Preferred Stock may provide that such series shall be superior or rank equally or be junior to any other series of Preferred Stock to the extent permitted by law.

The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares then outstanding) by the affirmative vote of the holders of a majority of the voting power of the capital stock of the Corporation entitled to vote thereon, voting as a single class, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law of the State of Delaware.

FIFTH: In furtherance of and not in limitation of powers conferred by statute, it is further provided:

1. The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors.
2. Election of directors need not be by written ballot.
3. The Board of Directors is expressly authorized to adopt., amend, alter or repeal the By-Laws of the Corporation.

SIXTH: Except to the extent that the General Corporation Law of Delaware prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty, no director of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability. No amendment to or repeal of this provision shall apply to or have any effect on the liability or alleged liability of any director or the Corporation for or with respect to any acts or omissions of such director occurring prior to such amendment.

SEVENTH: The Corporation shall, to the fullest extent permitted by Section 145 of the General Corporation Law of Delaware, as amended from time to time, indemnify each person who was or is a party or is

threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fuct that he or she is or was, or has agreed to become, a director or officer of the Corporation, or is or was serving, or has agreed to serve, at the request of the Corporation, as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan) (all such persons being referred to hereafter as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees),judgments, fines and amounts paid in settlement actually and reasonably incurred by or on behalf of an Indemnitee in connection with such action, suit or proceeding and any appeal therefrom.

As a condition precedent to an Indemnitee's right to be indemnified, the Indemnitee must notify the Corporation in writing as soon as practicable of any action, suit, proceeding or investigation involving such Indemnitee for which indemnity will or could be sought. With respect to any action, suit, proceeding or investigation of which the Corporation is so notified, the Corporation will be entitled to participate therein at its own expense and/or to assume the defense thereof at its own expense, with legal counsel reasonably acceptable to the Indemnitee.

In the event that the Corporation does not assume the defense of any action, suit, proceeding or investigation of which the Corporation receives notice under this Article, the Corporation shall pay in advance of the final disposition of such matter any expenses (including attorneys' fees) incurred by an Indemnitee in defending a civil or criminal action, suit, proceeding or investigation or any appeal therefrom; provided, however, that the payment of such expenses incurred by an Indemnitee in advance of the final disposition of such matter shall be made only upon receipt of an undertaking by or on behalf of the Indemnitee to repay all amounts so advanced in the event that it shall ultimately be determined that the Indemnitee is not entitled to be indemnified by the Corporation as authorized in this Article, which undertaking shall be accepted without reference to the financial ability of the Indemnitee to make such repayment; and further provided that no such advancement of expenses shall be made under this Article ifit is determined that (i) the Indemnitee did not act in good fuith and in a manner he reasonably believed to be in, or not opposed to, the best interests of the Corporation, or (ii) with respect to any criminal action or proceeding, the Indemnitee had reasonable cause to believe his conduct was unlawful.

The Corporation shall not indemnity an Indemnitee pursuant to this Article in connection with a proceeding (or part thereof) initiated by such Indemnitee unless the initiation thereof was approved by the Board of Directors of the Corporation. In addition, the Corporation shall not indemnity an Indemnitee to the extent such Indemnitee is reimbursed from the proceeds of insurance, and in the event the Corporation makes any indemnification payments to an Indemnitee and such Indemnitee is subsequently reimbursed from the proceeds of insurance, such Indemnitee shall promptly refund such indemnilication payments to the Corporation to the extent of such insurance reimbursement.

All determinations hereunder as to the entitlement of an Indemnitee to indemnification or advancement of expenses shall be made in each instance (a) by a majority vote of the directors of the Corporation consisting of persons who are not at that time parties to the action, suit or proceeding in question "disinterested directors"), whether or not a quorum, (b) by a committee of disinterested directors designated by majority vote of disinterested directors, whether or not a quorum, (e) if there are no disinterested directors, or if the disinterested directors so direct, by independent legal counsel (who may, to the extent permitted by law, be regular legal counsel to the Corporation) in a written opinion, or (d) by the stockholders of the Corporation.

The rights provided in this Article (i) shall not be deemed exclusive of any other rights to which an Indemnitee may be entitled under any law, agreement or vote of stockholders or disinterested directors or otherwise, and (ii) shall inure to the benefit of the heirs, executors and administrators of the Indemnitees. The Corporation may, to the extent authorized from time to time by its Board of Directors, grant indemnification rights to other employees or agents of the Corporation or other persons serving the Corporation and such rights may be equivalent to, or greater or less than, those set forth in th.is Article.

EIGHTH: The Corporation reserves the right to amend, aiter, change or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by statute and this Certificate of Incorporation, and all rights conferred upon stockholders herein are granted subject to this reservation.

EXECUTED on September 26, 2017

*/s/ John P. McGrain*
By: John P. McGrain
Title: President

**Exhibit 3.1.1**

AMENDMENT TO FOURTH AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

OF

HEATWURX, INC.

Heatwurx, Inc. (hereinafter called the "Corporation"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware, does hereby certify as follows:

I. The name of the corporation is Heatwurx, Inc. The date of the filing of its original Certificate of Incorporation with the Secretary of State of the State of Delaware was March 29, 2011. The Certificate of Incorporation was restated on April 15, 2011, October 25, 2011, and July 24, 2012, was amended on June 28, 2011, and June 21, 2013, and restated and amended on September 27, 2017.

2. This Amendment to the Fourth Amended and Restated Certificate of Incorporation was duly adopted by the board of directors and the stockholders of the Corporation in accordance with the applicable provisions of Sections 141, 228 and 242 of the General Corporation Law of the State of Delaware.

3. This Amendment to the Fourth Amended and Restated Certificate of Incorporation amends the text of the Article First and adds Article Ninth to read as herein set forth in full:

FIRST: The name of the Corporation is: Processa Pharmaceuticals, Inc.,

NINTH: Upon the filing of this Amendment to the Fourth Amended and Restated Certificate of Incorporation, each seven (7) shares of the Corporation's Common Stock, par value, $0.0001 per share, issued and outstanding immediately prior to the effective time, shall automatically be reclassified and converted into one (1) validly issued, fully paid and non-assessable share of Common Stock, par value $0.0001 per share, of the Corporation, without any action by any holder thereof.

EXECUTED on October 23, 2017

By: */s/ Wendy Guy*
Name: Wendy Guy
Title: Secretary



**State of Delaware**
**Secretary of State**
**Division of Corporations**
**Delivered 03:48 PM l0/23/17**
**FILED 03:48 PM l0/23/17**
**SR 20176743786 - File Number 4961094**

**APPENDIX A**

**CERTIFICATE OF AMENDMENT**
**TO**
**FOURTH AMENDED AND RESTATED CERTIFICATE OF INCORPORATION**
**OF**
**PROCESSA PHARMACEUTICALS, INC.**
**(a Delaware corporation)**

Processa Pharmaceuticals, Inc. (the "Corporation"), a corporation organized and existing under the General Corporation Law of the State of Delaware (the "DGCL"), hereby certifies as follows:

1. This Certificate of Amendment (the "Certificate of Amendment") amends the provisions of the Corporation's Fourth Amended and Restated Certificate of Incorporation filed with the Secretary of State on September 27, 2017 and amended on October 23, 2017 (the "Certificate of Incorporation").

2. The Board of Directors of the Corporation has duly adopted a resolution pursuant to Section 242 of the DGCL setting forth a proposed amendment to the Certificate of Incorporation and declaring said amendment to be advisable. The amendment amends the Certificate of Incorporation as follows:

The FOURTH paragraph of the Certificate of Incorporation is hereby deleted in its entirety and replaced with the following:

FOURTH: The total number of shares of all classes of stock which the Corporation shall have authority to issue is (i) 100,000,000 shares of Common Stock, $0.0001 par value per share ("Common Stock") and (ii) 1,000,000 shares of Preferred Stock, $0.0001 par value per share ("Preferred Stock").

The following is a statement of the designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation.

A. COMMON STOCK

1. General. The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights of the holders of the Preferred Stock of any series as may be designated by the Board of Directors upon any issuance of the Preferred Stock of any series.

2. Voting. The holders of the Common Stock shall have voting rights at all meetings of stockholders, each such holder being entitled to one vote for each share thereof held by such holder; provided, however, that, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Certificate of Incorporation (which, as used herein, shall mean the certificate of incorporation of the Corporation, as amended from time to time, including the terms of any certificate of designations of any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon pursuant to this Certificate of Incorporation. There shall be no cumulative voting.

   The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law of the State of Delaware.

3. Dividends. Dividends may be declared and paid on the Common Stock from funds lawfully available therefor as and when determined by the Board of Directors and subject to any preferential dividend or other rights of any then outstanding Preferred Stock.

4. Liquidation. Upon the dissolution or liquidation of the Corporation, whether voluntary or involuntary, holders of Common Stock will be entitled to receive all assets of the Corporation available for distribution to its stockholders, subject to any preferential or other rights of any then outstanding Preferred Stock.

B. PREFERRED STOCK

Preferred Stock may be issued from time to time in one or more series, each of such series to have such terms as stated or expressed herein and in the resolution or resolutions providing for the issue of such series adopted by the Board of Directors of the Corporation as hereinafter provided. Any shares of Preferred Stock which may be redeemed, purchased or acquired by the Corporation may be reissued except as otherwise provided by law.

Authority is hereby expressly granted to the Board of Directors from time to time to issue the Preferred Stock in one or more series, and in connection with the creation of any such series, by adopting, a resolution or resolutions providing for the issuance of the shares thereof and by filing a certificate of designations relating thereto in accordance with the General Corporation Law of the State of Delaware, to determine and fix the number of shares of such series and such voting powers, full or limited, or no voting powers, and such designations, preferences and relative participating, optional or other special rights, and qualifications, limitations or restrictions thereof, including without limitation thereof, dividend rights, conversion rights, redemption privileges and liquidation preferences, as shall be stated and expressed in such resolutions, as to the full extent now or hereafter permitted by the General Corporation Law of the State of Delaware. Without limiting the generality of the foregoing, the resolutions providing for issuance of any series of Preferred Stock may provide that such series shall be superior or rank equally or be junior to any other series of Preferred Stock to the extent permitted by law.

The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares then outstanding) by the affirmative vote of the holders of a majority of the voting power of the capital stock of the Corporation entitled to vote thereon, voting as a single class, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law of the State of Delaware.

3. The requisite stockholders of the Corporation have duly approved this Certificate of Amendment in accordance with Section 242 of the DGCL.

4. This Certificate of Amendment shall be effective at 5:00 p.m. Eastern Time on [ , 2019].

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Amendment to be executed as of the date set forth below.

Dated: [_____,2019]

**PROCESSA PHARMACEUTICALS, INC.**

By: _____
Name: David Young
Title: Chief Executive Officer

**APPENDIX A**

**CERTIFICATE OF AMENDMENT**
**TO**
**FOURTH AMENDED AND RESTATED CERTIFICATE OF INCORPORATION**
**OF**
**PROCESSA PHARMACEUTICALS, INC.**
**(a Delaware corporation)**

Processa Pharmaceuticals, Inc. (the "Corporation"), a corporation organized and existing under the General Corporation Law of the State of Delaware (the "DGCL"), hereby certifies as follows:

1. This Certificate of Amendment (the "Certificate of Amendment") amends the provisions of the Corporation's Fourth Amended and Restated Certificate of Incorporation filed with the Secretary of State of the State of Delaware on September 27, 2017, as amended on October 23, 2017, as amended on August 12, 2019, and as amended on December 23, 2019 (the "Certificate of Incorporation").

2. The Board of Directors of the Corporation has duly adopted a resolution pursuant to Section 242 of the DGCL setting forth a proposed amendment to the Certificate of Incorporation and declaring said amendment to be advisable. The Certificate of Amendment amends the Certificate of Incorporation as follows:

The FOURTH paragraph of the Certificate of Incorporation is hereby deleted in its entirety and replaced with the following:

FOURTH: The total number of shares of all classes of stock which the Corporation shall have authority to issue is (i) 30,000,000 shares of Common Stock, $0.0001 par value per share ("Common Stock") and (ii) 1,000,000 shares of Preferred Stock, $0.0001 par value per share ("Preferred Stock").

The following is a statement of the designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation.

A. COMMON STOCK

1. General. The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights of the holders of the Preferred Stock of any series as may be designated by the Board of Directors upon any issuance of the Preferred Stock of any series.

2. Voting. The holders of the Common Stock shall have voting rights at all meetings of stockholders, each such holder being entitled to one vote for each share thereof held by such holder; provided, however, that, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Certificate of Incorporation (which, as used herein, shall mean the certificate of incorporation of the Corporation, as amended from time to time, including the terms of any certificate of designations of any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon pursuant to this Certificate of Incorporation. There shall be no cumulative voting.

   The number of authorized shares of Common Stock may be increased or decreased (but not below the number of share thereof then outstanding) by the affirmative vote of the holders of a majority of the stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law of the State of Delaware.

3. Dividends. Dividends may be declared and paid on the Common Stock from funds lawfully available therefor as and when determined by the Board of Directors and subject to any preferential dividend or other rights of any then outstanding Preferred Stock.

4. Liquidation. Upon the dissolution or liquidation of the Corporation, whether voluntary or involuntary, holders of Common Stock will be entitled to receive all assets of the Corporation available for distribution to its stockholders, subject to any preferential or other rights of any then outstanding Preferred Stock.

B. PREFERRED STOCK

Preferred Stock may be issued from time to time in one or more series, each of such series to have such terms as stated or expressed herein and in the resolution or resolutions providing for the issue of such series adopted by the Board of Directors of the Corporation as hereinafter provided. Any shares of Preferred Stock which may be redeemed, purchased or acquired by the Corporation may be reissued except as otherwise provided by law.

Authority is hereby expressly granted to the Board of Directors from time to time to issue the Preferred Stock in one or more series, and in connection with the creation of any such series, by adopting, a resolution or resolutions providing for the issuance of the shares thereof and by filing a certificate of designations relating thereto in accordance with the General Corporation Law of the State of Delaware, to determine and fix the number of shares of such series and such voting powers, full or limited, or no voting powers, and such designations, preferences and relative participating, optional or other special rights, and qualifications, limitations or restrictions thereof, including without limitation thereof, dividend rights, conversion rights, redemption privileges and liquidation preferences, as shall be stated and expressed in such resolutions, as to the full extent now or hereafter permitted by the General Corporation Law of the State of Delaware. Without limiting the generality of the foregoing, the resolutions providing for issuance of any series of Preferred Stock may provide that such series shall be superior or rank equally or be junior to any other series of Preferred Stock to the extent permitted by law.

The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares then outstanding) by the affirmative vote of the holders of a majority of the voting power of the capital stock of the Corporation entitled to vote thereon, voting as a single class, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law of the State of Delaware.

3. The requisite stockholders of the Corporation have duly approved this Certificate of Amendment in accordance with Section 242 of the DGCL.

4. This Certificate of Amendment shall be effective at 5:00 p.m. Eastern Time on [●], 2020.

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Amendment to be executed as of the date set forth below.

Dated: [_____,2020]

**PROCESSA PHARMACEUTICALS, INC.**

By: _____
Name: David Young
Title: Chief Executive Officer

**Exhibit 3.1.4**

**CERTIFICATE OF AMENDMENT**
**TO**
**FOURTH AMENDED AND RESTATED CERTIFICATE OF INCORPORATION**
**OF**
**PROCESSA PHARMACEUTICALS, INC.**
**(a Delaware corporation)**

Processa Pharmaceuticals, Inc. (the "Corporation"), a corporation organized and existing under the General Corporation Law of the State of Delaware (the "DGCL"), hereby certifies as follows:

1. This Certificate of Amendment (the "Certificate of Amendment") amends the provisions of the Corporation's Fourth Amended and Restated Certificate of Incorporation filed with the Secretary of State of the State of Delaware on September 27, 2017, as amended on October 23, 2017, as amended on August 12, 2019, and as amended on December 23, 2019 (the "Certificate of Incorporation").

2. The Board of Directors of the Corporation has duly adopted a resolution pursuant to Section 242 of the DGCL setting forth a proposed amendment to the Certificate of Incorporation and declaring said amendment to be advisable. The Certificate of Amendment amends the Certificate of Incorporation as follows:

The FOURTH paragraph of the Certificate of Incorporation is hereby deleted in its entirety and replaced with the following:

FOURTH: The total number of shares of all classes of stock which the Corporation shall have authority to issue is (i) 30,000,000 shares of Common Stock, $0.0001 par value per share ("Common Stock") and (ii) 1,000,000 shares of Preferred Stock, $0.0001 par value per share ("Preferred Stock").

The following is a statement of the designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation.

A. COMMON STOCK

1. General. The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights of the holders of the Preferred Stock of any series as may be designated by the Board of Directors upon any issuance of the Preferred Stock of any series.

2. Voting. The holders of the Common Stock shall have voting rights at all meetings of stockholders, each such holder being entitled to one vote for each share thereof held by such holder; provided, however, that, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Certificate of Incorporation (which, as used herein, shall mean the certificate of incorporation of the Corporation, as amended from time to time, including the terms of any certificate of designations of any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon pursuant to this Certificate of Incorporation. There shall be no cumulative voting.

   The number of authorized shares of Common Stock may be increased or decreased (but not below the number of share thereof then outstanding) by the affirmative vote of the holders of a majority of the stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law of the State of Delaware.

3. Dividends. Dividends may be declared and paid on the Common Stock from funds lawfully available therefor as and when determined by the Board of Directors and subject to any preferential dividend or other rights of any then outstanding Preferred Stock.

4. Liquidation. Upon the dissolution or liquidation of the Corporation, whether voluntary or involuntary, holders of Common Stock will be entitled to receive all assets of the Corporation available for distribution to its stockholders, subject to any preferential or other rights of any then outstanding Preferred Stock.

B. PREFERRED STOCK

Preferred Stock may be issued from time to time in one or more series, each of such series to have such terms as stated or expressed herein and in the resolution or resolutions providing for the issue of such series adopted by the Board of Directors of the Corporation as hereinafter provided. Any shares of Preferred Stock which may be redeemed, purchased or acquired by the Corporation may be reissued except as otherwise provided by law.

Authority is hereby expressly granted to the Board of Directors from time to time to issue the Preferred Stock in one or more series, and in connection with the creation of any such series, by adopting, a resolution or resolutions providing for the issuance of the shares thereof and by filing a certificate of designations relating thereto in accordance with the General Corporation Law of the State of Delaware, to determine and fix the number of shares of such series and such voting powers, full or limited, or no voting powers, and such designations, preferences and relative participating, optional or other special rights, and qualifications, limitations or restrictions thereof, including without limitation thereof, dividend rights, conversion rights, redemption privileges and liquidation preferences, as shall be stated and expressed in such resolutions, as to the full extent now or hereafter permitted by the General Corporation Law of the State of Delaware. Without limiting the generality of the foregoing, the resolutions providing for issuance of any series of Preferred Stock may provide that such series shall be superior or rank equally or be junior to any other series of Preferred Stock to the extent permitted by law.

The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares then outstanding) by the affirmative vote of the holders of a majority of the voting power of the capital stock of the Corporation entitled to vote thereon, voting as a single class, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law of the State of Delaware.

3. The requisite stockholders of the Corporation have duly approved this Certificate of Amendment in accordance with Section 242 of the DGCL.

4. This Certificate of Amendment shall be effective at 5:00 p.m. Eastern Time on June 25, 2020.

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Amendment to be executed as of the date set forth below.

Dated: June 25, 2020

**PROCESSA PHARMACEUTICALS, INC.**

By: */s/ James Stanker*
Name: James Stanker
Title: Chief Financial Officer

# AMENDED AND RESTATED BYLAWS

# OF

# HEATWURX, INC.
# (A DELAWARE CORPORATION)

Adopted: October 22, 2012
Date

Amended: June 20, 2013

## TABLE OF CONTENTS

**AMENDED AND RESTATED BYLAWS**

**OF**

**HEATWURX, INC.**
**(A DELAWARE CORPORATION)**

## ARTICLE I

## OFFICES

**Section 1. Registered Office.** The registered office of the corporation in the State of Delaware shall be in the City of Dover, County of Kent.

**Section 2. Other Offices.** The corporation shall also have and maintain an office or principal place of business at such place as may be fixed by the Board of Directors, and may also have offices at such other places, both within and without the State of Delaware as the Board of Directors may from time to time determine or the business of the corporation may require.

## ARTICLE II

## CORPORATE SEAL

**Section 3. Corporate Seal.** The Board of Directors may adopt a corporate seal. The corporate seal shall consist of a die bearing the name of the corporation and the inscription, "Corporate Seal-Delaware." Said seal may be used by causing it or a facsimile thereof to be impressed or affixed or reproduced or otherwise.

## ARTICLE III

## STOCKHOLDERS' MEETINGS

**Section 4. Place Of Meetings.** Meetings of the stockholders of the corporation may be held at such place, either within or without the State of Delaware, as may be determined from time to time by the Board of Directors. The Board of Directors may, in its sole discretion, determine that the meeting shall not be held at any place, but may instead be held solely by means of remote communication as provided under the Delaware General Corporation Law ("**DGCL**").

**Section 5. Annual Meetings.**

**(a)** The annual meeting of the stockholders of the corporation, for the purpose of election of directors and for such other business as may properly come before it, shall be held on such date and at such time as may be designated from time to time by the Board of Directors. Nominations of persons for election to the Board of Directors of the corporation and the proposal of business to be considered by the stockholders may be made at an annual meeting of stockholders: (i) pursuant to the corporation's notice of meeting of stockholders (with respect to business other than nominations); (ii) brought specifically by or at the direction of the Board of Directors; or (iii) by any stockholder of the corporation who was a stockholder of record at the time of giving the stockholder's notice provided for in Section 5(b) below, who is entitled to vote at the meeting and who complied with the notice procedures set forth in Section 5. For the avoidance of doubt, clause (iii) above shall be the exclusive means for a stockholder to make nominations and submit other business (other than matters properly included in the corporation's notice of meeting of stockholders and proxy statement under Rule 14a-8 under the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (the "**1934 Act**")) before an annual meeting of stockholders.

**(b)** At an annual meeting of the stockholders, only such business shall be conducted as is a proper matter for stockholder action under Delaware law and as shall have been properly brought before the meeting in accordance with the procedures below.

**(i)** For nominations for the election to the Board of Directors to be properly brought before an annual meeting by a stockholder pursuant to clause (iii) of Section 5(a) of these Bylaws, the stockholder must deliver written notice to the Secretary at the principal executive offices of the corporation on a timely basis as set forth in Section 5(b)(iii) and must update and supplement such written notice on a timely basis as set forth in Section 5(c). Such stockholder's notice shall set forth: (A) as to each nominee such stockholder proposes to nominate at the meeting: (1) the name, age, business address and residence address of such nominee, (2) the principal occupation or employment of such nominee, (3) the class and number of shares of each class of capital stock of the corporation that are owned of record and beneficially by such nominee, (4) the date or dates on which such shares were acquired and the investment intent of such acquisition, (5) with respect to each nominee for election or re-election to the Board of Directors, include a completed and signed questionnaire, representation and agreement required by Section 5(e) of these Bylaws, and (6) such other information concerning such nominee as would be required to be disclosed in a proxy statement soliciting proxies for the election of such nominee as a director in an election contest (even if an election contest is not involved), or that is otherwise required to be disclosed pursuant to Section 14 of the 1934 Act and the rules and regulations promulgated thereunder (including such person's written consent to being named as a nominee and to serving as a director if elected); and (B) the information required by Section 5(b)(iv). The corporation may require any proposed nominee to furnish such other information as it may reasonably require to determine the eligibility of such proposed nominee to serve as an independent director of the corporation or that could be material to a reasonable stockholder's understanding of the independence, or lack thereof, of such proposed nominee.

**(ii)** Other than proposals sought to be included in the corporation's proxy materials pursuant to Rule 14(a)-8 under the 1934 Act, for business other than nominations for the election to the Board of Directors to be properly brought before an annual meeting by a stockholder pursuant to clause (iii) of Section 5(a) of these Bylaws, the stockholder must deliver written notice to the Secretary at the principal executive offices of the corporation on a timely basis as set forth in Section 5(b)(iii), and must update and supplement such written notice on a timely basis as set forth in Section 5(c). Such stockholder's notice shall set forth: (A) as to each matter such stockholder proposes to bring before the meeting, a brief description of the business desired to be brought before the meeting, the reasons for conducting such business at the meeting, and any material interest (including any anticipated benefit of such business to any Proponent (as defined below) other than solely as a result of its ownership of the corporation's capital stock, that is material to any Proponent individually, or to the Proponents in the aggregate) in such business of any Proponent; and (B) the information required by Section 5(b)(iv).

**(iii)** To be timely, the written notice required by Section 5(b)(i) or 5(b)(ii) must be received by the Secretary at the principal executive offices of the corporation not later than the close of business on the ninetieth ($90^{th}$) day nor earlier than the close of business on the one hundred twentieth ($120^{th}$) day prior to the first anniversary of the preceding year's annual meeting; *provided, however,* that, subject to the last sentence of this Section 5(b)(iii), in the event that the date of the annual meeting is advanced more than thirty (30) days prior to or delayed by more than thirty (30) days after the anniversary of the preceding year's annual meeting, notice by the stockholder to be timely must be so received not earlier than the close of business on the one hundred twentieth ($120^{th}$) day prior to such annual meeting and not later than the close of business on the later of the ninetieth ($90^{th}$) day prior to such annual meeting or the tenth ($10^{th}$) day following the day on which public announcement of the date of such meeting is first made. In no event shall an adjournment or a postponement of an annual meeting for which notice has been given, or the public announcement thereof has been made, commence a new time period for the giving of a stockholder's notice as described above.

**(iv)** The written notice required by Section 5(b)(i) or 5(b)(ii) shall also set forth, as of the date of the notice and as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination or proposal is made (each, a "**Proponent**" and collectively, the "**Proponents**"): (A) the name and address of each Proponent, as they appear on the corporation's books; (B) the class, series and number of shares of the corporation that are owned beneficially and of record by each Proponent; (C) a description of any agreement, arrangement or understanding (whether oral or in writing) with respect to such nomination or proposal between or among any Proponent and any of its affiliates or associates, and any others (including their names) acting in concert, or otherwise under the agreement, arrangement or understanding, with any of the foregoing; (D) a representation that the Proponents are holders of record or beneficial owners, as the case may be, of shares of the corporation entitled to vote at the meeting and intend to appear in person or by proxy at the meeting to nominate the person or persons specified in the notice (with respect to a notice under Section 5(b)(i)) or to propose the business that is specified in the notice (with respect to a notice under Section 5(b)(ii)); (E) a representation as to whether the Proponents intend to deliver a proxy statement and form of proxy to holders of a sufficient number of holders of the corporation's voting shares to elect such nominee or nominees (with respect to a notice under Section 5(b)(i)) or to carry such proposal (with respect to a notice under Section 5(b)(ii)); (F) to the extent known by any Proponent, the name and address of any other stockholder supporting the proposal on the date of such stockholder's notice; and (G) a description of all Derivative Transactions (as defined below) by each Proponent during the previous twelve (12) month period, including the date of the transactions and the class, series and number of securities involved in, and the material economic terms of, such Derivative Transactions.

For purposes of Sections 5 and 6, a "**Derivative Transaction**" means any agreement, arrangement, interest or understanding entered into by, or on behalf or for the benefit of, any Proponent or any of its affiliates or associates, whether record or beneficial:

(w) the value of which is derived in whole or in part from the value of any class or series of shares or other securities of the corporation,

(x) that otherwise provides any direct or indirect opportunity to gain or share in any gain derived from a change in the value of securities of the corporation,

(y) the effect or intent of which is to mitigate loss, manage risk or benefit of security value or price changes, or

(z) that provides the right to vote or increase or decrease the voting power of, such Proponent, or any of its affiliates or associates, with respect to any securities of the corporation,

which agreement, arrangement, interest or understanding may include, without limitation, any option, warrant, debt position, note, bond, convertible security, swap, stock appreciation right, short position, profit interest, hedge, right to dividends, voting agreement, performance-related fee or arrangement to borrow or lend shares (whether or not subject to payment, settlement, exercise or conversion in any such class or series), and any proportionate interest of such Proponent in the securities of the corporation held by any general or limited partnership, or any limited liability company, of which such Proponent is, directly or indirectly, a general partner or managing member.

**(c)** A stockholder providing written notice required by Section 5(b)(i) or (ii) shall update and supplement such notice in writing, if necessary, so that the information provided or required to be provided in such notice is true and correct in all material respects as of (i) the record date for the meeting and (ii) the date that is five (5) business days prior to the meeting and, in the event of any adjournment or postponement thereof, five (5) business days prior to such adjourned or postponed meeting. In the case of an update and supplement pursuant to clause (i) of this Section 5(c), such update and supplement shall be received by the Secretary at the principal executive offices of the corporation not later than five (5) business days after the record date for the meeting. In the case of an update and supplement pursuant to clause (ii) of this Section 5(c), such update and supplement shall be received by the Secretary at the principal executive offices of the corporation not later than two (2) business days prior to the date for the meeting, and, in the event of any adjournment or postponement thereof, two (2) business days prior to such adjourned or postponed meeting.

**(d)** Notwithstanding anything in Section 5(b)(iii) to the contrary, in the event that the number of directors of the Board of Directors of the corporation is increased and there is no public announcement of the appointment of a director, or, if no appointment was made, of the vacancy, made by the corporation at least ten (10) days before the last day a stockholder may deliver a notice of nomination in accordance with Section 5(b)(iii), a stockholder's notice required by this Section 5 and that complies with the requirements in Section 5(b)(i), other than the timing requirements in Section 5(b)(iii), shall also be considered timely, but only with respect to nominees for any new positions created by such increase, if it shall be received by the Secretary at the principal executive offices of the corporation not later than the close of business on the tenth (10th) day following the day on which such public announcement is first made by the corporation.

**(e)** To be eligible to be a nominee for election or re-election as a director of the corporation pursuant to a nomination under clause (iii) of Section 5(a), such proposed nominee or a person on such proposed nominee's behalf must deliver (in accordance with the time periods prescribed for delivery of notice under Section 5(b)(iii) or 5(d), as applicable) to the Secretary at the principal executive offices of the corporation a written questionnaire with respect to the background and qualification of such proposed nominee and the background of any other person or entity on whose behalf the nomination is being made (which questionnaire shall be provided by the Secretary upon written request) and a written representation and agreement (in the form provided by the Secretary upon written request) that such person (i) is not and will not become a party to (A) any agreement, arrangement or understanding with, and has not given any commitment or assurance to, any person or entity as to how such person, if elected as a director of the corporation, will act or vote on any issue or question (a "**Voting Commitment**") that has not been disclosed to the corporation in the questionnaire or (B) any Voting Commitment that could limit or interfere with such person's ability to comply, if elected as a director of the corporation, with such person's fiduciary duties under applicable law; (ii) is not and will not become a party to any agreement, arrangement or understanding with any person or entity other than the corporation with respect to any direct or indirect compensation, reimbursement or indemnification in connection with service or action as a director of the corporation that has not been disclosed therein; and (iii) in such person's individual capacity and on behalf of any person or entity on whose behalf the nomination is being made, would be in compliance, if elected as a director of the corporation, and will comply with, all applicable publicly disclosed corporate governance, conflict of interest, confidentiality and stock ownership and trading policies and guidelines of the corporation.

**(f)** A person shall not be eligible for election or re-election as a director unless the person is nominated either in accordance with clause (ii) of Section 5(a), or in accordance with clause (iii) of Section 5(a). Except as otherwise required by law, the chairman of the meeting shall have the power and duty to determine whether a nomination or any business proposed to be brought before the meeting was made, or proposed, as the case may be, in accordance with the procedures set forth in these Bylaws and, if any proposed nomination or business is not in compliance with these Bylaws, or the Proponent does not act in accordance with the representations in Sections 5(b)(iv)(D) and 5(b)(iv)(E), to declare that such proposal or nomination shall not be presented for stockholder action at the meeting and shall be disregarded, notwithstanding that proxies in respect of such nominations or such business may have been solicited or received.

**(g)** Notwithstanding the foregoing provisions of this Section 5, in order to include information with respect to a stockholder proposal in the proxy statement and form of proxy for a stockholders' meeting, a stockholder must also comply with all applicable requirements of the 1934 Act and the rules and regulations thereunder. Nothing in these Bylaws shall be deemed to affect any rights of stockholders to request inclusion of proposals in the corporation's proxy statement pursuant to Rule 14a-8 under the 1934 Act; *provided, however,* that any references in these Bylaws to the 1934 Act or the rules and regulations thereunder are not intended to and shall not limit the requirements applicable to proposals and/or nominations to be considered pursuant to Section 5(a)(iii) of these Bylaws.

**(h)** For purposes of Sections 5 and 6,

**(i)** "**public announcement**" shall mean disclosure in a press release reported by the Dow Jones News Service, Associated Press or comparable national news service or in a document publicly filed by the corporation with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the 1934 Act; and

**(ii)** "**affiliates**" and "**associates**" shall have the meanings set forth in Rule 405 under the Securities Act of 1933, as amended (the "1933 Act").

**Section 6. Special Meetings.**

**(a)** Special meetings of the stockholders of the corporation may be called, for any purpose as is a proper matter for stockholder action under Delaware law, by (i) the Chairman of the Board of Directors, (ii) the Chief Executive Officer, or (iii) the Board of Directors pursuant to a resolution adopted by a majority of the authorized number of directors (whether or not there exist any vacancies in previously authorized directorships at the time any such resolution is presented to the Board of Directors for adoption).

**(b)** The Board of Directors shall determine the time and place, if any, of such special meeting. Upon determination of the time and place, if any, of the meeting, the Secretary shall cause a notice of meeting to be given to the stockholders entitled to vote, in accordance with the provisions of Section 7 of these Bylaws. No business may be transacted at such special meeting otherwise than specified in the notice of meeting.

**(c)** Nominations of persons for election to the Board of Directors may be made at a special meeting of stockholders at which directors are to be elected (i) by or at the direction of the Board of Directors or (ii) by any stockholder of the corporation who is a stockholder of record at the time of giving notice provided for in this paragraph, who shall be entitled to vote at the meeting and who delivers written notice to the Secretary of the corporation setting forth the information required by Section 5(b)(i). In the event the corporation calls a special meeting of stockholders for the purpose of electing one or more directors to the Board of Directors, any such stockholder of record may nominate a person or persons (as the case may be), for election to such position(s) as specified in the corporation's notice of meeting, if written notice setting forth the information required by Section 5(b)(i) of these Bylaws shall be received by the Secretary at the principal executive offices of the corporation not later than the close of business on the later of the ninetieth ($90^{th}$) day prior to such meeting or the tenth ($10^{th}$) day following the day on which public announcement is first made of the date of the special meeting and of the nominees proposed by the Board of Directors to be elected at such meeting. The stockholder shall also update and supplement such information as required under Section 5(c). In no event shall an adjournment or a postponement of a special meeting for which notice has been given, or the public announcement thereof has been made, commence a new time period for the giving of a stockholder's notice as described above.

**(d)** Notwithstanding the foregoing provisions of this Section 6, a stockholder must also comply with all applicable requirements of the 1934 Act and the rules and regulations thereunder with respect to matters set forth in this Section 6. Nothing in these Bylaws shall be deemed to affect any rights of stockholders to request inclusion of proposals in the corporation's proxy statement pursuant to Rule 14a-8 under the 1934 Act; *provided, however,* that any references in these Bylaws to the 1934 Act or the rules and regulations thereunder are not intended to and shall not limit the requirements applicable to nominations for the election to the Board of Directors to be considered pursuant to Section 6(c) of these Bylaws.

**Section 7. Notice Of Meetings.** Except as otherwise provided by law, notice, given in writing or by electronic transmission, of each meeting of stockholders shall be given not less than ten (10) nor more than sixty (60) days before the date of the meeting to each stockholder entitled to vote at such meeting, such notice to specify the place, if any, date and hour, in the case of special meetings, the purpose or purposes of the meeting, and the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at any such meeting. If mailed, notice is given when deposited in the United States mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the records of the corporation. Notice of the time, place, if any, and purpose of any meeting of stockholders may be waived in writing, signed by the person entitled to notice thereof, or by electronic transmission by such person, either before or after such meeting, and will be

waived by any stockholder by his attendance thereat in person, by remote communication, if applicable, or by proxy, except when the stockholder attends a meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Any stockholder so waiving notice of such meeting shall be bound by the proceedings of any such meeting in all respects as if due notice thereof had been given.

**Section 8. Quorum.** At all meetings of stockholders, except where otherwise provided by statute or by the Certificate of Incorporation, or by these Bylaws, the presence, in person, by remote communication, if applicable, or by proxy duly authorized, of the holders of a majority of the voting power of the shares of stock entitled to vote shall constitute a quorum for the transaction of business. In the absence of a quorum, any meeting of stockholders may be adjourned, from time to time, either by the chairman of the meeting or by vote of the holders of a majority of the voting power of the shares represented thereat, but no other business shall be transacted at such meeting. The stockholders present at a duly called or convened meeting, at which a quorum is present, may continue to transact business until adjournment, notwithstanding the withdrawal of enough stockholders to leave less than a quorum. Except as otherwise provided by statute or by applicable stock exchange rules, or by the Certificate of Incorporation or these Bylaws, in all matters other than the election of directors, the affirmative vote of the holders of a majority of the voting power of the shares present in person, by remote communication, if applicable, or represented by proxy at the meeting and entitled to vote generally on the subject matter shall be the act of the stockholders. Except as otherwise provided by statute, the Certificate of Incorporation or these Bylaws, directors shall be elected by a plurality of the votes of the shares present in person, by remote communication, if applicable, or represented by proxy at the meeting and entitled to vote generally on the election of directors. Where a separate vote by a class or classes or series is required, except where otherwise provided by the statute or by the Certificate of Incorporation or these Bylaws, a majority of the outstanding shares of such class or classes or series, present in person, by remote communication, if applicable, or represented by proxy duly authorized, shall constitute a quorum entitled to take action with respect to that vote on that matter. Except where otherwise provided by statute or by the Certificate of Incorporation or these Bylaws, the affirmative vote of the holders of a majority (plurality, in the case of the election of directors) of shares of such class or classes or series present in person, by remote communication, if applicable, or represented by proxy at the meeting shall be the act of such class or classes or series.

**Section 9. Adjournment And Notice Of Adjourned Meetings.** Any meeting of stockholders, whether annual or special, may be adjourned from time to time either by the chairman of the meeting or by the vote of holder of a majority of the voting power of the shares present in person, by remote communication, if applicable, or represented by proxy at the meeting. When a meeting is adjourned to another time or place, if any, notice need not be given of the adjourned meeting if the time and place, if any, thereof are announced at the meeting at which the adjournment is taken. At the adjourned meeting, the corporation may transact any business that might have been transacted at the original meeting. If the adjournment is for more than thirty (30) days or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting.

**Section 10. Voting Rights.** For the purpose of determining those stockholders entitled to vote at any meeting of the stockholders, except as otherwise provided by law, only persons in whose names shares stand on the stock records of the corporation on the record date, as provided in Section 12 of these Bylaws, shall be entitled to vote at any meeting of stockholders. Every person entitled to vote shall have the right to do so either in person, by remote communication, if applicable, or by an agent or agents authorized by a proxy granted in accordance with Delaware law. An agent so appointed need not be a stockholder. No proxy shall be voted after three (3) years from its date of creation unless the proxy provides for a longer period.

**Section 11. Joint Owners Of Stock.** If shares or other securities having voting power stand of record in the names of two (2) or more persons, whether fiduciaries, members of a partnership, joint tenants, tenants in common, tenants by the entirety, or otherwise, or if two (2) or more persons have the same fiduciary relationship respecting the same shares, unless the Secretary is given written notice to the contrary and is furnished with a copy of the instrument or order appointing them or creating the relationship wherein it is so provided, their acts with respect to voting shall have the following effect: (a) if only one (1) votes, his act binds all; (b) if more than one (1) votes, the act of the majority so voting binds all; (c) if more than one (1) votes, but the vote is evenly split on any particular matter, each faction may vote the securities in question proportionally, or may apply to the Delaware Court of Chancery for relief as provided in the DGCL, Section 217(b). If the instrument filed with the Secretary shows that any such tenancy is held in unequal interests, a majority or even-split for the purpose of subsection (c) shall be a majority or even-split in interest.

**Section 12. List Of Stockholders.** The Secretary shall prepare and make, at least ten (10) days before every meeting of stockholders, a complete list of the stockholders entitled to vote at said meeting, arranged in alphabetical order, showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, (a) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (b) during ordinary business hours, at the principal place of business of the corporation. In the event that the corporation determines to make the list available on an electronic network, the corporation may take reasonable steps to ensure that such information is available only to stockholders of the corporation. The list shall be open to examination of any stockholder during the time of the meeting as provided by law.

**Section 13. [Reserved]**

**Section 14. Organization.**

**(a)** At every meeting of stockholders, the Chairman of the Board of Directors, or, if a Chairman has not been appointed or is absent, the Chief Executive Officer, or if no Chief Executive Officer is then serving or is absent, the President, or, if the President is absent, a Chairman of the meeting chosen by a majority in interest of the stockholders entitled to vote, present in person or by proxy, shall act as Chairman. The Chairman of the Board may appoint the Chief Executive Officer as Chairman of the meeting. The Secretary, or, in his or her absence, an Assistant Secretary or other officer or other person directed to do so by the Chairman of the meeting, shall act as secretary of the meeting.

**(b)** The Board of Directors of the corporation shall be entitled to make such rules or regulations for the conduct of meetings of stockholders as it shall deem necessary, appropriate or convenient. Subject to such rules and regulations of the Board of Directors, if any, the chairman of the meeting shall have the right and authority to prescribe such rules, regulations and procedures and to do all such acts as, in the judgment of such chairman, are necessary, appropriate or convenient for the proper conduct of the meeting, including, without limitation, establishing an agenda or order of business for the meeting, rules and procedures for maintaining order at the meeting and the safety of those present, limitations on participation in such meeting to stockholders of record of the corporation and their duly authorized and constituted proxies and such other persons as the chairman shall permit, restrictions on entry to the meeting after the time fixed for the commencement thereof, limitations on the time allotted to questions or comments by participants and regulation of the opening and closing of the polls for balloting on matters that are to be voted on by ballot. The date and time of the opening and closing of the polls for each matter upon which the stockholders will vote at the meeting shall be announced at the meeting. Unless and to the extent determined by the Board of Directors or the chairman of the meeting, meetings of stockholders shall not be required to be held in accordance with rules of parliamentary procedure.

## ARTICLE IV

## DIRECTORS

**Section 15. Number And Term Of Office.** The authorized number of directors of the corporation shall not be more than seven (7) nor less than (2). Directors need not be stockholders unless so required by the Certificate of Incorporation. If for any cause, the directors shall not have been elected at an annual meeting, they may be elected as soon thereafter as convenient at a special meeting of the stockholders called for that purpose in the manner provided in these Bylaws.

**Section 16. Powers.** The powers of the corporation shall be exercised, its business conducted and its property controlled by the Board of Directors, except as may be otherwise provided by statute or by the Certificate of Incorporation.

**Section 17. Board of Directors**

Subject to the rights of the holders of any series of Preferred Stock to elect additional directors under specified circumstances, directors shall be elected at each annual meeting of stockholders to serve until the next annual meeting of stockholders. Each director shall serve until his successor is duly elected and qualified or until his death, resignation or removal. No decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.

**Section 18. Vacancies.**

**(a)** Unless otherwise provided in the Certificate of Incorporation, and subject to the rights of the holders of any series of Preferred Stock, any vacancies on the Board of Directors resulting from death, resignation, disqualification, removal or other causes and any newly created directorships resulting from any increase in the number of directors shall, unless the Board of Directors determines by resolution that any such vacancies or newly created directorships shall be filled by stockholders, be filled only by the affirmative vote of a majority of the directors then in office, even though less than a quorum of the Board of Directors, or by a sole remaining director, and not by the stockholders, provided, however, that whenever the holders of any class or classes of stock or series thereof are entitled to elect one or more directors by the provisions of the Certificate of Incorporation, vacancies and newly created directorships of such class or classes or series shall, unless the Board of Directors determines by resolution that any such vacancies or newly created directorships shall be filled by stockholders, be filled by a majority of the directors elected by such class or classes or series thereof then in office, or by a sole remaining director so elected, and not by the stockholders. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director's successor shall have been elected and qualified. A vacancy in the Board of Directors shall be deemed to exist under this Bylaw in the case of the death, removal or resignation of any director.

**Section 19. Resignation.** Any director may resign at any time by delivering his or her notice in writing or by electronic transmission to the Secretary, such resignation to specify whether it will be effective at a particular time. If no such specification is made, the Secretary, in his or her discretion, may either (a) require confirmation from the director prior to deeming the resignation effective, in which case the resignation will be deemed effective upon receipt of such confirmation, or (b) deem the resignation effective at the time of delivery of the resignation to the Secretary. When one or more directors shall resign from the Board of Directors, effective at a future date, a majority of the directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective, and each Director so chosen shall hold office for the unexpired portion of the term of the Director whose place shall be vacated and until his successor shall have been duly elected and qualified.

**Section 20. Removal.**

The Board of Directors or any individual director may be removed from office at any time (a) with cause by the affirmative vote of the holders of a majority of the voting power of all the then-outstanding shares of capital stock of the corporation, entitled to vote generally at an election of directors or (b) without cause by the affirmative vote of the holders of at least sixty-six and two-thirds percent (66 2/3%) of the voting power of all the then-outstanding shares of the capital stock of the corporation entitled to vote generally at an election of directors.

**Section 21. Meetings.**

**(a) Regular Meetings.** Unless otherwise restricted by the Certificate of Incorporation, regular meetings of the Board of Directors may be held at any time or date and at any place within or without the State of Delaware that has been designated by the Board of Directors and publicized among all directors, either orally or in writing, by telephone, including a voice-messaging system or other system designed to record and communicate messages, facsimile, telegraph or telex, or by electronic mail or other electronic means. No further notice shall be required for regular meetings of the Board of Directors.

**(b) Special Meetings.** Unless otherwise restricted by the Certificate of Incorporation, special meetings of the Board of Directors may be held at any time and place within or without the State of Delaware whenever called by the Chairman of the Board, the Chief Executive Officer or a majority of the authorized number of directors.

**(c) Meetings by Electronic Communications Equipment.** Any member of the Board of Directors, or of any committee thereof, may participate in a meeting by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and participation in a meeting by such means shall constitute presence in person at such meeting.

**(d) Notice of Special Meetings.** Notice of the time and place of all special meetings of the Board of Directors shall be orally or in writing, by telephone, including a voice messaging system or other system or technology designed to record and communicate messages, facsimile, telegraph or telex, or by electronic mail or other electronic means, during normal business hours, at least twenty-four (24) hours before the date and time of the meeting. If notice is sent by US mail, it shall be sent by first class mail, charges prepaid, at least three (3) days before the date of the meeting. Notice of any meeting may be waived in writing, or by electronic transmission, at any time before or after the meeting and will be waived by any director by attendance thereat, except when the director attends the meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened.

**(e) Waiver of Notice.** The transaction of all business at any meeting of the Board of Directors, or any committee thereof, however called or noticed, or wherever held, shall be as valid as though it had been transacted at a meeting duly held after regular call and notice, if a quorum be present and if, either before or after the meeting, each of the directors not present who did not receive notice shall sign a written waiver of notice or shall waive notice by electronic transmission. All such waivers shall be filed with the corporate records or made a part of the minutes of the meeting.

**Section 22. Quorum And Voting.**

**(a)** Unless the Certificate of Incorporation requires a greater number, and except with respect to questions related to indemnification arising under Section 45 for which a quorum shall be one-third of the exact number of directors fixed from time to time, a quorum of the Board of Directors shall consist of a majority of the exact number of directors fixed from time to time by the Board of Directors in accordance with the Certificate of Incorporation; *provided, however,* at any meeting whether a quorum be present or otherwise, a majority of the directors present may adjourn from time to time until the time fixed for the next regular meeting of the Board of Directors, without notice other than by announcement at the meeting.

**(b)** At each meeting of the Board of Directors at which a quorum is present, all questions and business shall be determined by the affirmative vote of a majority of the directors present, unless a different vote be required by law, the Certificate of Incorporation or these Bylaws.

**Section 23. Action Without Meeting**. Unless otherwise restricted by the Certificate of Incorporation or these Bylaws, any action required or permitted to be taken at any meeting of the Board of Directors or of any committee thereof may be taken without a meeting, if all members of the Board of Directors or committee, as the case may be, consent thereto in writing or by electronic transmission, and such writing or writings or transmission or transmissions are filed with the minutes of proceedings of the Board of Directors or committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

**Section 24. Fees And Compensation.** Directors shall be entitled to such compensation for their services as may be approved by the Board of Directors, including, if so approved, by resolution of the Board of Directors, a fixed sum and expenses of attendance, if any, for attendance at each regular or special meeting of the Board of Directors and at any meeting of a committee of the Board of Directors. Nothing herein contained shall be construed to preclude any director from serving the corporation as an officer, agent, employee, or otherwise and receiving compensation therefor.

**Section 25. Committees.**

**(a) Executive Committee.** The Board of Directors may appoint an Executive Committee to consist of one (1) or more members of the Board of Directors. The Executive Committee, to the extent permitted by law and provided in a resolution of the Board of Directors shall have and may exercise all the powers and authority of the Board of Directors in the management of the business and affairs of the corporation, and may authorize the seal of the corporation to be affixed to all papers that may require it; but no such committee shall have the power or authority in reference to (i) approving or adopting, or recommending to the stockholders, any action or matter (other than the election or removal of directors) expressly required by the DGCL to be submitted to stockholders for approval, or (ii) adopting, amending or repealing any Bylaw of the corporation.

**(b) Other Committees.** The Board of Directors may, from time to time, appoint such other committees as may be permitted by law. Such other committees appointed by the Board of Directors shall consist of one (1) or more members of the Board of Directors and shall have such powers and perform such duties as may be prescribed by the resolution or resolutions creating such committees, but in no event shall any such committee have the powers denied to the Executive Committee in these Bylaws.

**(c) Term.** The Board of Directors, subject to any requirements of any outstanding series of Preferred Stock and the provisions of subsections (a) or (b) of this Section 25, may at any time increase or decrease the number of members of a committee or terminate the existence of a committee. The membership of a committee member shall terminate on the date of his death or voluntary resignation from the committee or from the Board of Directors. The Board of Directors may at any time for any reason remove any individual committee member and the Board of Directors may fill any committee vacancy created by death, resignation, removal or increase in the number of members of the committee. The Board of Directors may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee, and, in addition, in the absence or disqualification of any member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not he or they constitute a quorum, may unanimously appoint another member of the Board of Directors to act at the meeting in the place of any such absent or disqualified member.

**(d) Meetings.** Unless the Board of Directors shall otherwise provide, regular meetings of the Executive Committee or any other committee appointed pursuant to this Section 25 shall be held at such times and places as are determined by the Board of Directors, or by any such committee, and when notice thereof has been given to each member of such committee, no further notice of such regular meetings need be given thereafter. Special meetings of any such committee may be held at any place that has been determined from time to time by such committee, and may be called by any director who is a member of such committee, upon notice to the members of such committee of the time and place of such special meeting given in the manner provided for the giving of notice to members of the Board of Directors of the time and place of special meetings of the Board of Directors. Notice of any special meeting of any committee may be waived in writing or by electronic transmission at any time before or after the meeting and will be waived by any director by attendance thereat, except when the director attends such special meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Unless otherwise provided by the Board of Directors in the resolutions authorizing the creation of the committee, a majority of the authorized number of members of any such committee shall constitute a quorum for the transaction of business, and the act of a majority of those present at any meeting at which a quorum is present shall be the act of such committee.

**Section 26. Lead Independent Director.** The Chairman of the Board of Directors, or if the Chairman is not an independent director, one of the independent directors, may be designated by the Board of Directors as lead independent director to serve until replaced by the Board of Directors ("**Lead Independent Director**"). The Lead Independent Director will: with the Chairman of the Board of Directors, establish the agenda for regular Board meetings and serve as chairman of Board of Directors meetings in the absence of the Chairman of the Board of Directors; establish the agenda for meetings of the independent directors; coordinate with the committee chairs regarding meeting agendas and informational requirements; preside over meetings of the independent directors; preside over any portions of meetings of the Board of Directors at which the evaluation or compensation of the Chief Executive Officer is presented or discussed; preside over any portions of meetings of the Board of Directors at which the performance of the Board of Directors is presented or discussed; and perform such other duties as may be established or delegated by the Chairman of the Board of Directors.

**Section 27. Organization.** At every meeting of the directors, the Chairman of the Board of Directors, or, if a Chairman has not been appointed or is absent, the Lead Independent Director, or if the Lead Independent Director is absent, the Chief Executive Officer (if a director), or, if a Chief Executive Officer is absent, the President (if a director), or if the President is absent, the most senior Vice President (if a director), or, in the absence of any such person, a chairman of the meeting chosen by a majority of the directors present, shall preside over the meeting. The Secretary, or in his absence, any Assistant Secretary or other officer, director, or other person directed to do so by the President, shall act as secretary of the meeting.

**Section 28. Duties of Chairman of the Board of Directors.** The Chairperson of the Board of Directors, which position shall not be deemed to be an office of the corporation for the purposes of DGCL Section 142 (and such person shall not be deemed an officer solely by virtue of holding the office of Chairperson), when present, shall preside at all meetings of the Board of Directors. The Chairperson of the Board of Directors shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers, as the Board of Directors shall designate from time to time. The Chairperson shall be appointed by the Board of Directors and may be removed at any time by the Board of Directors.

## ARTICLE V

## OFFICERS

**Section 29. Officers Designated.** The officers of the corporation shall include, if and when designated by the Board of Directors, the Chief Executive Officer, the President, one or more Vice Presidents, the Secretary, the Chief Financial Officer and the Treasurer. The Board of Directors may also appoint one or more Assistant Secretaries and Assistant Treasurers and such other officers and agents with such powers and duties as it shall deem necessary. The Board of Directors may assign such additional titles to one or more of the officers as it shall deem appropriate. Any one person may hold any number of offices of the corporation at any one time unless specifically prohibited therefrom by law. The salaries and other compensation of the officers of the corporation shall be fixed by or in the manner designated by the Board of Directors or committee thereof to which the Board of Directors has delegated such responsibility.

**Section 30. Tenure And Duties Of Officers.**

**(a) General.** All officers shall hold office at the pleasure of the Board of Directors and until their successors shall have been duly elected and qualified, unless sooner removed. Any officer elected or appointed by the Board of Directors may be removed at any time by the Board of Directors. If the office of any officer becomes vacant for any reason, the vacancy may be filled by the Board of Directors.

**(b) Duties of Chief Executive Officer.** The Chief Executive Officer shall preside at all meetings of the stockholders and at all meetings of the Board of Directors (if a director), unless the Chairman of the Board of Directors or the Lead Independent Director has been appointed and is present. Unless an officer has been appointed Chief Executive Officer of the corporation, the President shall be the chief executive officer of the corporation. The Chief Executive Officer shall, subject to the control of the Board of Directors, have general supervision, direction and control of the business and officers of the corporation. To the extent that a Chief Executive Officer has been appointed and no President has been appointed, all references in these Bylaws to the President shall be deemed references to the Chief Executive Officer. The Chief Executive Officer shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers, as the Board of Directors shall designate from time to time.

**(c) Duties of President.** The President shall preside at all meetings of the stockholders and at all meetings of the Board of Directors (if a director), unless the Chairman of the Board of Directors, the Lead Independent Director, or the Chief Executive Officer has been appointed and is present. Unless another officer has been appointed Chief Executive Officer of the corporation, the President shall be the chief executive officer of the corporation and shall, subject to the control of the Board of Directors, have general supervision, direction and control of the business and officers of the corporation. The President shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers, as the Board of Directors (or the Chief Executive Officer, if the Chief Executive Officer and President are not the same person and the Board of Directors has delegated the designation of the President's duties to the Chief Executive Officer) shall designate from time to time.

**(d) Duties of Vice Presidents.** The Vice Presidents may assume and perform the duties of the President in the absence or disability of the President or whenever the office of President is vacant (unless the duties of the President are being filled by the Chief Executive Officer). The Vice Presidents shall perform other duties commonly incident to their office and shall also perform such other duties and have such other powers as the Board of Directors or the Chief Executive Officer, or, if the Chief Executive Officer has not been appointed or is absent, the President shall designate from time to time.

**(e) Duties of Secretary.** The Secretary shall attend all meetings of the stockholders and of the Board of Directors and shall record all acts and proceedings thereof in the minute book of the corporation. The Secretary shall give notice in conformity with these Bylaws of all meetings of the stockholders and of all meetings of the Board of Directors and any committee thereof requiring notice. The Secretary shall perform all other duties provided for in these Bylaws and other duties commonly incident to the office and shall also perform such other duties and have such other powers, as the Board of Directors shall designate from time to time. The Chief Executive Officer, or if no Chief Executive Officer is then serving, the President, may direct any Assistant Secretary or other officer to assume and perform the duties of the Secretary in the absence or disability of the Secretary, and each Assistant Secretary shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers as the Board of Directors or the Chief Executive Officer, or if no Chief Executive Officer is then serving, the President shall designate from time to time.

**(f) Duties of Chief Financial Officer.** The Chief Financial Officer shall keep or cause to be kept the books of account of the corporation in a thorough and proper manner and shall render statements of the financial affairs of the corporation in such form and as often as required by the Board of Directors or the Chief Executive Officer, or if no Chief Executive Officer is then serving, the President. The Chief Financial Officer, subject to the order of the Board of Directors, shall have the custody of all funds and securities of the corporation. The Chief Financial Officer shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers as the Board of Directors or the Chief Executive Officer, or if no Chief Executive Officer is then serving, the President, shall designate from time to time. To the extent that a Chief Financial Officer has been appointed and no Treasurer has been appointed, all references in these Bylaws to the Treasurer shall be deemed references to the Chief Financial Officer. The President may direct the Treasurer, if any, or any Assistant Treasurer, or the controller or any assistant controller to assume and perform the duties of the Chief Financial Officer in the absence or disability of the Chief Financial Officer, and each Treasurer and Assistant Treasurer and each controller and assistant controller shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers as the Board of Directors or the President shall designate from time to time.

**(g) Duties of Treasurer.** Unless another officer has been appointed Chief Financial Officer of the corporation, the Treasurer shall be the chief financial officer of the corporation and shall keep or cause to be kept the books of account of the corporation in a thorough and proper manner and shall render statements of the financial affairs of the corporation in such form and as often as required by the Board of Directors or the Chief Executive Officer, or if no Chief Executive Officer is then serving, the President, and, subject to the order of the Board of Directors, shall have the custody of all funds and securities of the corporation . The Treasurer shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers as the Board of Directors, the Chief Executive Officer, or if no Chief Executive Officer is then serving, the President, and the Chief Financial Officer (if not the Treasurer) shall designate from time to time.

**Section 31. Delegation Of Authority.** The Board of Directors may from time to time delegate the powers or duties of any officer to any other officer or agent, notwithstanding any provision hereof.

**Section 32. Resignations.** Any officer may resign at any time by giving notice in writing or by electronic transmission to the Board of Directors or to the Chief Executive Officer, or if no Chief Executive Officer is then serving, the President, or to the Secretary. Any such resignation shall be effective when received by the person or persons to whom such notice is given, unless a later time is specified therein, in which event the resignation shall become effective at such later time. Unless otherwise specified in such notice, the acceptance of any such resignation shall not be necessary to make it effective. Any resignation shall be without prejudice to the rights, if any, of the corporation under any contract with the resigning officer.

**Section 33. Removal.** Any officer may be removed from office at any time, either with or without cause, by the affirmative vote of a majority of the directors in office at the time, or by the unanimous written consent of the directors in office at the time, or by any committee or by the Chief Executive Officer or by other superior officers upon whom such power of removal may have been conferred by the Board of Directors.

## ARTICLE VI

## EXECUTION OF CORPORATE INSTRUMENTS AND VOTING OF SECURITIES OWNED BY THE CORPORATION

**Section 34. Execution Of Corporate Instruments** . The Board of Directors may, in its discretion, determine the method and designate the signatory officer or officers, or other person or persons, to execute on behalf of the corporation any corporate instrument or document, or to sign on behalf of the corporation the corporate name without limitation, or to enter into contracts on behalf of the corporation, except where otherwise provided by law or these Bylaws, and such execution or signature shall be binding upon the corporation.

All checks and drafts drawn on banks or other depositaries on funds to the credit of the corporation or in special accounts of the corporation shall be signed by such person or persons as the Board of Directors shall authorize so to do.

Unless authorized or ratified by the Board of Directors or within the agency power of an officer, no officer, agent or employee shall have any power or authority to bind the corporation by any contract or engagement or to pledge its credit or to render it liable for any purpose or for any amount.

**Section 35. Voting Of Securities Owned By The Corporation.** All stock and other securities of other corporations owned or held by the corporation for itself, or for other parties in any capacity, shall be voted, and all proxies with respect thereto shall be executed, by the person authorized so to do by resolution of the Board of Directors, or, in the absence of such authorization, by the Chairman of the Board of Directors, the Chief Executive Officer, the President, or any Vice President.

## ARTICLE VII

## SHARES OF STOCK

**Section 36. Form And Execution Of Certificates.** The shares of the corporation shall be represented by certificates, or shall be uncertificated if so provided by resolution or resolutions of the Board of Directors. Certificates for the shares of stock, if any, shall be in such form as is consistent with the Certificate of Incorporation and applicable law. Every holder of stock in the corporation represented by certificate shall be entitled to have a certificate signed by or in the name of the corporation by the Chairman of the Board of Directors, or the President or any Vice President and by the Treasurer or Assistant Treasurer or the Secretary or Assistant Secretary, certifying the number of shares owned by him in the corporation. Any or all of the signatures on the certificate may be facsimiles. In case any officer, transfer agent, or registrar who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to be such officer, transfer agent, or registrar before such certificate is issued, it may be issued with the same effect as if he were such officer, transfer agent, or registrar at the date of issue.

**Section 37. Lost Certificates.** A new certificate or certificates shall be issued in place of any certificate or certificates theretofore issued by the corporation alleged to have been lost, stolen, or destroyed, upon the making of an affidavit of that fact by the person claiming the certificate of stock to be lost, stolen, or destroyed. The corporation may require, as a condition precedent to the issuance of a new certificate or certificates, the owner of such lost, stolen, or destroyed certificate or certificates, or the owner’s legal representative, to agree to indemnify the corporation in such manner as it shall require or to give the corporation a surety bond in such form and amount as it may direct as indemnity against any claim that may be made against the corporation with respect to the certificate alleged to have been lost, stolen, or destroyed.

**Section 38. Transfers.**

**(a)** Transfers of record of shares of stock of the corporation shall be made only upon its books by the holders thereof, in person or by attorney duly authorized, and, in the case of stock represented by certificate, upon the surrender of a properly endorsed certificate or certificates for a like number of shares.

**(b)** The corporation shall have power to enter into and perform any agreement with any number of stockholders of any one or more classes of stock of the corporation to restrict the transfer of shares of stock of the corporation of any one or more classes owned by such stockholders in any manner not prohibited by the DGCL.

**Section 39. Fixing Record Dates.**

**(a)** In order that the corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors, and which record date shall, subject to applicable law, not be more than sixty (60) nor less than ten (10) days before the date of such meeting. If no record date is fixed by the Board of Directors, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or if notice is waived, at the close of business on the day next preceding the day on which the meeting is held. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; *provided, however,* that the Board of Directors may fix a new record date for the adjourned meeting.

**(b)** In order that the corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights or the stockholders entitled to exercise any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action, the Board of Directors may fix, in advance, a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted, and which record date shall be not more than sixty (60) days prior to such action. If no record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating thereto.

**Section 40. Registered Stockholders**. The corporation shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends, and to vote as such owner, and shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of any other person whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of Delaware.

## ARTICLE VIII

## OTHER SECURITIES OF THE CORPORATION

**Section 41. Execution Of Other Securities.** All bonds, debentures and other corporate securities of the corporation, other than stock certificates (covered in Section 36), may be signed by the Chairman of the Board of Directors, the Chief Executive Officer, the President or any Vice President, or such other person as may be authorized by the Board of Directors, and the corporate seal impressed thereon or a facsimile of such seal imprinted thereon and attested by the signature of the Secretary or an Assistant Secretary, or the Chief Financial Officer or Treasurer or an Assistant Treasurer; *provided, however,* that where any such bond, debenture or other corporate security shall be authenticated by the manual signature, or where permissible facsimile signature, of a trustee under an indenture pursuant to which such bond, debenture or other corporate security shall be issued, the signatures of the persons signing and attesting the corporate seal on such bond, debenture or other corporate security may be the imprinted facsimile of the signatures of such persons. Interest coupons appertaining to any such bond, debenture or other corporate security, authenticated by a trustee as aforesaid, shall be signed by the Treasurer or an Assistant Treasurer of the corporation or such other person as may be authorized by the Board of Directors, or bear imprinted thereon the facsimile signature of such person. In case any officer who shall

have signed or attested any bond, debenture or other corporate security, or whose facsimile signature shall appear thereon or on any such interest coupon, shall have ceased to be such officer before the bond, debenture or other corporate security so signed or attested shall have been delivered, such bond, debenture or other corporate security nevertheless may be adopted by the corporation and issued and delivered as though the person who signed the same or whose facsimile signature shall have been used thereon had not ceased to be such officer of the corporation.

## ARTICLE IX

## DIVIDENDS

**Section 42. Declaration Of Dividends.** Dividends upon the capital stock of the corporation, subject to the provisions of the Certificate of Incorporation and applicable law, if any, may be declared by the Board of Directors pursuant to law at any regular or special meeting. Dividends may be paid in cash, in property, or in shares of the capital stock, subject to the provisions of the Certificate of Incorporation and applicable law.

**Section 43. Dividend Reserve.** Before payment of any dividend, there may be set aside out of any funds of the corporation available for dividends such sum or sums as the Board of Directors from time to time, in their absolute discretion, think proper as a reserve or reserves to meet contingencies, or for equalizing dividends, or for repairing or maintaining any property of the corporation, or for such other purpose as the Board of Directors shall think conducive to the interests of the corporation, and the Board of Directors may modify or abolish any such reserve in the manner in which it was created.

## ARTICLE X

## FISCAL YEAR

**Section 44. Fiscal Year.** The fiscal year of the corporation shall be fixed by resolution of the Board of Directors.

## ARTICLE XI

## INDEMNIFICATION

**Section 45. Indemnification of Directors, Executive Officers, Other Officers, Employees and Other Agents.**

**(a) Directors and Executive Officers.** The corporation shall indemnify its directors and executive officers (for the purposes of this Article XI, "**executive officers**" shall have the meaning defined in Rule 3b-7 promulgated under the 1934 Act) to the extent not prohibited by the DGCL or any other applicable law; *provided, however,* that the corporation may modify the extent of such indemnification by individual contracts with its directors and executive officers; and, *provided, further,* that the corporation shall not be required to indemnify any director or executive officer in connection with any proceeding (or part thereof) initiated by such person unless (i) such indemnification is expressly required to be made by law, (ii) the proceeding was authorized by the Board of Directors of the corporation, (iii) such indemnification is provided by the corporation, in its sole discretion, pursuant to the powers vested in the corporation under the DGCL or any other applicable law or (iv) such indemnification is required to be made under subsection (d).

**(b) Other Officers, Employees and Other Agents.** The corporation shall have power to indemnify its other officers, employees and other agents as set forth in the DGCL or any other applicable law. The Board of Directors shall have the power to delegate the determination of whether indemnification shall be given to any such person except executive officers to such officers or other persons as the Board of Directors shall determine.

**(c) Expenses.** The corporation shall advance to any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he is or was a director or executive officer, of the corporation, or is or was serving at the request of the corporation as a director or executive officer of another corporation, partnership, joint venture, trust or other enterprise, prior to the final disposition of the proceeding, promptly following request therefor, all expenses incurred by any director or executive officer in connection with such proceeding provided, however, that if the DGCL requires, an advancement of expenses incurred by a director or executive officer in his or her capacity as a director or executive officer (and not in any other capacity in which service was or is rendered by such indemnitee, including, without limitation, service to an employee benefit plan) shall be made only upon delivery to the corporation of an undertaking (hereinafter an "**undertaking**"), by or on behalf of such indemnitee, to repay all amounts so advanced if it shall ultimately be determined by final judicial decision from which there is no further right to appeal (hereinafter a "final adjudication") that such indemnitee is not entitled to be indemnified for such expenses under this section or otherwise.

Notwithstanding the foregoing, unless otherwise determined pursuant to paragraph (e) of this section, no advance shall be made by the corporation to an executive officer of the corporation (except by reason of the fact that such executive officer is or was a director of the corporation in which event this paragraph shall not apply) in any action, suit or proceeding, whether civil, criminal, administrative or investigative, if a determination is reasonably and promptly made (i) by a majority vote of directors who were not parties to the proceeding, even if not a quorum, or (ii) by a committee of such directors designated by a majority vote of such directors, even though less than a quorum, or (iii) if there are no such directors, or such directors so direct, by independent legal counsel in a written opinion, that the facts known to the decision-making party at the time such determination is made demonstrate clearly and convincingly that such person acted in bad faith or in a manner that such person did not believe to be in or not opposed to the best interests of the corporation.

**(d) Enforcement.** Without the necessity of entering into an express contract, all rights to indemnification and advances to directors and executive officers under this Bylaw shall be deemed to be contractual rights and be effective to the same extent and as if provided for in a contract between the corporation and the director or executive officer. Any right to indemnification or advances granted by this section to a director or executive officer shall be enforceable by or on behalf of the person holding such right in any court of competent jurisdiction if (i) the claim for indemnification or advances is denied, in whole or in part, or (ii) no disposition of such claim is made within ninety (90) days of request therefor. To the extent permitted by law, the claimant in such enforcement action, if successful in whole or in part, shall be entitled to be paid also the expense of prosecuting the claim. In connection with any claim for indemnification, the corporation shall be entitled to raise as a defense to any such action that the claimant has not met the standards of conduct that make it permissible under the DGCL or any other applicable law for the corporation to indemnify the claimant for the amount claimed. In connection with any claim by an executive officer of the corporation (except in any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that such executive officer is or was a director of the corporation) for advances, the corporation shall be entitled to raise a defense as to any such action clear and convincing evidence that such person acted in bad faith or in a manner that such person did not believe to be in or not opposed to the best interests of the corporation, or with respect to any criminal action or proceeding that such person acted without reasonable cause to believe that his conduct was lawful. Neither the failure of the corporation (including its Board of Directors, independent legal counsel or its stockholders) to have made a determination prior to the commencement of such action that indemnification of the claimant is proper in the circumstances because he has met the applicable standard of conduct set forth in the DGCL or any other applicable law, nor an actual determination by the corporation (including its Board of Directors, independent legal counsel or its stockholders) that the claimant has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that claimant has not met the applicable standard of conduct. In any suit brought by a director or executive officer to enforce a right to indemnification or to an advancement of expenses hereunder, the burden of proving that the director or executive officer is not entitled to be indemnified, or to such advancement of expenses, under this section or otherwise shall be on the corporation.

**(e) Non-Exclusivity of Rights.** The rights conferred on any person by this Bylaw shall not be exclusive of any other right that such person may have or hereafter acquire under any applicable statute, provision of the Certificate of Incorporation, Bylaws, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in his official capacity and as to action in another capacity while holding office. The corporation is specifically authorized to enter into individual contracts with any or all of its directors, officers, employees or agents respecting indemnification and advances, to the fullest extent not prohibited by the DGCL, or by any other applicable law.

**(f) Survival of Rights.** The rights conferred on any person by this Bylaw shall continue as to a person who has ceased to be a director or executive officer or officer, employee or other agent and shall inure to the benefit of the heirs, executors and administrators of such a person.

**(g) Insurance.** To the fullest extent permitted by the DGCL or any other applicable law, the corporation, upon approval by the Board of Directors, may purchase insurance on behalf of any person required or permitted to be indemnified pursuant to this section.

**(h) Amendments.** Any repeal or modification of this section shall only be prospective and shall not affect the rights under this Bylaw in effect at the time of the alleged occurrence of any action or omission to act that is the cause of any proceeding against any agent of the corporation.

**(i) Saving Clause.** If this Bylaw or any portion hereof shall be invalidated on any ground by any court of competent jurisdiction, then the corporation shall nevertheless indemnify each director and executive officer to the full extent not prohibited by any applicable portion of this section that shall not have been invalidated, or by any other applicable law. If this section shall be invalid due to the application of the indemnification provisions of another jurisdiction, then the corporation shall indemnify each director and executive officer to the full extent under any other applicable law.

**(j) Certain Definitions.** For the purposes of this Bylaw, the following definitions shall apply:

**(i)** The term "**proceeding**" shall be broadly construed and shall include, without limitation, the investigation, preparation, prosecution, defense, settlement, arbitration and appeal of, and the giving of testimony in, any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative.

**(ii)** The term "**expenses**" shall be broadly construed and shall include, without limitation, court costs, attorneys' fees, witness fees, fines, amounts paid in settlement or judgment and any other costs and expenses of any nature or kind incurred in connection with any proceeding.

**(iii)** The term the "**corporation**" shall include, in addition to the resulting corporation, any constituent corporation (including any constituent of a constituent) absorbed in a consolidation or merger that, if its separate existence had continued, would have had power and authority to indemnify its directors, officers, and employees or agents, so that any person who is or was a director, officer, employee or agent of such constituent corporation, or is or was serving at the request of such constituent corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, shall stand in the same position under the provisions of this section with respect to the resulting or surviving corporation as he would have with respect to such constituent corporation if its separate existence had continued.

**(iv)** References to a "**director**," "**executive officer**," "**officer**," "**employee**," or "**agent**" of the corporation shall include, without limitation, situations where such person is serving at the request of the corporation as, respectively, a director, executive officer, officer, employee, trustee or agent of another corporation, partnership, joint venture, trust or other enterprise.

**(v)** References to "**other enterprises**" shall include employee benefit plans; references to "fines" shall include any excise taxes assessed on a person with respect to an employee benefit plan; and references to "**serving at the request of the corporation**" shall include any service as a director, officer, employee or agent of the corporation that imposes duties on, or involves services by, such director, officer, employee, or agent with respect to an employee benefit plan, its participants, or beneficiaries; and a person who acted in good faith and in a manner he reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner "not opposed to the best interests of the corporation" as referred to in this section.

## ARTICLE XII

## NOTICES

**Section 46. Notices.**

**(a) Notice To Stockholders.** Written notice to stockholders of stockholder meetings shall be given as provided in Section 7 herein. Without limiting the manner by which notice may otherwise be given effectively to stockholders under any agreement or contract with such stockholder, and except as otherwise required by law, written notice to stockholders for purposes other than stockholder meetings may be sent by U.S. mail or nationally recognized overnight courier, or by facsimile, telegraph or telex or by electronic mail or other electronic means.

**(b) Notice To Directors.** Any notice required to be given to any director may be given by the method stated in subsection (a), as otherwise provided in these Bylaws, or by overnight delivery service, facsimile, telex or telegram, except that such notice other than one that is delivered personally shall be sent to such address as such director shall have filed in writing with the Secretary, or, in the absence of such filing, to the last known post office address of such director.

**(c) Affidavit Of Mailing.** An affidavit of mailing, executed by a duly authorized and competent employee of the corporation or its transfer agent appointed with respect to the class of stock affected, or other agent, specifying the name and address or the names and addresses of the stockholder or stockholders, or director or directors, to whom any such notice or notices was or were given, and the time and method of giving the same, shall in the absence of fraud, be prima facie evidence of the facts therein contained.

**(d) Methods of Notice.** It shall not be necessary that the same method of giving notice be employed in respect of all recipients of notice, but one permissible method may be employed in respect of any one or more, and any other permissible method or methods may be employed in respect of any other or others.

**(e) Notice To Person With Whom Communication Is Unlawful.** Whenever notice is required to be given, under any provision of law or of the Certificate of Incorporation or Bylaws of the corporation, to any person with whom communication is unlawful, the giving of such notice to such person shall not be required and there shall be no duty to apply to any governmental authority or agency for a license or permit to give such notice to such person. Any action or meeting that shall be taken or held without notice to any such person with whom communication is unlawful shall have the same force and effect as if such notice had been duly given. In the event that the action taken by the corporation is such as to require the filing of a certificate under any provision of the DGCL, the certificate shall state, if such is the fact and if notice is required, that notice was given to all persons entitled to receive notice except such persons with whom communication is unlawful.

**(f) Notice to Stockholders Sharing an Address.** Except as otherwise prohibited under DGCL, any notice given under the provisions of DGCL, the Certificate of Incorporation or the Bylaws shall be effective if given by a single written notice to stockholders who share an address if consented to by the stockholders at that address to whom such notice is given. Such consent shall have been deemed to have been given if such stockholder fails to object in writing to the corporation within sixty (60) days of having been given notice by the corporation of its intention to send the single notice. Any consent shall be revocable by the stockholder by written notice to the corporation.

## ARTICLE XIII

## AMENDMENTS

**Section 47. Amendments**. Subject to the limitations set forth in Section 45(h) of these Bylaws or the provisions of the Certificate of Incorporation, the Board of Directors is expressly empowered to adopt, amend or repeal the Bylaws of the corporation. Any adoption, amendment or repeal of the Bylaws of the corporation by the Board of Directors shall require the approval of a majority of the authorized number of directors. The stockholders also shall have power to adopt, amend or repeal the Bylaws of the corporation; *provided, however,* that, in addition to any vote of the holders of any class or series of stock of the corporation required by law or by the Certificate of Incorporation, such action by stockholders shall require the affirmative vote of the holders of at least sixty-six and two-thirds percent (66-2/3%) of the voting power of all of the then-outstanding shares of the capital stock of the corporation entitled to vote generally in the election of directors, voting together as a single class.

APPROVED AND ADOPTED this 22nd day of October, 2012

AMENDED this 20th day of June, 2013

_____

Secretary

CERTIFICATE OF SECRETARY

I hereby certify that I am the Secretary of Heatwurx, Inc., and that the foregoing Bylaws, consisting of 20 pages, constitute the code of Bylaws of the Corporation, as duly adopted by unanimous written consent of the Board of Directors of the Corporation on October 22, 2012.

IN WITNESS WHEREOF, I have hereunto subscribed my name this 22th day of October, 2012.

**Exhibit 4.1**

(Front of Certificate)

Number_____ Shares_____

HEATWURX, INC.

INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE

AUTHORIZED: 20,000,000 COMMON SHARES,
$0.0001 PAR VALUE PER SHARE

*This Certifies That*

*is the owner of*

*Fully Paid and Non-Assessable Common Stock, $0.0001 Par Value of*

**HEATWURX, INC.**

*transferable on the books of this Corporation in person or by attorney upon surrender of this Certificate duly endorsed or assigned. This Certificate and the shares represented hereby are subject to the laws of the State of Delaware, and to the Articles of Incorporation and the Bylaws of the Corporation, as now or hereafter amended. This Certificate is not valid until countersigned by the Transfer Agent.*

*IN WITNESS WHEREOF, the Corporation has caused this Certificate to be signed by the facsimile signatures of its duly authorized officers and to be sealed with the facsimile seal of the Corporation.*

*Dated*:

PRESIDENT (SEAL) SECRETARY

(Back of Certificate)

CORPORATE STOCK TRANSFER, INC.
TRANSFER FEE: AS REQUIRED

The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations:

TEN COM - as tenants in common
TEN ENT - as tenants by the entireties
JT TEN - as joint tenants with right of survivorship and not as tenants in common

UNIF GIFT MIN ACT - _____ Custodian _____
(Cust) (Minor)
under Uniform Gifts to Minors

Act _____
(State)

Additional abbreviations may also be used though not in the above list.

_____

PLEASE INSERT SOCIAL SECURITY OR OTHER
IDENTIFYING NUMBER OF ASSIGNEE

FOR VALUE RECEIVED, hereby sell, assign and transfer unto

PLEASE PRINT OR TYPEWRITE NAME AND ADDRESS INCLUDING POSTAL ZIP CODE OF ASSIGNEE

Shares

of the Common Stock represented by the within Certificate and do hereby irrevocably constitute and appoint

_____Attorney to transfer the said stock on the books of the within-named Corporation, with full power of substitution in the premises.

Dated: _____20_____,

Signature:

X_____

Signature(s) Guaranteed:

Signature:

X_____

THE SIGNATURE(S) TO THIS ASSIGNMENT MUST CORRESPOND WITH THE NAME(S) AS WRITTEN UPON THE FACE OF THE CERTIFICATE IN EVERY PARTICULAR, WITHOUT ALTERATION OR ENLARGEMENT OR ANY CHANGE WHATEVER. THE SIGNATURE(S) SHOULD BE GUARANTEED BY AN ELIGIBLE GUARANTOR INSTITUTION (Banks, Stockbrokers, Savings and Loan Associations and Credit Unions) WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUARANTEE MEDALLION PROGRAM, PURSUANT TO S.E.C. RULE 17Ad-15

**THIS SECURITY HAS NOT BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS.**

**COMMON STOCK PURCHASE WARRANT**

**PROCESSA PHARMACEUTICALS, INC.**

Warrant Number: POC-1 Initial Exercise Date: November 15, 2018
Warrant Shares: 396,476 Issue Date: May _25, 2018

THIS COMMON STOCK PURCHASE WARRANT (the "Warrant") certifies that, for value received, PoC Capital, LLC, a California limited liability company, or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the Initial Exercise Date and on or prior to 5:00 p.m. New York time on June 29, 2021 (the "Termination Date") but not thereafter, to subscribe for and purchase from Processa Pharmaceuticals, Inc., a Delaware corporation (the "Company"), up to 396,476 shares (as subject to adjustment hereunder, the "Warrant Shares") of Common Stock. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

Section 1. Omitted.

Section 2. Exercise.

(a) Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company (or such other office or agency of the Company as it may designate by notice in writing to the registered Holder at the address of the Holder appearing on the books of the Company) of a duly executed facsimile copy (or e-mail attachment) of the Notice of Exercise in the form annexed hereto. Within two (2) Trading Days following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the shares specified in the applicable Notice of Exercise by wire transfer or cashier's check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise form be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within two (2) Trading Days of the date the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Business Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

(b) Exercise Price. The exercise price per share of the Common Stock under this Warrant shall be **$2.724**, subject to adjustment hereunder (the "Exercise Price").

(c) Cashless Exercise. If, after the six month anniversary of the Initial Exercise Date, at the time of exercise hereof there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of the Warrant Shares to the Holder, then this Warrant may also be exercised, in whole or in part, at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B)*(X)] by (A), where:

(A) = the VWAP immediately preceding the date of delivery of the Notice of Exercise giving rise to the applicable "cashless exercise," as set forth in the applicable Notice of Exercise;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised, and the holding period of the Warrants being exercised may be tacked on to the holding period of the Warrant Shares. The Company agrees not to take any position contrary to this Section 2(c). For avoidance of doubt, no "cashless exercise" under this Section 2(c) may occur (i) during the first six months following the Initial Exercise Date or (ii) after the six months following the Initial Exercise Date if there is not an effective registration statement registering the issuance of the Warrant Shares to the Holder.

"VWAP" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a stock exchange or the OTCQB or OTCQX, the volume weighted average price of the Common Stock for the preceding thirty (30) trading days; (b) if prices for the Common Stock are reported in the "Pink Sheets" published by OTC Markets, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the average closing bid price per share of the Common Stock so reported for the preceding thirty (30) trading days, or (c) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holder and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

(d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by Holder or (B) this Warrant is being exercised via "cashless exercise", and otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is two (2) Trading Days after the delivery to the Company of the Notice of Exercise (such date, the "Warrant Share Delivery Date").The Warrant Shares shall be deemed to have been issued, and Holder or any other person so designated to be named therein shall be deemed to have become a holder of record of such shares for all purposes, as of the date the Warrant has been exercised, with payment to the Company of the Exercise Price (or by cashless exercise, if permitted) and all taxes required to be paid by the Holder, if any, pursuant to Section 2(d)(v) prior to the issuance of such shares, having been paid.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.

iv. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price.

v. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vi. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

(e) Call Provision. If at any time prior to the expiration of, or the exercise by the Holder of this Warrant the closing price (as reported by the OTC Markets or a Trading Market, if listed) of Company's Common Stock is equal to $5.448 or more (200% or more than the Exercise Price) for twenty (20) consecutive Trading Days (the "Trading Price Condition"), the Company shall have the right to call, redeem and cancel this Warrant on the tenth day after written notice by the Company to the Holder and payment to the Holder in cash of $0.0001 per Warrant Share. To effectively exercise this call provision, such written notice of intent to exercise the call provision under this Section 2(e) must be provided by the Company no later than the close of business on the second Trading Day following satisfaction of the Trading Price Condition. The Holder may exercise this Warrant on a cash basis (or cashless basis if there is not an effective registration statement registering the issuance of the Warrant Shares to the Holder) after written notice by the Company, but before the tenth day after such written notice, which exercise shall nullify the Company's right to call, redeem and cancel this Warrant. Failure by the Company to provide timely notice shall preclude the Company from exercising this call provision with respect to the satisfaction of the Trading Price Condition over that twenty (20) consecutive Trading Day period but shall not preclude the Company from exercising this call provision with respect to satisfaction of the Trading Price Condition over any other subsequent twenty (20) consecutive Trading Days. The Company may not call, redeem or cancel any portion of this Warrant that may not be exercised during the ten (10) day notification period pursuant to the restrictions on exercise in Section 2(a).

Section 3. Certain Adjustments.

(a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

(b) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

(c) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by facsimile or email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by facsimile or email to the Holder at its last facsimile number of email address as it shall appear upon the Warrant Register of the Company, (unless such notice is filed with the Commission, which in such case, no additional notice is required to be provided to the Holder), at least 10 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 4. Transfer of Warrant.

(a) Transferability. This Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within two (2) Trading Days of the date the Holder delivers an assignment form to the Company assigning this Warrant full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

(b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

(c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 5. Miscellaneous.

(a) No Rights as Stockholder Until Exercise. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i).

(b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

(c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then, such action may be taken or such right may be exercised on the next succeeding Business Day.

(d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of executing stock certificates to execute and issue the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

(e) Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be determined in accordance with the provisions of the Agreement by and between the Company and PoC Capital, LLC dated May 25, 2018 (the "Agreement").

(f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, will have restrictions upon resale imposed by state and federal securities laws.

(g) Non-waiver. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies.

(h) Notices. Any notice, request or other document required or permitted to be given or delivered to the Holder by the Company shall be delivered in accordance with the notice provisions of the Agreement.

(i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

(j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

(k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

(l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company and the Holder.

(m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

(n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

**********

*(Signature Page Follows)*

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

**PROCESSA PHARMACEUTICALS, INC.**

By *__/s/ David Young__*
Name: David Young
Title: Chief Executive Officer

**NOTICE OF EXERCISE**

TO: PROCESSA PHARMACEUTICALS, INC.

1. The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

2. Payment shall take the form of (check applicable box):

[ ] in lawful money of the United States; or

[ ] if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

3. Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

_____

The Warrant Shares shall be delivered to the following DWAC Account Number:

_____

_____

_____

[SIGNATURE OF HOLDER]

Name of Investing Entity:_____
*Signature of Authorized Signatory of Investing Entity*:_____
Name of Authorized Signatory:_____
Title of Authorized Signatory:_____
Date:_____

**ASSIGNMENT FORM**

*(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)*

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name:

(Please Print)

Address:

(Please Print)

Dated: _____ __, _____

Holder's Signature:_____

Holder's Address: _____

_____

**Exhibit 4.3**

**THIS SECURITY HAS NOT BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS.**

**COMMON STOCK PURCHASE WARRANT**

**PROCESSA PHARMACEUTICALS, INC.**

Warrant Shares: 79,423

Initial Exercise Date: November 15, 2018
Issue Date: May 25, 2018

THIS COMMON STOCK PURCHASE WARRANT (the "Warrant") certifies that, for value received,Boustead Securities or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the Initial Exercise Date and on or prior to 5:00 p.m. New York time on June 29, 2021 (the "Termination Date") but not thereafter, to subscribe for and purchase from Processa Pharmaceuticals, Inc., a Delaware corporation (the "Company"), up to 79,423 shares (as subject to adjustment hereunder, the "Warrant Shares") of Common Stock. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

Section 1. Definitions. Capitalized terms used and not otherwise defined herein shall have the meanings set forth in that certain Securities Purchase Agreement (the "Securities Purchase Agreement"), dated as of May 25, 2018, among the Company and the holders signatory thereto.

Section 2. Exercise.

(a) Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company (or such other office or agency of the Company as it may designate by notice in writing to the registered Holder at the address of the Holder appearing on the books of the Company) of a duly executed facsimile copy (or e-mail attachment) of the Notice of Exercise in the form annexed hereto. Within two (2) Trading Days following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the shares specified in the applicable Notice of Exercise by wire transfer or cashier's check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise form be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within two (2) Trading Days of the date the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Business Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

(b) Exercise Price. The exercise price per share of the Common Stock under this Warrant shall be **$2.724**, subject to adjustment hereunder (the "Exercise Price").

(c) Cashless Exercise. If, after the six month anniversary of the Initial Exercise Date, at the time of exercise hereof there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of the Warrant Shares to the Holder, then this Warrant may also be exercised, in whole or in part, at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B)*(X)] by (A), where:

(A) = the last VWAP immediately preceding the date of delivery of the Notice of Exercise giving rise to the applicable "cashless exercise," as set forth in the applicable Notice of Exercise (to clarify, the "last VWAP" will be the last VWAP as calculated over an entire Trading Day such that, in the event that this Warrant is exercised at a time that the Trading Market is open, the prior Trading Day's VWAP shall be used in this calculation);

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised, and the holding period of the Warrants being exercised may be tacked on to the holding period of the Warrant Shares. The Company agrees not to take any position contrary to this Section 2(c). For avoidance of doubt, no "cashless exercise" under this Section 2(c) may occur (i) during the first six months following the Initial Exercise Date or (ii) after the six months following the Initial Exercise Date if there is not an effective registration statement registering the issuance of the Warrant Shares to the Holder.

"VWAP" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:00 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the "Pink Sheets" published by OTC Markets, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Purchasers of a majority in interest of the Securities then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

(d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by Holder or (B) this Warrant is being exercised via "cashless exercise", and otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is two (2) Trading Days after the delivery to the Company of the Notice of Exercise (such date, the "Warrant Share Delivery Date").The Warrant Shares shall be deemed to have been issued, and Holder or any other person so designated to be named therein shall be deemed to have become a holder of record of such shares for all purposes, as of the date the Warrant has been exercised, with payment to the Company of the Exercise Price (or by cashless exercise, if permitted) and all taxes required to be paid by the Holder, if any, pursuant to Section 2(d)(v) prior to the issuance of such shares, having been paid.

i i . Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

i i i . Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.

iv. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price.

v. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vi. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

(e) Call Provision. If at any time prior to the expiration of, or the exercise by the Holder of this Warrant the closing price (as reported by the OTC Markets or a Trading Market, if listed) of Company's Common Stock is equal to 200% or more than the Exercise Price for twenty (20) consecutive Trading Days (the "Trading Price Condition"), the Company shall have the right to call, redeem and cancel this Warrant on the tenth day after written notice by the Company to the Holder and payment to the Holder in cash of $0.0001 per Warrant Share. To effectively exercise this call provision, such written notice of intent to exercise the call provision under this Section 2(e) must be provided by the Company no later than the close of business on the second Trading Day following satisfaction of the Trading Price Condition. The Holder may exercise this Warrant on a cash basis (or cashless basis if there is not an effective registration statement registering the issuance of the Warrant Shares to the Holder) after written notice by the Company, but before the tenth day after such written notice, which exercise shall nullify the Company's right to call, redeem and cancel this Warrant. Failure by the Company to provide timely notice shall preclude the Company from exercising this call provision with respect to the satisfaction of the Trading Price Condition over that twenty (20) consecutive Trading Day period but shall not preclude the Company from exercising this call provision with respect to satisfaction of the Trading Price Condition over any other subsequent twenty (20) consecutive Trading Days. The Company may not call, redeem or cancel any portion of this Warrant that may not be exercised during the ten (10) day notification period pursuant to the restrictions on exercise in Section 2(a).

Section 3. Certain Adjustments.

(a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

(b) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

(c) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by facsimile or email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by facsimile or email to the Holder at its last facsimile number of email address as it shall appear upon the Warrant Register of the Company, (unless such notice is filed with the Commission, which in such case, no additional notice is required to be provided to the Holder), at least 10 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 4. Transfer of Warrant.

(a) Transferability. This Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within two (2) Trading Days of the date the Holder delivers an assignment form to the Company assigning this Warrant full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

( b ) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

(c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 5. Miscellaneous.

(a) No Rights as Stockholder Until Exercise. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i).

(b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

(c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then, such action may be taken or such right may be exercised on the next succeeding Business Day.

(d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of executing stock certificates to execute and issue the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

(e) Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be determined in accordance with the provisions of the Securities Purchase Agreement.

(f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, will have restrictions upon resale imposed by state and federal securities laws.

(g) Non-waiver. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies.

( h ) Notices. Any notice, request or other document required or permitted to be given or delivered to the Holder by the Company shall be delivered in accordance with the notice provisions of the Securities Purchase Agreement.

( i ) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

( j ) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

(k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

(l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company and the Holder.

(m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

( n ) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

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*(Signature Page Follows)*

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

**PROCESSA PHARMACEUTICALS, INC.**

By: */s/ David Young*
Name: David Young
Title: Chief Executive Officer

**NOTICE OF EXERCISE**

TO: PROCESSA PHARMACEUTICALS, INC.

1. The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

2. Payment shall take the form of (check applicable box):

   [ ] in lawful money of the United States; or

   [ ] if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

3. Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

_____

The Warrant Shares shall be delivered to the following DWAC Account Number:

_____

_____

_____

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____
*Signature of Authorized Signatory of Investing Entity*: _____
Name of Authorized Signatory: _____
Title of Authorized Signatory: _____
Date: _____

**ASSIGNMENT FORM**

*(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)*

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name:

(Please Print)

Address:

(Please Print)

Dated: _____ __, _____

Holder's Signature:_____

Holder's Address: _____
_____

**PROCESSA**
**PHARMACEUTICALS, INC.**

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**SUBSCRIPTION AGREEMENT**
**SUBSCRIBER QUESTIONNAIRE**
**ACCREDITED INVESTOR CERTIFICATE**

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**SUBSCRIPTION AGREEMENT**
**INVESTOR QUESTIONNAIRE**
**ACCREDITED INVESTOR CERTIFICATE**

# PROCESSA PHARMACEUTICALS, INC.

This SUBSCRIPTION AGREEMENT (the "Subscription Agreement") is made as of this _____ day of _____, 2019 between Processa Pharmaceuticals, Inc., a Delaware corporation ("PCSA" or the "Company") with its principal offices at7380 Coca Cola Drive, Suite 106, Hanover, Maryland and the undersigned (the "Subscriber").

**WHEREAS**, the Company requires substantial additional funds to maintain and fund ongoing operations; and

**WHEREAS**, the Company intends to seek, in a private placement, to issue and sell newly created 8% Senior Convertible Notes (the "Convertible Notes");

**WHEREAS**, [for each $1,000 principal amount of Convertible Notes purchased], the Company shall issue to the Subscriber a warrant for the purchase of 440 shares of common stock of the Company an exercise price equal to the greater of (i) the reported closing price of the Company's common stock on the OTCQB® Venture Market on the closing day of this offering or (ii) $2.72 (the "Warrants" and together with the Convertible Notes, the "Securities");

**WHEREAS**, the Convertible Notes shall be sold under the terms and conditions hereinafter set forth, with the Subscriber acquiring the aggregate principal amount of Convertible Notes set forth on the signature page hereof (securities underlying the "Convertible Notes hereinafter be referred to as the "Convertible Notes"); and

**WHEREAS**, the Subscriber has received and carefully reviewed the form of Convertible Note attached hereto as Appendix I and the form of Warrant attached hereto as Appendix II; and

**WHEREAS**, the Subscriber has received and carefully reviewed the Term Sheet outlining the terms and provisions of the financing attached hereto as Appendix III; and

**WHEREAS**, the Subscriber has received and carefully reviewed or otherwise had the opportunity to obtain and carefully review the Company's most recent Annual Report on Form 10-K and subsequently filed quarterly reports on Form 10-Q; which among other things describes the operations of the Company and the significant Risk Factors associated with an investment in PCSA which can result in complete loss.

**NOW, THEREFORE**, for and in consideration of the premises and the mutual covenants hereinafter set forth, the parties hereto do hereby agree as follows:

## 1. SUBSCRIPTION FOR NOTES AND REPRESENTATIONS BY AND COVENANTS OF SUBSCRIBER

1.1 Subject to the terms and conditions hereinafter set forth, the Subscriber hereby subscribes for and agrees to purchase from the Company, the Convertible Notes in the principal amount as is set forth upon the signature page hereof, and the Company agrees to sell such Convertible Notes and related Warrants to the Subscriber for said purchase price, subject to the Company's right to sell to the Subscriber such lesser principal amount of Convertible Notes and related Warrants as it may, in its sole discretion, deem necessary or desirable. The purchase price is payable by certified or bank check

made payable to "Processa Pharmaceuticals, Inc." contemporaneously with the execution and delivery of this Subscription Agreement. The Company shall deliver the Convertible Notes and related Warrants to Subscriber(s) concurrently with execution by the parties of this Subscription Agreement but in any event not later than two business days following delivery of good funds to the Company, as set forth in Article 3 hereof. The Subscriber understands however, that this purchase of Convertible Notes is not contingent upon the Company making sales of any minimum amount of Convertible Notes prior to the Termination Date as defined in Article 3 hereof.

1.2 The Subscriber recognizes that the purchase of Securities involves a high degree of risk in that (i) the Company, its current and its proposed operations are subject to all of the risks inherent in the establishment of a new and highly regulated business enterprise, including the absence of an operating history or a tangible net worth adequate to pursue its current business plan; (ii) **an investment in the Company is highly speculative and only investors who can afford the loss of their entire investment should consider investing in the Company** and the Securities; (iii) Subscriber may not be able to liquidate his, her or its investment; (iv) transferability of the securities comprising the Securities is extremely limited; (v) in the event of a dissolution, Subscriber could sustain the loss of his, her or its entire investment; (vi) outcomes of regulatory trials may prove to be inconclusive or even harmful; and (vii) the Company will be required to raise additional capital in the future in order to have sufficient funds to implement its business and marketing plans and to meet anticipated growth and currently has a going concern opinion issued by its independent registered public accounting firm.

1.3 The Subscriber represents that he, she or it is an "Accredited Investor" as such term in defined Rule 501 of Regulation D promulgated under the Securities Act of 1933, as amended (the "Act"), as indicated by Subscriber's responses to the Confidential Investor Questionnaire, and that Subscriber is able to bear the economic risk of an investment in the Securities.

1.4 The Subscriber acknowledges that he, she or it has prior investment experience, including investment in non-listed and non-registered securities, or Subscriber has employed the services of an investment advisor, attorney or accountant to read all of the documents furnished or made available by the Company (including filings made by PCSA with the U.S. Securities and Exchange Commission ("SEC")) both to him, her or it and to all other prospective investors in the Securities and to evaluate the merits and risks of such an investment on Subscriber's behalf, and that Subscriber recognizes the highly speculative nature of this investment.

1.5 The Subscriber acknowledges receipt and careful review of the Company's most recent Annual Report on Form 10-K and subsequently filed quarterly reports on Form 10-Q, the form of Convertible Note, form of Warrant and the Term Sheet (the "Offering Documents") and hereby represents that he, she or it has been furnished by the Company during the course of this transaction with all information regarding the Company which Subscriber had requested or desired to know; that all documents which could be reasonably provided, including filings with the SEC , have been made available for Subscriber's inspection and review; and that such information and documents have, in Subscriber's opinion, afforded the Subscriber with substantially the same information that would be provided him, her or it in a registration statement filed under the Act; that Subscriber has been afforded the opportunity to ask questions of and receive answers from duly authorized officers or other representatives of the Company concerning the terms and conditions of the offering, and any additional information which he had requested.

1.6 The Subscriber acknowledges that this offering of Securities may involve tax consequences, and that the contents of the Offering Documents do not contain tax advice or information. The Subscriber acknowledges that he, she or it must retain his, her or its own professional advisors to evaluate the tax and other consequences of an investment in the Securities.

1.7 The Subscriber acknowledges that this offering of Securities has not been reviewed by the United States Securities and Exchange Commission (the "SEC") because of the Company's

representations that this is intended to be a non-public offering pursuant to Sections 4(a)(2) of the Act. The Subscriber represents that the Securities are being purchased for his, her or its own account, for investment and not for distribution or resale to others. The Subscriber agrees that he, she or it will not sell or otherwise transfer such Securities unless they are registered under the Act and qualified under applicable state securities or "blue sky" laws or unless an exemption from such registration and qualification requirements is available.

1.8 The Subscriber understands that the Convertible Notes and Warrants (and common stock issuable thereunder) have not been registered under the Act by reason of a claimed exemption under the provisions of the Act which depends, in part, upon Subscriber's investment intention. In this connection, the Subscriber understands that it is the position of the SEC that the statutory basis for such exemption would not be present if Subscriber's representation merely meant that his, her or its present intention was to hold such Securities for a short period, for a deferred sale, for a market rise, assuming that a market develops, or for any other fixed period.

1.9 The Subscriber understands that there is no public market for the Securities. The Subscriber consents that the Company may, if it desires, permit the transfer of the Securities, or shares of common stock issuable upon conversion or exercise of the Securities, as the case may be, thereof out of Subscriber's name only when Subscriber's request for transfer is accompanied by an opinion of counsel reasonably satisfactory to the Company that neither the sale nor the proposed transfer results in a violation of the Act or any applicable state "blue sky" laws (collectively "Securities Laws") and subject to the provisions of Section 1.10 hereof. The Subscriber agrees to hold the Company and its directors, officers and controlling persons and their respective heirs, representatives, successors and assigns harmless and to indemnify them against all liabilities, costs and expenses incurred by them as a result of any misrepresentation made by Subscriber contained herein or in the Confidential Investor Questionnaire or any sale or distribution by the undersigned Subscriber in violation of any Securities Laws.

1.10 The Subscriber consents to the placement of a legend on any certificate or other document evidencing the Convertible Notes, the Warrants and the Common Stock issuable upon conversion or exercise of such Securities stating that they have not been registered under the Act or qualified under applicable state securities or "blue sky" laws and setting forth or referring to the restrictions on transferability and sale thereof in substantially the following form:

> "THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT") OR REGISTERED OR QUALIFIED UNDER THE SECURITIES LAWS OF ANY STATE, AND SUCH SECURITIES MAY NOT BE OFFERED OR SOLD OR OTHERWISE TRANSFERRED, PLEDGED OR HYPOTHECATED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT RELATING THERETO OR AN OPINION OF COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE ACT AND THE SECURITIES LAWS OF ANY STATE."

1.11 The Subscriber understands that the Company will review this Subscription Agreement and the Confidential Investor Questionnaire and is hereby given authority by the undersigned, upon one business day's prior written notice, to call his, her or its bank or place of employment or otherwise review the financial standing of the Subscriber; and it is further agreed that the Company reserves the unrestricted right to reject or limit any subscription and to close the offer at any time.

1.12 The Subscriber hereby represents that the address of Subscriber furnished by him, her or it at the end of this Subscription Agreement is the undersigned's principal residence if he, she or it is an individual or its principal business address if it is a corporation or other entity. The Subscriber further represents that the Taxpayer Identification Number or Social Security Number shown on the signature portion of this document is true, correct, and complete, and the Subscriber is not subject to backup withholding either (i) because the Subscriber has not been notified that he or she is subject to backup

withholding as a result of a failure to report all interest or dividends, or (ii) because the Internal Revenue Service has notified the Subscriber that he or she is no longer subject to backup withholding.

1.13 Intentionally Omitted.

1.14 The Subscriber hereby represents that, except as set forth in the Offering Documents, no representations or warranties have been made to the Subscriber by the Company or any agent, employee or affiliate of the Company and in entering into this transaction, the Subscriber is not relying on any information, other than that contained in the Offering Documents and the results of independent investigation by the Subscriber.

1.15 The Subscriber acknowledges that the Convertible Notes will represent unsecured indebtedness of the Company.

1.16 Subscriber understands the meaning and legal consequences of the foregoing representations and warranties, which are true and correct as of the date hereof and will be true and correct as of the date of the investment in the Securities, and upon the issuance of any shares of Common Stock thereunder. Each such representation and warranty shall survive such purchase. Subscriber hereby agrees to indemnify and hold harmless the Company and its affiliated persons, and the Company's counsel, from any and all damages, losses, costs, and expenses (including reasonable attorney's fees) that they, or any of them, may incur by reason of my failure, or alleged failure, to fulfill any of the terms and conditions of this subscription or by reason of Subscriber's breach of any of the representations and warranties contained herein.

## 2. REPRESENTATIONS BY THE COMPANY

The Company represents and warrants to the Subscriber that prior to the consummation of this offering and at the Closing Date:

2.1 The Company is a corporation organized, existing and in good standing under the laws of the State of Delaware. The Company is qualified to transact business and is in good standing as a foreign limited liability company in all jurisdictions where the conduct of its business or ownership or lease of its properties makes such qualification necessary, except for those jurisdictions in which the failure to so qualify would not reasonably be expected to have a material adverse effect on its business or properties.

2.2 The execution, delivery and performance of this Subscription Agreement by the Company will have been duly approved by the Board of Directors of the Company and all other actions required to authorize and effect the offer and sale of the Securities and the securities contained therein will have been duly taken and approved.

2.3 The Securities have been duly and validly authorized and when issued and paid for in accordance with the terms hereof, will be valid and binding obligations of the Company enforceable in accordance with their respective terms.

2.4 The Company will at all times during the term of the Securities have authorized and reserved a sufficient number of equity securities and of shares of Common Stock to provide for conversion or exercise of the Securities.

2.5 The Company is in the development stage and requires the proceeds from the sales of the Convertible Notes and Warrants for additional operating capital, including payments of salaries, consulting and professional fees and costs of studies and other costs associated with seeking domestic and offshore regulatory approvals. In addition, the Company will require substantial further capital to implement its business plan and no assurance can be given that the Company's intellectual property or pharmaceutical products will ever prove to have any commercial value.

2.6 The Company knows of no pending or threatened legal or governmental proceedings to which the Company is a party which could materially adversely affect the business, property, financial condition, results of operations or prospects of the Company.

2.7 The Company is not in violation of or default under, nor will the execution and delivery of this Subscription Agreement, the issuance of the Securities, and the incurrence of the obligations herein and therein set forth and the consummation of the transactions herein or therein contemplated, result in a violation of, or constitute a default under, the certificate of formation or by- laws, in the performance or observance of any material obligations, agreement, covenant or condition contained in any bond, debenture, note or other evidence of indebtedness or in any material contract, indenture, mortgage, loan agreement, lease, joint venture or other agreement or instrument to which the Company is a party or by which it or any of its properties may be bound or in violation of any material order, rule, regulation, writ, injunction, or decree of any government, governmental instrumentality or court, domestic or foreign.

**3. TERMS OF SUBSCRIPTION**

3.1 The subscription period will begin as of July__, 2019 and will terminate at 11:59 PM Pacific time on December 31, 2019, subject to extension in the Company's sole discretion to a date not later than March 31, 2020 (the "Termination Date"). The Securities will be offered on a "reasonable commercial efforts," basis with no minimum principal amount, up to a maximum determined at the discretion of the Company.

3.2 Intentionally left blank

3.3 The Subscriber understands that the Company may obtain subscriptions from affiliated holders and is not required to receive any minimum amount in subscriptions before accepting such subscriptions for investment in the Company.

3.4 The Subscriber hereby authorizes and directs the Company to deliver the Securities to be issued to such Subscriber pursuant to this Subscription Agreement either to the residential or business address indicated in the Subscriber Questionnaire.

3.5 The Subscriber hereby authorizes and directs the Company to return any funds for unaccepted subscriptions to the Subscriber in the form of a cashier's check or to same account from which the funds were drawn.

3.6 The Subscriber hereby authorizes and directs the Company to repay the Convertible Notes by delivering the funds therefore to Subscriber in the form of a cashier's check or directly to the Subscriber's account if such information is provided to the Company.

3.7 The Company shall permit Subscribers in this offering a pro rata right to participate in any future offerings made by the Company which occur prior to December 31, 2021.

## 4. REGISTRATION RIGHTS

4.1 Intentionally omitted.

4.2 Registration Procedures. During the one year following the Closing, if the Company files with the SEC a registration statement related to an offering or for its own account or the account of others under the Act, as amended, of any of its equity securities then the Company shall include in such registration statement without any further request from the Holder all the securities of the Holder, unless and to the extent that, such Holder requests otherwise in writing. If and whenever the Company is required to affect the registration of Registrable Securities under the Act, the Company will:

(a) prepare and file with the SEC a registration statement with respect to such securities, and use its reasonable commercial efforts to cause such registration statement to become and remain effective for such period as may be reasonably necessary to effect the sale of such securities, not to exceed 180 days;

(b) prepare and file with the SEC such amendments to such registration and supplements to the prospectus contained therein as may be necessary to keep such registration statement effective for such period as may be reasonably necessary to affect the sale of such securities, not to exceed 180 days;

(c) furnish to the security holders participating in such registration and to the underwriters of the securities being registered such reasonable number of copies of the registration statement, preliminary prospectus, final prospectus and other documents as such underwriters may reasonably request in order to facilitate the public offering of such securities;

(d) use reasonable commercial efforts to register or qualify the securities covered by such registration statement under such state securities or blue sky laws of such jurisdictions as such participating holders may reasonably request in writing within twenty (20) days following the original filing of such registration statement, except that the Company shall not for any purpose be required to execute a general consent to service of process or to qualify to do business as a foreign limited liability company in any jurisdiction wherein it is not so qualified;

(e) notify the security holders participating in such registration, promptly after it shall receive notice thereof, of the time when such registration statement has become effective or a supplement to any prospectus forming a part of such registration statement has been filed;

(f) notify such holders promptly of any request by the SEC for the amending or supplementing of such registration statement or prospectus or for additional information;

(g) prepare and file with the SEC, promptly upon the request of any such holders, any amendments or supplements to such registration statement or prospectus which, in the opinion of counsel for such holders (and concurred in by counsel for the Company), is required under the Act or the rules and regulations thereunder in connection with the distribution of Common Stock by such holder;

(h) prepare and promptly file with the SEC and promptly notify such holders of the filing of such amendment or supplement to such registration statement or prospectus as may be necessary to correct any statements or omissions if, at the time when a prospectus relating to such securities is required to be delivered under the ACT, any event shall have occurred as the result of which any such prospectus or any other prospectus as then in effect would include an untrue statement of a material or omit to state any material fact necessary to make the statements therein, in the light of the circumstances in whey they were made, not misleading; and

(i) advise such holders, promptly after it shall receive notice or obtain knowledge thereof, of the issuance of any stop order by the SEC suspending the effectiveness of such registration statement or the initiation or threatening of any proceeding for the purpose and promptly use its

reasonable commercial efforts to prevent the issuance of any stop order or to obtain its withdrawal if such stop order should be issued.

4.3 Expenses.

(a) All fees, costs and expenses of and incidental to such registration shall be borne by the Company, provided, however, that any security holders participating in such registration shall bear their pro rata share of the underwriting discount and commissions and transfer taxes.

(b) The fees, costs and expenses of registration to be borne by the Company as provided in paragraph (a) above shall include, without limitation, all registration, filing, and NASD fees, printing expenses, fees and disbursements of counsel and accountants for the Company, and all legal fees and disbursements and other expenses of complying with state securities or blue sky laws of any jurisdictions in which the securities to be offered are to be registered and qualified (except as provided in 4.3(a) above). Fees and disbursements of counsel and accountants for the selling security holders and any other expenses incurred by the selling security holders not expressly included above shall be borne by the selling security holders.

4.4 Indemnification.

(a) The Company will indemnify, defend and hold harmless each holder of Registrable Securities which are included in a registration statement pursuant to the provisions of Section 4 hereof, its directors and officers, and any underwriter (as defined in the Act) for such holder and each person, if any, who controls such holder or such underwriter within the meaning of the Act, from and against, and will reimburse such holder and each such underwriter and controlling person with respect to, any and all loss, damage, liability, costs and expense (including without limitation attorney's fees, accountant's fees, expert witness fees, investigative fees and the costs incurred as a result of utilizing the services of any of the foregoing) to which such Holder or any such underwriter or controlling person may become subject under the Act or otherwise, insofar as such losses, damages, liabilities, costs or expenses are caused by any untrue statement or alleged untrue statement of any material fact contained in such registration statement, any prospectus contained therein or any amendment or supplement thereto, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances in which they were made, not misleading; provided, however, that the Company will not be liable in any such case to the extent that any such loss, damage, liability, costs or expenses arises out of or is based upon an untrue statement or alleged untrue statement or omission or alleged omission so made in conformity with information furnished by such holder, such underwriter or such controlling person in writing specifically for use in the preparation thereof.

(b) Each holder of Registrable Securities included in a registration pursuant to the provisions of Section 4 hereof will indemnify, defend and hold harmless the Company, its directors and officers, any controlling person and any underwriter from and against, and will reimburse the Company, its directors and officers, any controlling person and any underwriter with respect to, any and all loss, damage, liability, cost or expense (including without limitation attorney's fees, accountant's fees, expert witness fees, investigative fees and the costs incurred as a result of utilizing the services of any of the foregoing) to which the Company or any controlling person and/or any underwriter may become subject under the Act or otherwise, insofar as such losses, damages, liabilities, costs or expenses are caused by any untrue statement or alleged untrue statement of any material fact contained in such registration statement, any prospectus contained therein or any amendment or supplement thereto, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances in which they were made, not misleading, in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was so made in reliance upon and in strict conformity with written information furnished by or on behalf of such holder specifically for use in the preparation thereof.

(c) Promptly after receipt by an indemnified party pursuant to the provisions of paragraph (a) or (b) of this Section 4.4 of notice of the commencement of any action involving the subject matter of the foregoing indemnity provisions such indemnified party will, if a claim thereof is to be made against the indemnifying party pursuant to the provisions of said paragraph (a) or (b), promptly notify the indemnifying party of the commencement thereof; but the omission to so notify the indemnifying party will not relieve it from any liability which it may have to any indemnified party otherwise than hereunder. In case such action is brought against any indemnified party and it notifies the indemnifying party of the commencement thereof, the indemnifying party shall have the right to participate in, and, to the extent that it may wish, jointly with any other indemnifying party similarly notified, to assume the defense thereof, with counsel satisfactory to such indemnified party, provided, however, if the defendants in any action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded that there may be legal defenses available to it and/or other indemnified parties which are different from or in addition to those available to the indemnified party, or if there is a conflict of interest which would prevent counsel for the indemnifying party from also representing the indemnified party, the indemnified party or parties have the right to select separate counsel to participate in the defense of such action on behalf of such indemnified party or parties. After notice from the indemnifying party to such indemnified party of its election so to assume the defense thereof, the indemnifying party will not be liable to such indemnified party pursuant to the provisions of said paragraph (a) or (b) for any legal or other expense subsequently incurred by such indemnified party in connection with the defense thereof other than reasonable costs of investigation, unless (i) the indemnified party shall have employed counsel in accordance with the provisions of the preceding sentence, (ii) the indemnifying party shall not have employed counsel satisfactory to the indemnified party to represent the indemnified party within a reasonable time after the notice of the commencement of the action or (iii) the indemnifying party has authorized the employment of counsel for the indemnified party at the expense of the indemnifying party.

(d) If the indemnification provided for in this Section 4.4 shall for any reason be held by a court to be unavailable to an indemnified party under paragraph (a) or (b) of this Section (c) Promptly after receipt by an indemnified party pursuant to the provisions of paragraph (a) or (b) of this Section 4.4 in respect of any loss, claim, damage or liability, or any action in respect thereof, then, in lieu of the amount paid or payable under paragraph (a) or (b) of this Section 4.4, the indemnified party and the indemnifying party under paragraph (a) or (b) of this Section 4.4 shall contribute to the aggregate losses, claims, damages and liabilities (including legal or other expenses reasonably incurred in connection with and investigating the same), (i) in such proportion as is appropriate to reflect the relative fault of the Company and the Subscriber which resulted in such loss, claim, damage or liability, or action in respect thereof, as well as any other relevant equitable considerations or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as shall be appropriate to reflect the relative benefits received by the Company and the Subscriber from the offering of the securities covered by such registration statement; provided, however, that in any such case, (x) the Subscriber will not be required to contribute any amount in excess of the public offering price of all such Registrable Securities offered by it pursuant to such registration statement; and (y) no person or entity guilty of fraudulent misrepresentation, within the meaning of Section 11(f) of the Act, will be entitled to contribution from any person or entity who was not guilty of such fraudulent misrepresentation.

## 5. MISCELLANEOUS

5.1 Any notice or other communication given hereunder shall be deemed sufficient if in writing and sent by registered or certified mail, return receipt requested, addressed to the Company, at its registered office, Processa Pharmaceuticals, Inc., Attention: David Young, and to the Subscriber at his, her or its address indicated on the signature page of this Subscription Agreement. Notices shall be deemed to have been given on the date of mailing, except notices of change of address, which shall be deemed to have been given when received.

5.2 This Subscription Agreement shall not be changed, modified or amended except by a writing signed by the parties to be charged, and this Subscription Agreement may not be discharged except by performance in accordance with its terms or by a writing signed by the party to be charged.

5.3 This Subscription Agreement shall be binding upon and inure to the benefit of the parties hereto and to their respective heirs, legal representatives, successors and assigns. This Subscription Agreement sets forth the entire agreement and understanding between the parties as to the subject matter thereof and merges and supersedes all prior discussions, agreements and understandings of any and every nature among them.

5.4 Notwithstanding the place where this Subscription Agreement may be executed by any of the parties hereto, the parties expressly agree that all the terms and provisions hereof shall be construed in accordance with and governed by the internal substantive laws of the State of Maryland without regard to it conflicts of law or choice of law principles. The parties hereby agree that any dispute which may arise between them arising out of or in connection with this Subscription Agreement shall be adjudicated before a court located in Hanover, Maryland and they hereby submit to the exclusive jurisdiction of the courts of the State of Maryland located in Hanover, Maryland and of the federal courts located in Hanover, Maryland with respect to any action or legal proceeding commenced by any party, and irrevocably waive any objection they now or hereafter may have respecting the venue of any such action or proceeding brought in such a court or respecting the fact that such court is an inconvenient forum, relating to or arising out of this Subscription Agreement or any acts or omissions relating to the sale of the securities hereunder, and consent to the service of process in any such action or legal proceeding by means of registered or certified mail, return receipt requested, in care of the address set forth below or such other address as the undersigned shall furnish in writing to the other.

5.5 This Subscription Agreement may be executed in counterparts, each of which shall be an original but all of which, when taken together, shall constitute one and the same instrument. Upon the execution and delivery of this Subscription Agreement by the Subscriber, this Subscription Agreement shall become a binding obligation of the Subscriber with respect to the purchase of the Convertible Notes as herein provided; subject, however, to the right hereby reserved to the Company to enter into the same agreements with other subscribers to add and/or to delete other persons as subscribers and to accept or reject, in whole or in part, the Subscriber's subscription.

5.6 The holding of any provision of this Subscription Agreement to be invalid or unenforceable by a court of competent jurisdiction shall not affect any other provision of this Subscription Agreement, which shall remain in full force and effect.

5.7 It is agreed that a waiver by either party of a breach of any provision of this Subscription Agreement shall not operate, or be construed, as a waiver of any subsequent breach by that same party

5.8 The parties agree to execute and deliver all such further documents, agreements and instruments and take such other and further action as may be necessary or appropriate to carry out the purposes and intent of this Subscription Agreement.

[remainder of page left intentionally blank]

**CONFIDENTIAL INVESTOR QUESTIONNAIRE**

**PLEASE CAREFULLY COMPLETE EACH ITEM**
(ALL INFORMATION WILL BE TREATED CONFIDENTIALLY)

I. For each Subscriber please provide your name (also set forth your spouse's name), residence address and telephone number:

_____ _____
Name Spouse's Name

_____

_____
Address

_____
Telephone Number

_____
Facsimile Number

II. Please provide your financial information (the information submitted below may be either your individual financial condition or your combined financial condition together with your spouse, if any):

Estimated Net Worth: _____

Annual Gross Income in each of 2017 and 2018: _____

Anticipated Annual Gross Income for 2019: _____

III. Please send all correspondence to (check one): □ Residence Address

□ Business Address

IV. For each Subscriber that is a corporation, partnership, trust or other entity, please provide the name of the entity (include the name of any equity owner 10% or more of the issued and outstanding stock):

_____

Business Address: _____

Telephone Number: _____

State and Date of Organization:_____

Business Activities: _____

Estimated Total Assets: _____

Was this entity formed for the specific purpose of making this investment?

□ Yes □ No

V. Please indicate whether (if the answer to either of these questions is yes, explain fully on a separate sheet of paper):

You have ever filed personal bankruptcy? □ Yes □ No

There are any outstanding judgments against you? □ Yes □ No

VI. Has the Subscriber relied upon the advice of any professional advisor(s) and/or purchaser representative(s) in evaluating the merits and risks of this investment?

□ Yes □ No

VII. If the answer to the previous question is "Yes," please identify such person and indicate his/her business address and telephone number in the space below.

Name(s): _____

Occupation: _____

Business Address: _____

_____

Telephone Number: _____

VIII. Has the Subscriber purchased other securities previously which were sold in reliance on a private offering exemption from registration under the Securities Act?

□ Yes □ No

IX. Indicate the frequency of investments in:

Marketable Securities:

Often □; occasionally □; seldom □; never □.

Securities Purchased on Margin:

Often □; occasionally □; seldom □; never □.

Illiquid Securities:

Often □; occasionally □; seldom □; never □.

| | |
|---|---|
| _____ | _____ |
| Taxpayer Identification Number or Social Security Number | Signature of Subscriber |
| | _____ |
| | Printed Name |
| _____ | _____ |
| Taxpayer Identification Number or Social Security Number | Signature of Subscriber |
| | _____Printed Name |

**ACCREDITED INVESTOR CERTIFICATE**

The undersigned Subscriber hereby certifies that the undersigned is an Accredited Investor as that term is defined in Regulation D adopted pursuant to the Securities Act of 1933 (the "Act"). The specific category(s) of Accredited Investor applicable to the undersigned is checked below.

_____a. an individual whose individual net worth, or joint net worth with that individual's spouse, exceeds $1,000,000 (excluding your principal residence), cash, short term investments, stocks and securities. Equity in personal property and real estate should be based on the fair market value of such property less debt secured by such property.);

_____b. an individual who had an individual income in excess of $200,000 in each of the two most recent years or joint income with that person's spouse in excess of $300,000 in each of those years and who reasonably expects to reach the same income level in the current year;

_____c. a bank as defined in Section 3(a)(2) of the Act, or a savings and loan association or other institution as defined in Section 3(a)(5)(A) of the Act, whether acting in its individual or fiduciary capacity; a broker dealer registered pursuant to Section 15 of the Securities Exchange Act of 1934; an insurance company as defined in Section 2(13) of the Act; an investment company registered under the Investment Company Act of 1940 (the "1940 Act") or a business development company as defined in Section 2(a)(48) of the 1940 Act; a Small Business Investment Company licensed by the U.S. Small Business Administration under Section 301(c) or (d) of the Small Business Investment Act of 1958; a plan established and maintained by a state, its political subdivisions, or any agency or instrumentality of a state or its political subdivisions, for the benefit of its employees, if such plan has total assets in excess of $5,000,000; or an employee benefit plan within the meaning of Title I of the Employee Retirement Income Security Act of 1974 ("ERISA"), if the investment decision is made by a plan fiduciary, as defined in Section 3(21) of ERISA, which is either a bank, savings and loan association, insurance company or registered investment adviser, or if the employee benefit plan has total assets in excess of $5,000,000 or, if a self-directed plan, with investment decisions made solely by persons that are accredited investors;

_____d. a private business development company as defined in Section 202(a)(22) of the Investment Advisers Act of 1940;

_____e. an organization described in Section 501(c)(3) of the Internal Revenue Code, a corporation, a Massachusetts or similar business trust, or a partnership, not formed for the specific purpose of acquiring the Interests with total assets in excess of $5,000,000;

_____f. a trust with total assets in excess of $5,000,000, not formed for the specific purpose of acquiring the Interests whose purchase is directed by a person who has such knowledge and experience in financial and business matters that he is capable of evaluating the merits and risks of the prospective investment; or

_____g. an entity in which all of the equity owners are Accredited Investors as set forth above. (Each equity owner of such entity must also complete, sign and return a Subscription Agreement. Failure of any equity owner to do so will result in a denial of the entity's subscription.)

**INDIVIDUAL SUBSCRIBER SIGNATURE PAGE**

IN WITNESS WHEREOF, the parties have executed this Subscription Agreement as of the day and year first written above.

**Principal Amount of Convertible Notes $_____**

**Number of Related Warrants:_____**

| | |
|---|---|
| _____<br>Signature | _____<br>Signature (if purchasing jointly) |
| _____<br>Name Typed or Printed Name | _____<br>Typed or Printed |
| _____<br>Address | _____<br>Address |
| _____<br>City, State and Zip Code | _____<br>City, State and Zip Code |
| _____<br>Telephone - Business | _____<br>Telephone - Business |
| _____<br>Telephone - Residence | _____<br>Telephone - Residence |
| _____<br>Facsimile – Business | _____<br>Facsimile - Business |
| _____<br>Facsimile - Residence | _____<br>Facsimile - Residence |
| _____<br>Tax ID# or Social Security # | _____<br>Tax ID# or Social Security # |

Name in Which Securities Should be issued: _____

Dated: _____, 2019

This Subscription Agreement is agreed to and accepted as of _____ 2019.

PROCESSA PHARMACEUTICALS, INC.

_____
Name: David Young
Title: Chief Executive Officer

**INSTITUTIONAL SUBSCRIBER SIGNATURE PAGE**

I N WITNESS WHEREOF, the parties have executed this Subscription Agreement as of the day and year first written above.

**Principal Amount of Convertible Notes $_____**

**Number of Related Warrants:_____**

| | |
|---|---|
| Name of Institution | Number of Partners (If Applicable) |
| Address | Number of Shareholders (If Applicable) |
| City, State and Zip Code | State of Formation |
| Telephone | Date of Formation |
| Facsimile | Tax ID# or Social Security # |

Signature

Name (Typed or Printed) of Individual Signing of Behalf of Institution

Position or Title

Name in Which Securities Should be issued: _____

Dated: _____, 2019

This Subscription Agreement is agreed to and accepted as of _____, 2019.

Processa Pharmaceuticals, Inc.

Name: David Young
Title: Chief Executive Officer

**CERTIFICATE OF SIGNATORY**

(To be completed if Securities are being subscribed for by an entity)

I, _____ am the _____
of _____of the "Entity").

I certify that I am empowered and duly authorized by the Entity to execute and carry out the terms of the Subscription Agreement and to purchase and hold the Securities, and certify further that the Subscription Agreement has been duly and validly executed on behalf of the Entity and constitutes a legal and binding obligation of the Entity.

IN WITNESS WHEREOF, executed this day of _____, 2019.

_____
(Signature)

**APPENDIX I**

(Form of Convertible Note)

**APPENDIX II**

(Form of Warrant)

**APPENDIX III**

(Term Sheet)

**Exhibit 4.6**

**THIS SECURITY HAS NOT BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS.**

**COMMON STOCK PURCHASE WARRANT**

**PROCESSA PHARMACEUTICALS, INC.**

Warrant Shares: _____ Initial Exercise Date: _____

Issue Date: _____

THIS COMMON STOCK PURCHASE WARRANT (the "Warrant") certifies that, for value received, _____ or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the Initial Exercise Date and on or prior to 5:00 p.m. New York time on _____, 2023 (the "Termination Date") but not thereafter, to subscribe for and purchase from Processa Pharmaceuticals, Inc., a Delaware corporation (the "Company"), up to _____ shares (as subject to adjustment hereunder, the "Warrant Shares") of Common Stock. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 1(b).

Section 1. Exercise.

(a) Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company (or such other office or agency of the Company as it may designate by notice in writing to the registered Holder at the address of the Holder appearing on the books of the Company) of a duly executed facsimile copy (or e-mail attachment) of the Notice of Exercise in the form annexed hereto. Within two (2) Trading Days following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the shares specified in the applicable Notice of Exercise by wire transfer or cashier's check drawn on a United States bank. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise form be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within two (2) Trading Days of the date the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Business Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

(b) Exercise Price. The exercise price per share of the Common Stock under this Warrant shall be **$2.72**, subject to adjustment hereunder (the "Exercise Price").

(c) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system or otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is two (2) Trading Days after the delivery to the Company of the Notice of Exercise (such date, the "Warrant Share Delivery Date").The Warrant Shares shall be deemed to have been issued, and Holder or any other person so designated to be named therein shall be deemed to have become a holder of record of such shares for all purposes, as of the date the Warrant has been exercised, with payment to the Company of the Exercise Price and all taxes required to be paid by the Holder, if any, pursuant to Section 1(c)(v) prior to the issuance of such shares, having been paid.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 1(c)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.

iv. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price.

v. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vi. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

(d) Call Provision. If at any time prior to the expiration of, or the exercise by the Holder of this Warrant the closing price (as reported by the OTC Markets or a Trading Market, if listed) of Company's Common Stock is equal to 200% or more than the Exercise Price for twenty (20) consecutive Trading Days (the "Trading Price Condition"), the Company shall have the right to call, redeem and cancel this Warrant on the tenth day after written notice by the Company to the Holder and payment to the Holder in cash of $0.0001 per Warrant Share. To effectively exercise this call provision, such written notice of intent to exercise the call provision under this Section 1(d) must be provided by the Company no later than the close of business on the second Trading Day following satisfaction of the Trading Price Condition. The Holder may exercise this Warrant on a cash basis after written notice by the Company, but before the tenth day after such written notice, which exercise shall nullify the Company's right to call, redeem and cancel this Warrant. Failure by the Company to provide timely notice shall preclude the Company from exercising this call provision with respect to the satisfaction of the Trading Price Condition over that twenty (20) consecutive Trading Day period but shall not preclude the Company from exercising this call provision with respect to satisfaction of the Trading Price Condition over any other subsequent twenty (20) consecutive Trading Days. The Company may not call, redeem or cancel any portion of this Warrant that may not be exercised during the ten (10) day notification period pursuant to the restrictions on exercise in Section 1(a).

Section 2. Certain Adjustments.

(a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 2(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

(b) Calculations. All calculations under this Section 2 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 2, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

(c) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 2, the Company shall promptly deliver to the Holder by facsimile or email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by facsimile or email to the Holder at its last facsimile number of email address as it shall appear upon the Warrant Register of the Company, (unless such notice is filed with the Commission, which in such case, no additional notice is required to be provided to the Holder), at least 10 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 3. Transfer of Warrant.

(a) Transferability. This Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within two (2) Trading Days of the date the Holder delivers an assignment form to the Company assigning this Warrant full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

(b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 3(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

(c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 4. Miscellaneous.

(a) No Rights as Stockholder Until Exercise. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 1(c)(i).

(b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

(c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then, such action may be taken or such right may be exercised on the next succeeding Business Day.

(d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of executing stock certificates to execute and issue the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

(e) Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be determined in accordance with the provisions of the Securities Purchase Agreement.

(f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, will have restrictions upon resale imposed by state and federal securities laws.

(g) Non-waiver. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies.

(h) Notices. Any notice, request or other document required or permitted to be given or delivered to the Holder by the Company shall be delivered in accordance with the notice provisions of the Securities Purchase Agreement.

(i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

(j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

(k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

(l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company and the Holder.

(m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

(n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

**********

*(Signature Page Follows)*

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

**PROCESSA PHARMACEUTICALS, INC.**

By: _____
Name: David Young
Title: Chief Executive Officer

**NOTICE OF EXERCISE**

TO: PROCESSA PHARMACEUTICALS, INC.

1. The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

2. Payment shall take the form of lawful money of the United States.

3. Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

_____

The Warrant Shares shall be delivered to the following DWAC Account Number:

_____

_____

_____

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____
*Signature of Authorized Signatory of Investing Entity*: _____
Name of Authorized Signatory: _____
Title of Authorized Signatory: _____
Date: _____

**ASSIGNMENT FORM**

*(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)*

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name:

(Please Print)

Address:

(Please Print)

Dated: _____ __, _____
Holder's Signature: _____
Holder's Address: _____
_____

**Exhibit 5.1**

FOLEY & LARDNER LLP

**ATTORNEYS AT LAW**

ONE INDEPENDENT DRIVE, SUITE 1300
JACKSONVILLE, FLORIDA 32202-5017
904.359.2000 TEL
904.359.8700 FAX
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September 16, 2020

Processa Pharmaceuticals, Inc.
7380 Coca Cola Drive, Suite 106
Hanover, Maryland 21076

Re: Registration Statement on Form S-1

Ladies and Gentlemen:

We have acted as counsel to Processa Pharmaceuticals, Inc., a Delaware corporation (the "Company"), in connection with the preparation and filing with the Securities and Exchange Commission (the "Commission") of the Company's Registration Statement on Form S-1, File No. 333-235511 (as amended, and including any subsequent registration statement on Form S-1 filed pursuant to Rule 462(b), the "Registration Statement"), under the Securities Act of 1933, as amended (the "Act"), relating to the registration of the offer, issuance and sale by the Company of up to 2,472,500 shares of the Company's common stock, par value $0.0001 per share (the "Shares").

The Shares are to be sold by the Company pursuant to an underwriting agreement among the Company and the underwriters named therein (the "Underwriting Agreement"), the form of which is filed as Exhibit 1.1 to the Registration Statement.

In so acting, we have examined originals or copies (certified or otherwise identified to our satisfaction) of (i) the Fourth Amended and Restated Certificate of Incorporation of the Company, as in effect on the date hereof and as amended to date; (ii) the Amended and Restated Bylaws of the Company as in effect on the date hereof and as amended to date; (iii) the Registration Statement; (iv) the prospectus contained within the Registration Statement; (v) the form of the Underwriting Agreement and (vi) such corporate records, agreements, documents and other instruments, and such certificates or comparable documents of public officials and of officers and representatives of the Company, and have made inquiries of such officers and representatives, as we have deemed relevant and necessary as a basis for the opinion hereinafter set forth.

In such examination, we have assumed the genuineness of all signatures, the legal capacity of all natural persons, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as certified, conformed or photostatic copies, and the authenticity of the originals of such latter documents. As to all questions of fact material to this opinion that have not been independently established, we have relied upon certificates or comparable documents of officers and representatives of the Company.

Based upon, subject to and limited by the foregoing, we are of the opinion that, when the Shares are issued and paid for in accordance with the terms and conditions of the Underwriting Agreement, the Shares will be validly issued, fully paid and non-assessable.

The opinion expressed herein is limited to the General Corporation Law of the State of Delaware (including reported judicial decisions interpreting the General Corporation Law of the State of Delaware) and we express no opinion as to the effect on the matters covered by this letter of the laws of any other jurisdiction.

We hereby consent to the filing of this letter as an exhibit to the Registration Statement and to the reference to our firm under the caption "Legal Matters" in the prospectus which is a part of the Registration Statement. In giving such consents, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Act or the Rules and Regulations of the Commission promulgated thereunder.

Sincerely,

*/s/ FOLEY & LARDNER LLP*

**Exhibit 10.1**

**HEATWURX, INC.**

**AMENDED AND RESTATED**

**2011 EQUITY INCENTIVE PLAN**

**ADOPTED BY THE BOARD OF DIRECTORS: OCTOBER 18, 2012**
**APPROVED BY THE STOCKHOLDERS: OCTOBER 18, 2012**
**TERMINATION DATE: APRIL 15, 2021**

## 1. GENERAL.

**(a) Eligible Stock Award Recipients.** The persons eligible to receive Stock Awards are Employees, Directors, Advisors and Consultants.

**(b) Available Stock Awards.** The Plan provides for the grant of the following Stock Awards: (i) Incentive Stock Options and (ii) Nonstatutory Stock Options.

**(c) Purpose.** The Company, by means of the Plan, seeks to secure and retain the services of the group of persons eligible to receive Stock Awards as set forth in Section , to provide incentives for such persons to exert maximum efforts for the success of the Company and any Affiliate, and to provide a means by which such eligible recipients may be given an opportunity to benefit from increases in value of the Common Stock through the granting of Stock Awards.

## 2. ADMINISTRATION.

**(a) Administration by Board.** The Board shall administer the Plan unless and until the Board delegates administration of the Plan to a Committee, as provided in Section .

**(b) Powers of Board.** The Board shall have the power, subject to, and within the limitations of, the express provisions of the Plan:

**(i)** To determine from time to time (A) which of the persons eligible under the Plan shall be granted Stock Awards; (B) when and how each Stock Award shall be granted; (C) what type or combination of types of Stock Award shall be granted; (D) the provisions of each Stock Award granted (which need not be identical), including the time or times when a person shall be permitted to receive cash or Common Stock pursuant to a Stock Award; (E) the number of shares of Common Stock with respect to which a Stock Award shall be granted to each such person; and (F) the Fair Market Value applicable to a Stock Award.

**(ii)** To construe and interpret the Plan and Stock Awards granted under it, and to establish, amend and revoke rules and regulations for its administration. The Board, in the exercise of this power, may correct any defect, omission or inconsistency in the Plan or in any Stock Award Agreement, in a manner and to the extent it shall deem necessary or expedient to make the Plan or Stock Award fully effective.

**(iii)** To settle all controversies regarding the Plan and Stock Awards granted under it.

**(iv)** To accelerate the time at which a Stock Award may first be exercised or the time during which a Stock Award or any part thereof will vest in accordance with the Plan, notwithstanding the provisions in the Stock Award stating the time at which it may first be exercised or the time during which it will vest.

**(v)** To suspend or terminate the Plan at any time. Suspension or termination of the Plan shall not impair rights and obligations under any Stock Award granted while the Plan is in effect except with the written consent of the affected Participant.

**(vi)** To amend the Plan in any respect the Board deems necessary or advisable, including, without limitation, relating to Incentive Stock Options and certain nonqualified deferred compensation under Section 409A of the Code and/or to bring the Plan or Stock Awards granted under the Plan into compliance therewith, subject to the limitations, if any, of applicable law. However, except as provided in Section relating to Capitalization Adjustments, to the extent required by applicable law, stockholder approval shall be required for any amendment of the Plan that either (i) materially increases the number of shares of Common Stock available for issuance under the Plan, (ii) materially expands the class of individuals eligible to receive Stock Awards under the Plan, (iii) materially increases the benefits accruing to Participants under the Plan or materially reduces the price at which shares of Common Stock may be issued or purchased under the Plan, (iv) materially extends the term of the Plan, or (v) expands the types of Stock Awards available for issuance under the Plan. Except as provided above, rights under any Stock Award granted before amendment of the Plan shall not be impaired by any amendment of the Plan unless (i) the Company requests the consent of the affected Participant, and (ii) such Participant consents in writing.

**(vii)** To submit any amendment to the Plan for stockholder approval, including, but not limited to, amendments to the Plan intended to satisfy the requirements of Section 422 of the Code regarding Incentive Stock Options.

**(viii)** To approve forms of Stock Award Agreements for use under the Plan and to amend the terms of any one or more Stock Awards, including, but not limited to, amendments to provide terms more favorable than previously provided in the Stock Award Agreement, subject to any specified limits in the Plan that are not subject to Board discretion; *provided however,* that, the rights under any Stock Award shall not be impaired by any such amendment unless (i) the Company requests the consent of the affected Participant, and (ii) such Participant consents in writing. Notwithstanding the foregoing, subject to the limitations of applicable law, if any, and without the affected Participant's consent, the Board may amend the terms of any one or more Stock Awards if necessary to maintain the qualified status of the Stock Award as an Incentive Stock Option or to bring the Stock Award into compliance with Section 409A of the Code and the related guidance thereunder.

**(ix)** Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of the Plan or Stock Awards.

**(x)** To adopt such procedures and sub-plans as are necessary or appropriate to permit participation in the Plan by Employees, Directors or Consultants who are foreign nationals or employed outside the United States.

**(xi)** To effect, at any time and from time to time, with the consent of any adversely affected Optionholder, (1) the reduction of the exercise price of any outstanding Option under the Plan, (2) the cancellation of any outstanding Option under the Plan and the grant in substitution therefor of a new Option under the Plan or another equity plan of the Company covering the same or a different number of shares of Common Stock, or (3) any other action that is treated as a repricing under generally accepted accounting principles; *provided, however*, that no such reduction or cancellation may be effected if it is determined, in the Company's sole discretion, that such reduction or cancellation would result in any such outstanding Option becoming subject to the requirements of Section 409A of the Code.

**(c) Delegation to Committee.** The Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration of the Plan is delegated to a Committee, the Committee shall have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to a subcommittee of the Committee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board shall thereafter be to the Committee or subcommittee), subject, however, to such resolutions, not inconsistent with the provisions of the Plan, as may be adopted from time to time by the Board. The Board may retain the authority to concurrently administer the Plan with the Committee and may, at any time, revest in the Board some or all of the powers previously delegated.

**(d) Delegation to an Officer.** The Board may delegate to one or more Officers the authority to do one or both of the following: (i) designate Employees who are not Officers to be recipients of Options (and, to the extent permitted by applicable law, other Stock Awards) and the terms thereof, and (ii) determine the number of shares of Common Stock to be subject to such Stock Awards granted to such Employees; *provided, however,* that the Board resolutions regarding such delegation shall specify the total number of shares of Common Stock that may be subject to the Stock Awards granted by such Officer and that such Officer may not grant a Stock Award to himself or herself. Notwithstanding the foregoing, the Board may not delegate authority to an Officer to determine the Fair Market Value of the Common Stock pursuant to Section below.

**(e) Effect of Board's Decision.** All determinations, interpretations and constructions made by the Board in good faith shall not be subject to review by any person and shall be final, binding and conclusive on all persons.

**3. SHARES SUBJECT TO THE PLAN.**

**(a)** Subject to Section relating to Capitalization Adjustments, the aggregate number of shares of Common Stock of the Company that may be issued pursuant to Stock Awards after the Effective Date shall not exceed One Million Eight Hundred Thousand (1,800,000) shares. For clarity, the limitation in this Section is a limitation in the number of shares of Common Stock that may be issued pursuant to the Plan. Accordingly, this Section does not limit the granting of Stock Awards except as provided in Section. Furthermore, if a Stock Award (i) expires or otherwise terminates without having been exercised in full or (ii) is settled in cash (*i.e.*, the holder of the Stock Award receives cash rather than stock), such expiration, termination or settlement shall not reduce (or otherwise offset) the number of shares of Common Stock that may be issued pursuant to the Plan.

**(b)** If any shares of Common Stock issued pursuant to a Stock Award are forfeited back to the Company because of the failure to meet a contingency or condition required to vest such shares in the Participant, then the shares which are forfeited shall revert to and again become available for issuance under the Plan. Also, any shares reacquired by the Company pursuant to Section or as consideration for the exercise of an Option shall again become available for issuance under the Plan. Notwithstanding the provisions of this Section, any such shares shall not be subsequently issued

pursuant to the exercise of Incentive Stock Options.

**(c) Incentive Stock Option Limit.** Notwithstanding anything to the contrary in this Section , subject to the provisions of Section relating to Capitalization Adjustments, the aggregate maximum number of shares of Common Stock that may be issued pursuant to the exercise of Incentive Stock Options shall be One Million Eight Hundred Thousand (1,800,000) shares of Common Stock unless otherwise amended.

**(d) Source of Shares.** The stock issuable under the Plan shall be shares of authorized but unissued or reacquired Common Stock. The total number of shares available for issuance under the Plan shall be One Million Eight Hundred Thousand (1,800,000) shares of Common Stock unless otherwise amended.

**4. ELIGIBILITY.**

**(a) Eligibility for Specific Stock Awards** . Incentive Stock Options may be granted only to employees of the Company or a "**parent corporation**" or "**subsidiary corporation**" thereof (as such terms are defined in Sections 424(e) and (f) of the Code). Nonstatutory Stock Options may be granted to Employees, Directors and Consultants.

**(b) Ten Percent Stockholders.** A holder of 10% or more of the Company's stock (a "**Ten Percent Stockholder**") shall not be granted an Incentive Stock Option without a vote of a majority of the members of the Board (excluding any member of the Board who is the proposed recipient of the grant), and unless the exercise price of such Option is at least one hundred ten percent (110%) of the Fair Market Value of the Common Stock on the date of grant and the Option is not exercisable after the expiration of five (5) years from the date of grant.

**5. OPTION PROVISIONS.**

Each Option shall be in such form and shall contain such terms and conditions as the Board shall deem appropriate. All Options shall be separately designated Incentive Stock Options or Nonstatutory Stock Options at the time of grant, and, if certificates are issued, a separate certificate or certificates shall be issued for shares of Common Stock purchased on exercise of each type of Option. If an Option is not specifically designated as an Incentive Stock Option, then the Option shall be a Nonstatutory Stock Option. The provisions of separate Options need not be identical; *provided, however*, that each Option Agreement shall include (through incorporation of provisions hereof by reference in the Option Agreement or otherwise) the substance of each of the following provisions:

**(a) Term.** Subject to the provisions of Section regarding Ten Percent Stockholders, no Option shall be exercisable after the expiration of ten (10) years from the date of its grant or such shorter period specified in the Option Agreement.

**(b) Exercise Price.** Subject to the provisions of Section regarding Ten Percent Stockholders, the exercise price of each Option shall be not less than one hundred percent (100%) of the Fair Market Value of the Common Stock subject to the Option on the date the Option is granted. Notwithstanding the foregoing, an Option may be granted with an exercise price lower than one hundred percent (100%) of the Fair Market Value of the Common Stock subject to the Option if such Option is granted pursuant to an assumption or substitution for another option in a manner consistent with the provisions of Section 424(a) of the Code (whether or not such options are Incentive Stock Options).

**(c) Consideration.** The purchase price of Common Stock acquired pursuant to the exercise of an Option shall be paid, to the extent permitted by applicable law and as determined by the Board in its sole discretion, by any combination of the methods of payment set forth below. The Board shall have the authority to grant Options that do not permit all of the following methods of payment (or otherwise restrict the ability to use certain methods) and to grant Options that require the consent of the Company to utilize a particular method of payment. The permitted methods of payment are as follows:

**(i)** by cash, check, bank draft or money order payable to the Company;

**(ii)** pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of the stock subject to the Option, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds;

**(iii)** by delivery to the Company (either by actual delivery or attestation) of shares of Common Stock equal to the Fair Market Value of the aggregate Option exercise price;

**(iv)** by a "**net exercise**" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issued upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; *provided, however,* that the Company shall accept a cash or other payment from the Participant to the extent of any remaining balance of the aggregate exercise price not satisfied by such reduction in the number of whole shares to be issued; *provided, further,* that shares of Common Stock will no longer be outstanding under an

Option and will not be exercisable thereafter to the extent that (A) shares are used to pay the exercise price pursuant to the "**net exercise**," (B) shares are delivered to the Participant as a result of such exercise, and (C) shares are withheld to satisfy tax withholding obligations; or

**(v)** in any other form of legal consideration that may be acceptable to the Board.

**(d) Transferability of Options.** The Board may, in its sole discretion, impose such limitations on the transferability of Options as the Board shall determine. In the absence of such a determination by the Board to the contrary, the following restrictions on the transferability of Options shall apply:

**(i) Restrictions on Transfer.** An Option shall not be transferable except by will or by the laws of descent and distribution and shall be exercisable during the lifetime of the Optionholder only by the Optionholder.

**(ii) Domestic Relations Orders.** Notwithstanding the foregoing, an Option may be transferred pursuant to a domestic relations order, *provided, however,* that an Incentive Stock Option may be deemed to be a Nonstatutory Stock Option as a result of such transfer.

**(iii) Beneficiary Designation.** Notwithstanding the foregoing, the Optionholder may, by delivering written notice to the Company, in a form provided by or otherwise satisfactory to the Company, designate a third party who, in the event of the death of the Optionholder, shall thereafter be the beneficiary of an Option with the right to exercise the Option and receive the Common Stock or other consideration resulting from the Option exercise.

**(e) Vesting of Options Generally.** The total number of shares of Common Stock subject to an Option may vest and therefore become exercisable in periodic installments that may or may not be equal. The Option may be subject to such other terms and conditions on the time or times when it may or may not be exercised (which may be based on the satisfaction of performance goals or other criteria) as the Board may deem appropriate. The vesting provisions of individual Options may vary. The provisions of this Section are subject to any Option provisions governing the minimum number of shares of Common Stock as to which an Option may be exercised.

**(f) Termination of Continuous Service.** Except as otherwise provided in the applicable Option Agreement or other agreement between the Optionholder and the Company, in the event that an Optionholder's Continuous Service terminates (other than for Cause or upon the Optionholder's death or Disability), the Optionholder may exercise his or her Option (to the extent that the Optionholder was entitled to exercise such Option as of the date of termination of Continuous Service) but only within such period of time ending on the earlier of (i) the date three (3) months following the termination of the Optionholder's Continuous Service (or such longer or shorter period specified in the Option Agreement, which period shall not be less than thirty (30) days unless such termination is for Cause), or (ii) the expiration of the term of the Option as set forth in the Option Agreement. If, after termination of Continuous Service, the Optionholder does not exercise his or her Option within the time specified herein or in the Option Agreement (as applicable), the Option shall terminate.

**(g) Extension of Termination Date.** Except as otherwise provided in the applicable Option Agreement or other agreement between the Optionholder and the Company, if the exercise of the Option following the termination of the Optionholder's Continuous Service (other than for Cause or upon the Optionholder's death or Disability) would be prohibited at any time solely because the issuance of shares of Common Stock would violate the registration requirements under the Securities Act, then the Option shall terminate on the earlier of (i) the expiration of a period of three (3) months after the termination of the Optionholder's Continuous Service during which the exercise of the Option would not be in violation of such registration requirements, or (ii) the expiration of the term of the Option as set forth in the Option Agreement.

**(h) Disability of Optionholder.** Except as otherwise provided in the applicable Option Agreement or other agreement between the Optionholder and the Company, in the event that an Optionholder's Continuous Service terminates as a result of the Optionholder's Disability, the Optionholder may exercise his or her Option (to the extent that the Optionholder was entitled to exercise such Option as of the date of termination of Continuous Service), but only within such period of time ending on the earlier of (i) the date twelve (12) months following such termination of Continuous Service (or such longer or shorter period specified in the Option Agreement, which period shall not be less than six (6) months), or (ii) the expiration of the term of the Option as set forth in the Option Agreement. If, after termination of Continuous Service, the Optionholder does not exercise his or her Option within the time specified herein or in the Option Agreement (as applicable), the Option shall terminate.

**(i) Death of Optionholder.** Except as otherwise provided in the applicable Option Agreement or other agreement between the Optionholder and the Company, in the event that (i) an Optionholder's Continuous Service terminates as a result of the Optionholder's death, or (ii) the Optionholder dies within the period (if any) specified in the Option Agreement after the termination of the Optionholder's Continuous Service for a reason other than death, then the Option may be

exercised (to the extent the Optionholder was entitled to exercise such Option as of the date of death) by the Optionholder's estate, by a person who acquired the right to exercise the Option by bequest or inheritance or by a person designated as the beneficiary of the Option upon the Optionholder's death, but only within the period ending on the earlier of (i) the date eighteen (18) months following the date of death (or such longer or shorter period specified in the Option Agreement, which period shall not be less than six (6) months), or (ii) the expiration of the term of such Option as set forth in the Option Agreement. If, after the Optionholder's death, the Option is not exercised within the time specified herein or in the Option Agreement (as applicable), the Option shall terminate. If the Optionholder designates a third party beneficiary of the Option in accordance with Section , then upon the death of the Optionholder such designated beneficiary shall have the sole right to exercise the Option and receive the Common Stock or other consideration resulting from the Option exercise.

**(j) Termination for Cause.** Except as explicitly provided otherwise in an Optionholder's Option Agreement, in the event that an Optionholder's Continuous Service is terminated for Cause, the Option shall terminate upon the termination date of such Optionholder's Continuous Service, and the Optionholder shall be prohibited from exercising his or her Option from and after the time of such termination of Continuous Service.

**(k) Non-Exempt Employees**. No Option granted to an Employee that is a non-exempt employee for purposes of the Fair Labor Standards Act of 1938, as amended, shall be first exercisable for any shares of Common Stock until at least six months following the date of grant of the Option. The foregoing provision is intended to operate so that any income derived by a non-exempt employee in connection with the exercise or vesting of an Option will be exempt from his or her regular rate of pay.

**(l) Right of Repurchase**. Subject to the "**Repurchase Limitation**" in Section , the Option may include a provision whereby the Company may elect to repurchase all or any part of the vested shares of Common Stock acquired by the Optionholder pursuant to the exercise of the Option. Provided that the "**Repurchase Limitation**" in Section is not violated, the Company shall not be required to exercise its repurchase option until at least six (6) months (or such longer or shorter period of time necessary to avoid classification of the Option as a liability for financial accounting purposes) have elapsed following exercise of the Option unless otherwise specifically provided in the Option Agreement.

**(m) Right of First Refusal**. The Option may include a provision whereby the Company may elect to exercise a right of first refusal following receipt of notice from the Optionholder of the intent to transfer all or any part of the shares of Common Stock received upon the exercise of the Option. Except as expressly provided in this Section 5(m) or in the Stock Award Agreement for the Option, such right of first refusal shall otherwise comply with any applicable provisions of the Bylaws of the Company. The Company will not exercise its right of first refusal until at least six (6) months (or such longer or shorter period of time necessary to avoid classification of the Option as a liability for financial accounting purposes) have elapsed following exercise of the Option unless otherwise specifically provided in the Option Agreement.

## 6. COVENANTS OF THE COMPANY.

**(a) Availability of Shares.** During the terms of the Stock Awards, the Company shall keep available at all times the number of shares of Common Stock reasonably required to satisfy such Stock Awards.

**(b) Securities Law Compliance.** The Company shall seek to obtain from each regulatory commission or agency having jurisdiction over the Plan such authority as may be required to grant Stock Awards and to issue and sell shares of Common Stock upon exercise of the Stock Awards; *provided, however,* that this undertaking shall not require the Company to register under the Securities Act the Plan, any Stock Award or any Common Stock issued or issuable pursuant to any such Stock Award. If, after reasonable efforts, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary for the lawful issuance and sale of Common Stock under the Plan, the Company shall be relieved from any liability for failure to issue and sell Common Stock upon exercise of such Stock Awards unless and until such authority is obtained.

**(c) No Obligation to Notify.** The Company shall have no duty or obligation to any holder of a Stock Award to advise such holder as to the time or manner of exercising such Stock Award. Furthermore, the Company shall have no duty or obligation to warn or otherwise advise such holder of a pending termination or expiration of a Stock Award or a possible period in which the Stock Award may not be exercised. The Company has no duty or obligation to minimize the tax consequences of a Stock Award to the holder of such Stock Award.

## 7. MISCELLANEOUS.

**(a) Use of Proceeds from Sales of Common Stock.** Proceeds from the sale of shares of Common Stock pursuant to Stock Awards shall constitute general funds of the Company.

**(b) Corporate Action Constituting Grant of Stock Awards.** Corporate action

constituting a grant by the Company of a Stock Award to any Participant shall be deemed completed as of the date of such corporate action, unless otherwise determined by the Board, regardless of when the instrument, certificate, or letter evidencing the Stock Award is communicated to, or actually received or accepted by, the Participant.

**(c) Stockholder Rights.** No Participant shall be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to such Stock Award unless and until such Participant has satisfied all requirements for exercise of the Stock Award pursuant to its terms and the Participant shall not be deemed to be a stockholder of record until the issuance of the Common Stock pursuant to such exercise has been entered into the books and records of the Company.

**(d) No Employment or Other Service Rights.** Nothing in the Plan, any Stock Award Agreement or any other instrument executed thereunder or in connection with any Stock Award granted pursuant thereto shall confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Stock Award was granted or shall affect the right of the Company or an Affiliate to terminate (i) the employment of an Employee with or without notice and with or without cause, (ii) the service of a Consultant pursuant to the terms of such Consultant's agreement with the Company or an Affiliate, or (iii) the service of a Director pursuant to the Bylaws of the Company or an Affiliate, and any applicable provisions of the corporate law of the state in which the Company or the Affiliate is incorporated, as the case may be.

**(e) Incentive Stock Option $100,000 Limitation.** To the extent that the aggregate Fair Market Value (determined at the time of grant) of Common Stock with respect to which Incentive Stock Options are exercisable for the first time by any Optionholder during any calendar year (under all plans of the Company and any Affiliates) exceeds one hundred thousand dollars ($100,000), the Options or portions thereof that exceed such limit (according to the order in which they were granted) shall be treated as Nonstatutory Stock Options, notwithstanding any contrary provision of the applicable Option Agreement(s).

**(f) Investment Assurances.** The Company may require a Participant, as a condition of exercising or acquiring Common Stock under any Stock Award, (i) to give written assurances satisfactory to the Company as to the Participant's knowledge and experience in financial and business matters and/or to employ a purchaser representative reasonably satisfactory to the Company who is knowledgeable and experienced in financial and business matters and that he or she is capable of evaluating, alone or together with the purchaser representative, the merits and risks of exercising the Stock Award; and (ii) to give written assurances satisfactory to the Company stating that the Participant is acquiring Common Stock subject to the Stock Award for the Participant's own account and not with any present intention of selling or otherwise distributing the Common Stock. The foregoing requirements, and any assurances given pursuant to such requirements, shall be inoperative if (x) the issuance of the shares upon the exercise or acquisition of Common Stock under the Stock Award has been registered under a then currently effective registration statement under the Securities Act, or (y) as to any particular requirement, a determination is made by counsel for the Company that such requirement need not be met in the circumstances under the then applicable securities laws. The Company may, upon advice of counsel to the Company, place legends on stock certificates issued under the Plan as such counsel deems necessary or appropriate in order to comply with applicable securities laws, including, but not limited to, legends restricting the transfer of the Common Stock.

**(g) Withholding Obligations.** To the extent provided by the terms of a Stock Award Agreement, the Company may, in its sole discretion, satisfy any federal, state or local tax withholding obligation relating to a Stock Award by any of the following means (in addition to the Company's right to withhold from any compensation paid to the Participant by the Company) or by a combination of such means: (i) causing the Participant to tender a cash payment; (ii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to the Participant in connection with the Stock Award; *provided, however*, that no shares of Common Stock are withheld with a value exceeding the minimum amount of tax required to be withheld by law (or such lower amount as may be necessary to avoid classification of the Stock Award as a liability for financial accounting purposes); (iii) withholding payment from any amounts otherwise payable to the Participant; (iv) withholding cash from a Stock Award settled in cash; or (v) by such other method as may be set forth in the Stock Award Agreement.

**(h) Electronic Delivery**. Any reference herein to a "written" agreement or document shall include any agreement or document delivered electronically or posted on the Company's intranet.

**(i) Deferrals.** To the extent permitted by applicable law, the Board, in its sole discretion, may determine that the delivery of Common Stock or the payment of cash, upon the exercise, vesting or settlement of all or a portion of any Stock Award may be deferred and may establish programs and procedures for deferral elections to be made by Participants. Deferrals by Participants will be made in accordance with Section 409A of the Code. Consistent with Section 409A of the Code, the Board may provide for distributions while a Participant is still an employee. The Board is authorized to make deferrals of Stock Awards and determine when, and in what annual percentages, Participants may receive payments, including lump sum payments, following the Participant's termination of employment or retirement, and implement such other terms and conditions consistent with the provisions of the Plan and in accordance with applicable law.

**(j) Compliance with Section 409A.** To the extent that the Board determines that any Stock Award granted hereunder is subject to Section 409A of the Code, the Stock Award Agreement evidencing such Stock Award shall incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code. To the extent applicable, the Plan and Stock Award Agreements shall be interpreted in accordance with Section 409A of the Code and Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued or amended after the Effective Date. Notwithstanding any provision of the Plan to the contrary, in the event that following the Effective Date the Board determines that any Stock Award may be subject to Section 409A of the Code and related Department of Treasury guidance (including such Department of Treasury guidance as may be issued after the Effective Date), the Board may adopt such amendments to the Plan and the applicable Stock Award Agreement or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, that the Board determines are necessary or appropriate to (1) exempt the Stock Award from Section 409A of the Code and/or preserve the intended tax treatment of the benefits provided with respect to the Stock Award, or (2) comply with the requirements of Section 409A of the Code and related Department of Treasury guidance.

**(k) Information Obligation.** To the extent required by Section 260.140.46 of Title 10 of the California Code of Regulations, the Company shall deliver financial statements to Participants at least annually. This Section shall not apply to key Employees whose duties in connection with the Company assure them access to equivalent information.

**(l) Repurchase Limitation.** The terms of any repurchase option shall be specified in the Stock Award, and the repurchase price may be either the Fair Market Value of the shares of Common Stock on the date of termination of Continuous Service or the lower of (i) the Fair Market Value of the shares of Common Stock on the date of repurchase or (ii) their original purchase price.

**8. ADJUSTMENTS UPON CHANGES IN COMMON STOCK; OTHER CORPORATE EVENTS.**

**(a) Capitalization Adjustments**. In the event of a Capitalization Adjustment, the Board shall proportionately and appropriately adjust: (i) the class(es) and maximum number of securities subject to the Plan pursuant to Section , (ii) the class(es) and maximum number of securities that may be issued pursuant to the exercise of Incentive Stock Options pursuant to Section , (iii) the class(es) and number of securities and price per share of stock subject to outstanding Stock Awards, (iv) the class(es) and maximum number of securities that may be issued under the Plan pursuant to Section . The Board shall make such adjustments, and its determination shall be final, binding and conclusive.

**(b) Dissolution or Liquidation**. Except as otherwise provided in the Stock Award Agreement, in the event of a dissolution or liquidation of the Company, all outstanding Stock Awards (other than Stock Awards consisting of vested and outstanding shares of Common Stock not subject to the Company's right of repurchase) shall terminate immediately prior to the completion of such dissolution or liquidation, and the shares of Common Stock subject to the Company's repurchase option may be repurchased by the Company notwithstanding the fact that the holder of such Stock Award is providing Continuous Service, *provided, however,* that the Board may, in its sole discretion, cause some or all Stock Awards to become fully vested, exercisable and/or no longer subject to repurchase or forfeiture (to the extent such Stock Awards have not previously expired or terminated) before the dissolution or liquidation is completed but contingent on its completion.

**(c) Corporate Transaction.** The following provisions shall apply to Stock Awards in the event of a Corporate Transaction unless otherwise provided in the instrument evidencing the Stock Award or any other written agreement between the Company or any Affiliate and the holder of the Stock Award or unless otherwise expressly provided by the Board at the time of grant of a Stock Award.

**(i) Stock Awards May Be Assumed.** Except as otherwise stated in the Stock Award Agreement, in the event of a Corporate Transaction, any surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) may assume or continue any or all Stock Awards outstanding under the Plan or may substitute similar stock awards for Stock Awards outstanding under the Plan (including but not limited to, awards to acquire the same consideration paid to the stockholders of the Company pursuant to the Corporate Transaction), and any reacquisition or repurchase rights held by the Company in respect of Common Stock issued pursuant to Stock Awards may be assigned by the Company to the successor of the Company (or the successor's parent company, if any), in connection with such Corporate Transaction. A surviving corporation or acquiring corporation (or its parent) may choose to assume or continue only a portion of a Stock Award or substitute a similar stock award for only a portion of a Stock Award. The terms of any assumption, continuation or substitution shall be set by the Board in accordance with the provisions of Section .

**(ii) Stock Awards Held by Current Participants.** Except as otherwise stated in the Stock Award Agreement, in the event of a Corporate Transaction in which the surviving corporation or acquiring corporation (or its parent company) does not assume or continue such outstanding Stock Awards or substitute similar stock awards for such outstanding Stock Awards, then with respect to Stock Awards that have not been assumed, continued or substituted and that are held

by Participants whose Continuous Service has not terminated prior to the effective time of the Corporate Transaction (referred to as the "**Current Participants**"), the vesting of such Stock Awards (and, if applicable, the time at which such Stock Awards may be exercised) shall (contingent upon the effectiveness of the Corporate Transaction) be accelerated in full to a date prior to the effective time of such Corporate Transaction as the Board shall determine (or, if the Board shall not determine such a date, to the date that is five (5) days prior to the effective time of the Corporate Transaction), and such Stock Awards shall terminate if not exercised (if applicable) at or prior to the effective time of the Corporate Transaction, and any reacquisition or repurchase rights held by the Company with respect to such Stock Awards shall lapse (contingent upon the effectiveness of the Corporate Transaction).

**(iii) Stock Awards Held by Persons other than Current Participants.** Except as otherwise stated in the Stock Award Agreement, in the event of a Corporate Transaction in which the surviving corporation or acquiring corporation (or its parent company) does not assume or continue such outstanding Stock Awards or substitute similar stock awards for such outstanding Stock Awards, then with respect to Stock Awards that have not been assumed, continued or substituted and that are held by persons other than Current Participants, the vesting of such Stock Awards (and, if applicable, the time at which such Stock Award may be exercised) shall not be accelerated and such Stock Awards (other than a Stock Award consisting of vested and outstanding shares of Common Stock not subject to the Company's right of repurchase) shall terminate if not exercised (if applicable) prior to the effective time of the Corporate Transaction; *provided, however,* that any reacquisition or repurchase rights held by the Company with respect to such Stock Awards shall not terminate and may continue to be exercised notwithstanding the Corporate Transaction.

**(iv) Payment for Stock Awards in Lieu of Exercise.** Notwithstanding the foregoing, in the event a Stock Award will terminate if not exercised prior to the effective time of a Corporate Transaction, the Board may provide, in its sole discretion, that the holder of such Stock Award may not exercise such Stock Award but will receive a payment, in such form as may be determined by the Board, equal in value to the excess, if any, of (A) the value of the property the holder of the Stock Award would have received upon the exercise of the Stock Award, over (B) any exercise price payable by such holder in connection with such exercise.

**(d) Change in Control.** A Stock Award may be subject to additional acceleration of vesting and exercisability upon or after a Change in Control as may be provided in the Stock Award Agreement for such Stock Award or as may be provided in any other written agreement between the Company or any Affiliate and the Participant, but in the absence of such provision, no such acceleration shall occur.

**9. TERMINATION OR SUSPENSION OF THE PLAN.**

**(a) Plan Term.** The Board may suspend or terminate the Plan at any time. Unless sooner terminated by the Board pursuant to Section , the Plan shall automatically terminate on the day before the tenth (10th) anniversary of the earlier of (i) the date the Plan is adopted by the Board, or (ii) the date the Plan is approved by the stockholders of the Company. No Stock Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

**(b) No Impairment of Rights.** Suspension or termination of the Plan shall not impair rights and obligations under any Stock Award granted while the Plan is in effect except with the written consent of the affected Participant.

**10. EFFECTIVE DATE OF PLAN.**

This Plan shall become effective on the Effective Date.

**11. CHOICE OF LAW.**

The law of the State of Delaware shall govern all questions concerning the construction, validity and interpretation of this Plan, without regard to that state's conflict of laws rules.

**12. DEFINITIONS.** As used in the Plan, the following definitions shall apply to the capitalized terms indicated below:

**(a)** "***Affiliate***" means, at the time of determination, any "**parent**" or "**majority-owned subsidiary**" of the Company, as such terms are defined in Rule 405 of the Securities Act. The Board shall have the authority to determine the time or times at which "**parent**" or "**majority-owned subsidiary**" status is determined within the foregoing definition.

**(b)** "***Board***" means the Board of Directors of the Company.

**(c)** "***Capitalization Adjustment***" means any change that is made in, or other events that occur with respect to, the Common Stock subject to the Plan or subject to any Stock Award after the Effective Date without the receipt of consideration by the Company (through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or other transaction not involving the receipt of consideration by the Company). Notwithstanding the foregoing, the conversion of any convertible securities of the Company shall not be treated as a transaction "without the receipt of consideration" by the Company.

**(d)** "***Cause***" means with respect to a Participant, the occurrence of any of the following events: (i) such Participant's commission of any felony or any crime involving fraud, dishonesty or moral turpitude under the laws of the United States or any state thereof; (ii) such Participant's attempted commission of, or participation in, a fraud or act of dishonesty against the Company; (iii) such Participant's intentional, material violation of any contract or agreement between the Participant and the Company or of any statutory duty owed to the Company; (iv) such Participant's unauthorized use or disclosure of the Company's confidential information or trade secrets; or (v) such Participant's gross misconduct. The determination that a termination of the Participant's Continuous Service is either for Cause or without Cause shall be made by the Company in its sole discretion. Any determination by the Company that the Continuous Service of a Participant was terminated by reason of dismissal without Cause for the purposes of outstanding Stock Awards held by such Participant shall have no effect upon any determination of the rights or obligations of the Company or such Participant for any other purpose. Notwithstanding the foregoing, if a Participant has a written employment agreement with the Company that defines "***Cause***", then the definition of Cause in such employment agreement shall be deemed to be controlling for the purposes of this Plan and any Award or Stock Option Agreement issued to such Participant under this Plan.

**(e)** "***Change in Control***" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

**(i)** any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control shall not be deemed to occur (A) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Exchange Act Person that acquires the Company's securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities or (B) solely because the level of Ownership held by any Exchange Act Person (the "***Subject Person***") exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned by the Subject Person over the designated percentage threshold, then a Change in Control shall be deemed to occur;

**(ii)** there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction or (B) more than fifty percent (50%) of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction;

**(iii)** there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; or

**(iv)** individuals who, on the date this Plan is adopted by the Board, are members of the Board (the "***Incumbent Board***") cease for any reason to constitute at least a majority of the members of the Board; *provided, however,* that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member shall, for purposes of this Plan, be considered as a member of the Incumbent Board.

For the avoidance of doubt, the term Change in Control shall not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company.

Notwithstanding the foregoing or any other provision of this Plan, the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Participant shall supersede the foregoing definition with respect to Stock Awards subject to such agreement; *provided, however,* that if no definition of Change in Control or any analogous term is set forth in such an individual written agreement, the foregoing definition shall apply.

**(f)** "***Code***" means the Internal Revenue Code of 1986, as amended.

**(g)** "***Committee***" means a committee of one (1) or more Directors to whom authority has

been delegated by the Board in accordance with Section .

**(h)** "***Common Stock***" means the common stock of the Company.

**(i)** "***Company***" means Heatwurx, Inc., a Delaware corporation.

**(j)** "***Consultant***" means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of an Affiliate and is compensated for such services. However, service solely as a Director, or payment of a fee for such service, shall not cause a Director to be considered a "Consultant" for purposes of the Plan.

**(k)** "***Continuous Service***" means that the Participant's service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Consultant or Director or a change in the Entity for which the Participant renders such service, provided that there is no interruption or termination of the Participant's service with the Company or an Affiliate, shall not terminate a Participant's Continuous Service; *provided, however*, if the Entity for which a Participant is rendering service ceases to qualify as an Affiliate, as determined by the Board in its sole discretion, such Participant's Continuous Service shall be considered to have terminated on the date such Entity ceases to qualify as an Affiliate. For example, a change in status from an employee of the Company to a consultant of an Affiliate or to a Director shall not constitute an interruption of Continuous Service. To the extent permitted by law, the Board or the chief executive officer of the Company, in that party's sole discretion, may determine whether Continuous Service shall be considered interrupted in the case of any leave of absence approved by that party, including sick leave, military leave or any other personal leave. Notwithstanding the foregoing, a leave of absence shall be treated as Continuous Service for purposes of vesting in a Stock Award only to such extent as may be provided in the Company's leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Participant, or as otherwise required by law.

**(l)** "***Corporate Transaction***" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

**(i)** the consummation of a sale or other disposition of all or substantially all, as determined by the Board in its sole discretion, of the consolidated assets of the Company and its Subsidiaries;

**(ii)** the consummation of a sale or other disposition of at least ninety percent (90%) of the outstanding securities of the Company;

**(iii)** the consummation of a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

**(iv)** the consummation of a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

**(m)** "***Director***" means a member of the Board.

**(n)** "***Disability***" means the inability of a Participant to engage in any substantially gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than twelve (12) months, and shall be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances.

**(o)** "***Effective Date***" means the effective date of this Plan, which is the earlier of (i) the date that this Plan is first approved by the Company's stockholders, or (ii) the date this Plan is adopted by the Board.

**(p)** "***Employee***" means any person employed by the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, shall not cause a Director to be considered an "Employee" for purposes of the Plan.

**(q)** "***Entity***" means a corporation, partnership, limited liability company or other entity.

**(r)** "***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

**(s)** "***Exchange Act Person***" means any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that "Exchange Act Person" shall not include (i) the Company or any Subsidiary of the Company, (ii) any employee benefit plan of the Company or any Subsidiary of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, (iii) an underwriter temporarily holding securities pursuant to an offering of such securities, (iv) an Entity Owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their Ownership of stock of the Company; or (v) any natural person, Entity or "group" (within the meaning

of Section 13(d) or 14(d) of the Exchange Act) that, as of the Effective Date of the Plan as set forth in Section , is the Owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities.

**(t)** "***Fair Market Value***" means, as of any date, the value of the Common Stock determined as follows:

**(i)** if the Common Stock is listed on any established stock exchange or traded on any established market, the Fair Market Value of a share of Common Stock will be the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the date of determination, as reported in such source as the Board deems reliable. Unless otherwise provided by the Board, if there is no closing sales price for the Common Stock on the date of determination, then the Fair Market Value will be the closing sales price (or closing bid if no sales were reported) on the last preceding date for which such quotation exists.

**(ii)** in the absence of such markets, the Fair Market Value will be determined by the Board (a) in a manner consistent with Section 260.140.50 of Title 10 of the California Code of Regulations and (b) in compliance with Section 409A of the Code or, in the case of an Incentive Stock Option, in compliance with Section 422 of the Code.

**(u)** "***Incentive Stock Option***" means an Option that qualifies as an "incentive stock option" within the meaning of Section 422 of the Code and the regulations promulgated thereunder.

**(v)** "***Nonstatutory Stock Option***" means an Option that does not qualify as an Incentive Stock Option.

**(w)** "***Officer***" means any person designated by the Company as an officer.

**(x)** "***Option***" means an Incentive Stock Option or a Nonstatutory Stock Option to purchase shares of Common Stock granted pursuant to the Plan.

**(y)** "***Option Agreement***" means a written agreement between the Company and an Optionholder evidencing the terms and conditions of an Option grant. Each Option Agreement shall be subject to the terms and conditions of the Plan.

**(z)** "***Optionholder***" means a person to whom an Option is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Option.

**(aa)** "***Own***," "***Owned***," "***Owner***," "***Ownership***" A person or Entity shall be deemed to "Own," to have "Owned," to be the "Owner" of, or to have acquired "Ownership" of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

**(bb)** "***Participant***" means a person to whom a Stock Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Stock Award.

**(cc)** "***Plan***" means this Amended and Restated Heatwurx, Inc. 2011 Equity Incentive Plan.

**(dd)** "***Securities Act***" means the Securities Act of 1933, as amended.

**(ee)** "***Stock Award***" means any right to receive Common Stock granted under the Plan, including an Incentive Stock Option or a Nonstatutory Stock Option.

**(ff)** "***Stock Award Agreement***" means a written agreement between the Company and a Participant evidencing the terms and conditions of a Stock Award grant. Each Stock Award Agreement shall be subject to the terms and conditions of the Plan.

**(gg)** "***Subsidiary***" means, with respect to the Company, (i) any corporation of which more than fifty percent (50%) of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation shall have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership, limited liability company or other entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than fifty percent (50%) .

**(hh)** "***Ten Percent Stockholder***" means a person who Owns (or is deemed to Own pursuant to Section 424(d) of the Code) stock possessing more than ten percent (10%) of the total combined voting power of all classes of stock of the Company or any Affiliate.

APPROVED AND ADOPTED this 18th day of October, 2012

CERTIFICATE OF SECRETARY

I hereby certify that I am the Secretary of Heatwurx, Inc., and that the foregoing Amended and Restated 2011 Equity Incentive Plan (the "**Plan**"), consisting of 16 pages, constitute the Plan of the Company, as duly adopted at a regular meeting of the Board of Directors of the Corporation held October 18, 2012.

IN WITNESS WHEREOF, I have hereunto subscribed my name this 18th day of October, 2012.

/s/ Howard J. Kern

Howard J. Kern, Secretary

EXECUTION COPY

# OPTION AND LICENSE AGREEMENT

BY AND BETWEEN

PROMET THERAPEUTICS, LLC

AND

CONCERT PHARMACEUTICALS, INC.

DATED AS OF OCTOBER 4th, 2017

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**OPTION AND LICENSE AGREEMENT**

**THIS OPTION AND LICENSE AGREEMENT** is entered into this ___ day of October, 2017 (the "Effective Date"), by and between Promet Therapeutics, LLC, a limited liability company organized under the laws of _____, having a business address at 7380 Coca Cola Drive, Suite 106, Hanover, MD 21076 ("Promet"), and CoNCERT Pharmaceuticals, Inc., a corporation organized under the laws of Delaware, having a business address at 99 Hayden Avenue, Suite 500, Lexington, MA 02421 ("CoNCERT").

WHEREAS, CoNCERT has developed or obtained rights to CoNCERT Know-How, CoNCERT Patent Rights and the CoNCERT Compound (each as defined below); and

WHEREAS, Promet desires to obtain an option to license the CoNCERT Patent Rights and the CoNCERT Know-How to Develop and Commercialize Compounds and Products (each as defined below), under the terms and conditions set forth herein, and CoNCERT desires to grant such an option;

NOW, THEREFORE, the Parties agree as follows:

## ARTICLE I
## DEFINITIONS

The following terms, whether used in the singular or plural, shall have the following meanings:

1.1 "Act". Act means both the U.S. Federal Food, Drug, and Cosmetic Act, as amended from time to time, and the regulations promulgated under the foregoing, as amended from time to time.

1.2 "Affiliate". Affiliate means any Person directly or indirectly controlled by, controlling or under common control with, a Party, but only for so long as such control shall continue. For purposes of this definition, "control" (including, with correlative meanings, "controlled by", "controlling" and "under common control with") means, with respect to a Person, possession, direct or indirect, of (a) the power to direct or cause direction of the management and policies of such Person (whether through ownership of securities or partnership or other ownership interests, by contract or otherwise), or (b) at least 50% of the voting securities (whether directly or pursuant to any vested and exercisable option, warrant or other similar arrangement) or other comparable equity interests. For clarity, neither of the Parties shall be deemed to be an "Affiliate" of the other.

1.3 "Bankruptcy Code". Bankruptcy Code means Title 11 of the U.S. Code, as amended from time to time.

1.4 "Business Day". Business Day means a day that is not a Saturday, Sunday or a day on which banking institutions in Boston, Massachusetts are authorized by Law to remain closed.

1.5 "Calendar Quarter". Calendar Quarter means each of the periods ending on March 31, June 30, September 30 and December 31 of any Calendar Year.

1.6 "Calendar Year". Calendar Year means each calendar year during the Term.

1.7 "Combination Product". Combination Product means (a) any pharmaceutical product that is a single formulation consisting of a Compound and one or more other active compounds or active ingredients, which other active compounds or active ingredients are not Compounds ("Other API") or (b) any combination of a Compound sold together with any separately formulated Other API for a single invoiced price.

1.8 "Commercialization" or "Commercialize". Commercialization or Commercialize means activities directed to obtaining pricing and reimbursement approvals, marketing, promoting, Manufacturing commercial supplies of, distributing, importing, offering for sale or selling a product.

1.9 "Commercially Reasonable Efforts". Commercially Reasonable Efforts means, with respect to an objective, the reasonable, diligent, good faith efforts of a Party (including the efforts of its Affiliates and Sublicensees) to accomplish such objective that a biopharmaceutical company of comparable size and resources would normally use to accomplish a similar objective under similar circumstances, and, specifically with respect to obligations hereunder relating to a Compound or Product, the carrying out of such obligations with those efforts and resources that a biopharmaceutical company of comparable size and resources would use were it Developing, Manufacturing or Commercializing its own pharmaceutical products that are at a similar stage of development or product life cycle and of similar market potential as the Compound or Product, taking into account actual and potential issues of safety, efficacy or stability, product profile (including product modality, category and mechanism of action), stage of development or life cycle status, product labeling or anticipated labeling, the present and future market potential, past performance of the Compound or Product, actual and projected Development, Regulatory Approval, pricing and reimbursement approval, Manufacturing and Commercialization costs, existing or projected pricing, sales, reimbursement and financial return, medical and clinical considerations, present and future regulatory environment, any issues regarding the ability to Manufacture the Compound or Product, the likelihood and timing of obtaining Regulatory Approvals and pricing and reimbursement approvals, proprietary position, strength and duration of patent protection and anticipated exclusivity, competitive Third Party products at the time and the likely competitive environment at the time of projected entry into the market and thereafter, and any other relevant scientific, technical, operational and commercial factors, all as measured by the facts and circumstances at the time such efforts are due. Commercially Reasonable Efforts will be determined on a country-by-country and indication-by-indication basis for the Compound or Product, and the level of effort is expected to change over time, reflecting changes in the status and value of the Compound or Product and the market conditions and country(ies) involved.

1.10 "Compound". Compound means CTP-499 and each metabolite thereof.

1.11 "CoNCERT Intellectual Property". CoNCERT Intellectual Property means the CoNCERT Know-How and the CoNCERT Patent Rights.

1.12 "CoNCERT Know-How". CoNCERT Know-How means all Know-How that is Controlled by CoNCERT or any of its Affiliates as of the Effective Date or thereafter during the Term (other than any Know-How included in Joint Intellectual Property) that is necessary or useful to Develop, Manufacture or Commercialize any Compound or Product; provided, however, that, if CoNCERT is acquired by a Third Party, "CoNCERT Know-How" shall exclude any Know-How that (a) is Controlled by such Third Party or the Affiliates of such Third Party (other than CoNCERT and the Persons that were CoNCERT's Affiliates immediately prior to the closing of such acquisition transaction (such Affiliates, "CoNCERT Pre-Existing Affiliates")) ("CoNCERT Excluded Affiliates") and (b) was not Controlled by CoNCERT or any of the CoNCERT Pre-Existing Affiliates immediately prior to the closing of such acquisition transaction; provided further that, if, after the closing of such acquisition, any such CoNCERT Excluded Affiliate Develops or Commercializes any Compound or Product or otherwise performs any activities or obtains any rights with respect to any Compound or Product, such Affiliate will cease to be a CoNCERT Excluded Affiliate and applicable Know-How that is Controlled by such Affiliate shall be included in CoNCERT Know-How.

1.13 "CoNCERT Patent Rights". CoNCERT Patent Rights means all Patent Rights in the Territory that are Controlled by CoNCERT or any of its Affiliates as of the Effective Date or thereafter during the Term (other than Joint Patent Rights) that Cover any Compound or Product. The CoNCERT Patent Rights existing as of the Effective Date are set forth on Schedule 1.13; provided, however, that, if CoNCERT is acquired by a Third Party, "CoNCERT Patent Rights" shall exclude any Patent Rights that (a) are Controlled by such Third Party or the Affiliates of such Third Party (other than CoNCERT and CoNCERT Pre-Existing Affiliates) and (b) were not Controlled by CoNCERT or any of the CoNCERT Pre-Existing Affiliates immediately prior to the closing of such acquisition transaction; provided further that, if, after the closing of such acquisition, any such CoNCERT Excluded Affiliate Develops or Commercializes any Compound or Product or otherwise performs any activities or obtains any rights with respect to any Compound or Product, such Affiliate will cease to be a CoNCERT Excluded Affiliate and applicable Patent Rights that are Controlled by such Affiliate shall be included in CoNCERT Patent Rights.

1.14 "Control" or "Controlled". Control or Controlled means, with respect to any tangible property or intellectual property right or other intangible property, the possession (whether by ownership or license (other than by grant of a license to one Party by the other Party pursuant to this Agreement or by grant of a license or sublicense to a Sublicensee by Promet pursuant to a license or sublicense agreement)) by a Person of the ability to grant to another Person access to such tangible property or access to or a license or sublicense to such intellectual property right or other intangible property, as provided herein without violating the terms of any agreement with any other Person.

1.15 "Cover", "Covering" or "Covered". Cover, Covering or Covered means, with respect to a compound, product, technology, process or method that, in the absence of ownership of or a license granted under a Patent Right, the manufacture, use, offer for sale, sale or importation of such compound or product or the practice of such technology, process or method would infringe such Patent Right (or, in the case of a Patent Right that has not yet issued, would infringe such Patent Right if it were to issue).

1.16 "Development" or "Develop". Development or Develop means pre-clinical, non-clinical and clinical drug research, discovery and development activities, including IND-enabling toxicology and other IND-enabling pre-clinical development efforts, stability testing, process development, compound property optimization, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, clinical pharmacology, Manufacturing supplies of compounds and products for pre-clinical, non-clinical and clinical use, clinical studies (including pre- and post-approval studies and investigator sponsored clinical studies), regulatory affairs, and Regulatory Approval and clinical study regulatory activities (excluding regulatory activities directed to obtaining pricing and reimbursement approvals).

1.17 "EMA". EMA means the European Medicines Agency and any successor agency.

1.18 "FDA". FDA means the U.S. Food and Drug Administration and any successor agency.

1.19 "Field". Field means all medical uses.

1.20 "First Commercial Sale". First Commercial Sale means, with respect to a Product in a country, the first sale of such Product in such country by Promet, any of its Affiliates or any Sublicensee to the first unrelated Third Party (excluding any Sublicensee) in such country for use or consumption of such Product in such country after receipt of the first Regulatory Approval for such Product in such country.

1.21 "Governmental Authority". Governmental Authority means any national, federal, state or local government, or political subdivision thereof, or any multinational organization or authority or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body.

1.22 "IND". IND means an investigational new drug application filed with the FDA with respect to a Compound or Product, or an equivalent application filed with the Regulatory Authority of a country or regulatory jurisdiction in the Territory other than the U.S., and all amendments and supplements thereto.

1.23 "Joint Intellectual Property". Joint Intellectual Property means the Joint Inventions and Joint Patent Rights.

1.24 "Know-How". Know-How means all unpatented technical information, trade secrets, formulae, standards, knowledge, directions, instructions, test protocols, procedures and results, studies, analyses, raw material sources, data, manufacturing data, and any other confidential or proprietary interest in information.

1.25 "Law" or "Laws". Law or Laws means all laws, statutes, rules, regulations, orders, judgments or ordinances of any Governmental Authority.



1.26 "Losses". Losses means any and all (a) claims, losses, liabilities, damages, fines, royalties, governmental penalties or punitive damages, deficiencies, interest, awards, judgments, and settlement amounts (including special, indirect, incidental, and consequential damages, lost profits, and Third Party punitive and multiple damages), and (b) in connection with all of the items referred to in clause (a) above, any and all costs and expenses (including reasonable counsel fees and all other expenses reasonably incurred in investigating, preparing or defending any litigation or proceeding, commenced or threatened).

1.27 "Major European Country". Major European Country means France, Germany or the United Kingdom.

1.28 "Major Markets". Major Markets means, collectively, the U.S., each of the Major European Countries and Japan, and Major Market means any one of the foregoing.

1.29 "Manufacture" or "Manufacturing". Manufacture or Manufacturing means activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and storage of a product.

1.30 "MHLW". MHLW means the Japanese Ministry of Health, Labour and Welfare, and any successor agency.

1.31 "MTA". MTA means the Material Transfer Agreement by and between the Parties, dated as of May 2, 2017, as amended.

1.32 "NDA". NDA means a New Drug Application, as defined in the Act, filed with the FDA with respect to a Compound or Product, or an equivalent application filed with the Regulatory Authority of a country in the Territory other than the U.S., and all amendments and supplements thereto.

1.33 "Net Sales". Net Sales means the gross amounts billed or invoiced by Promet, or any of its Affiliates or Sublicensees, to any Third Party that is not a Sublicensee with respect to sales of Products in the Territory, calculated in the same manner as reported in such Person's audited financial statements, less the following:

(a) Volume, cash or trade discounts, credits or allowances, including discounts in the form of inventory management fees paid to wholesalers and distributors;

(b) Credits, refunds or allowances granted upon returns, rejections or recalls and for retroactive price reductions or billing errors;

(c) Freight, postage, shipping and insurance costs incurred in transporting the applicable Products;

(d) Amounts paid (including rebates and chargeback payments or credits or other equivalents thereof) to formularies, government or government agency programs, trade customers, managed health care organizations and pharmacy benefit managers (or equivalents thereof) to obtain listing or purchase of the applicable Products;

(e) Bad debts and uncollectible amounts relating to the sale of Products that are actually written off; and

(f) Taxes, tariffs, duties or other governmental charges (other than income taxes) levied on, absorbed, or otherwise imposed on the sales, transportation, delivery, use, exportation, or importation of the applicable Products.

Sales of Products between Promet and its Affiliates or Sublicensees for resale shall be excluded from the computation of Net Sales, provided that the subsequent resale of such Products to a Third Party are included in the computation of Net Sales. Disposal or use of Products at or below cost for marketing, regulatory, development or charitable purposes, such as clinical trials, compassionate use, named patient use, or indigent patient programs, shall not be deemed a sale hereunder.

If a Product is sold as part of a Combination Product, Net Sales will be the product of (x) Net Sales of the Combination Product calculated as above (*i.e.*, calculated as for a non-Combination Product) and (y) the fraction (A/(A+B)), where:

(i) A is the average selling price of the Product comprising a Compound as the sole therapeutically active ingredient during the most recently completed Calendar Quarter during which such non-Combination Product was sold in such country; and

(ii) B is the average selling price in such country of products containing the Other API contained in the Combination Product as the sole therapeutically active ingredient when sold separately during the most recently completed Calendar Quarter during which such products were sold in such country.

If both A and B cannot be determined by reference to non-Combination Product sales as described above, then Net Sales for purposes of determining royalty payments will be calculated as above, but the average selling price in the above equation shall be determined by mutual agreement reached in good faith by the Parties prior to the end of the accounting period in question based on an equitable method of determining same that takes into account, in the applicable country, variations in dosage units and the relative fair market value of each therapeutically active ingredient in the Combination Product. If the Parties are unable to reach such an agreement prior to the end of the applicable accounting period, then the Parties will refer such matter to a jointly selected Third Party with expertise in the pricing of pharmaceutical products that is not an employee, consultant, legal advisor, officer, director or stockholder of, and does not have any conflict of interest with respect to, either Party for resolution, which will be final and binding on the Parties.

1.34 "Option Period". Option Period means the period of time beginning on the Effective Date and ending on the date nine (9) months after the Effective Date.

1.35 "Party". Party means either CoNCERT or Promet; "Parties" means both CoNCERT and Promet.

1.36 "Patent Rights". Patent Rights means all patent applications, patents, certificates of invention, applications for certificates of invention and priority patent filings, including any continuations, continuations-in-part, renewals, requests for continued examination and divisions of any such patents and patent applications, any patents or certificates of invention issuing from any of the foregoing, any extensions, reissues, reexaminations, substitutions, confirmations, registrations, revalidations, revisions, additions or supplementary patent certificates thereto, and all foreign counterparts thereof.

1.37 "Payments". Payments means royalties and other amounts payable by Promet to CoNCERT pursuant to this Agreement.

1.38 "Person". Person means any natural person or any corporation, company, partnership, joint venture, firm, Governmental Authority or other entity, including a Party.

1.39 "Product". Product means any pharmaceutical preparation containing one or more Compounds as its only active ingredient(s) or any Combination Product. For the avoidance of doubt, nothing in this Agreement grants to Promet any right or license under any Patent Rights or Know-How Controlled by CoNCERT with respect to any Other API.

1.40 "Promet Intellectual Property" means, collectively, Promet Know-How and Promet Patent Rights.

1.41 "Promet Know-How". Promet Know-How means all Know-How Controlled as of the Effective Date or thereafter during the Term by Promet or any of its Affiliates (other than any Know-How included in Joint Intellectual Property) that is used by Promet or any of its Affiliates in the Development, Manufacture or Commercialization of any Compound or Product; provided, however, that, if Promet is acquired by a Third Party, "Promet Know-How" shall exclude any Know-How that (a) is Controlled by such Third Party or the Affiliates of such Third Party (other than Promet and the Persons that were Promet's Affiliates immediately prior to the closing of such acquisition transaction (such Affiliates, "Promet Pre-Existing Affiliates")) ("Promet Excluded Affiliates") and (b) was not Controlled by Promet or any of the Promet Pre-Existing Affiliates immediately prior to the closing of such acquisition transaction; provided further that, if, after the closing of such acquisition, any such Promet Excluded Affiliate Develops or Commercializes any Compound or Product or otherwise performs any activities or obtains any rights with respect to any Compound or Product, such Affiliate will cease to be a Promet Excluded Affiliate and applicable Know-How that is Controlled by such Affiliate shall be included in Promet Know-How.

1.42 "Promet Patent Rights". Promet Patent Rights means all Patent Rights in the Territory Controlled as of the Effective Date or thereafter during the Term by Promet or any of its Affiliates (other than Joint Patent Rights) that Cover any Compound or Product and are used by Promet or any of its Affiliates in the Development, Manufacture or Commercialization of any Compound or Product; provided, however, that, if Promet is acquired by a Third Party, "Promet Patent Rights" shall exclude any Patent Rights that (a) are Controlled by such Third Party or the Affiliates of such Third Party (other than Promet and Promet Pre-Existing Affiliates) and (b) were not Controlled by Promet or any of the Promet Pre-Existing Affiliates immediately prior to the closing of such acquisition transaction; provided further that, if, after the closing of such

acquisition, any such Promet Excluded Affiliate Develops or Commercializes any Compound or Product or otherwise performs any activities or obtains any rights with respect to any Compound or Product, such Affiliate will cease to be a Promet Excluded Affiliate and applicable Patent Rights that are Controlled by such Affiliate shall be included in Promet Patent Rights.

1.43 "Regulatory Approval". Regulatory Approval means an approval by the applicable Regulatory Authority of an NDA and any other approval, license, registration, permit, notification or authorization (or waiver) of the applicable Regulatory Authority, which is necessary for the manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale, or other commercialization of pharmaceutical products in a given country or regulatory jurisdiction, other than any pricing or reimbursement approval.

1.44 "Regulatory Authority". Regulatory Authority means any Governmental Authority with responsibility for granting licenses or approvals necessary for the development, manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale or other commercialization of pharmaceutical products in a country or regulatory jurisdiction, including the FDA, EMA or MHLW.

1.45 "Regulatory Exclusivity". Regulatory Exclusivity means exclusive marketing rights or data protection or other exclusivity rights conferred by any Regulatory Authority with respect to a Product in a country or regulatory jurisdiction within the Territory, other than a Patent Right, including orphan drug exclusivity, pediatric exclusivity and rights conferred in the U.S. under the Hatch-Waxman Act.

1.46 "Satisfactory Financing Round". Satisfactory Financing Round means the first financing round that enables Promet to satisfy all of the conditions in Sections 2.1(b)(i) and (ii).

1.47 "Satisfactory Financing Round Securities". Satisfactory Financing Round Securities means shares of the same class and series of capital stock of Promet issued to other investors in the Satisfactory Financing Round.

1.48 "Senior Executive". Senior Executive means, with respect to CoNCERT, the Chief Executive Officer of CoNCERT, or his or her designee, and, with respect to Promet, the _____ of Promet, or his or her designee. "Senior Executives" means the applicable officers of CoNCERT and Promet.

1.49 "Sublicensee". Sublicensee means a Third Party that has been granted a sublicense under the rights granted to Promet pursuant to Section 2.2 of this Agreement, beyond the mere right to purchase Compound or Product from Promet or its Affiliates or Sublicensees.

1.50 "Territory". Territory means all countries of the world.

1.51 "Third Party". Third Party means any Person other than CoNCERT or Promet or any of their respective Affiliates.

1.52 "U.S.". U.S. means the United States of America, including its territories and possessions.

1.53 "Valid Claim". Valid Claim means any claim of (a) an issued and unexpired patent within the CoNCERT Patent Rights that has not been revoked or held unenforceable or invalid by a final decision of a court or other Governmental Authority of competent jurisdiction, or that has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise; or (b) a patent application within the CoNCERT Patent Rights; provided that such a claim within a patent application has not been canceled, withdrawn, or abandoned or been pending for more than seven (7) years from the date of its first priority filing in the applicable country. For clarity, a claim of a patent that, pursuant to clause (b), had ceased to be a Valid Claim before it issued but that subsequently issues and is otherwise described by clause (a), shall again be considered to be a Valid Claim once it issues until it is no longer considered a Valid Claim in accordance with clause (a).

1.54 Additional Definitions. Each of the following definitions is set forth in the Section of this Agreement indicated below:

| **Definition:** | **Section:** |
|---|---|
| Abandoned Patents | Section 7.2(a) |
| Agents | Section 8.1 |
| Board | Section 2.6 |
| Commercialization Plan | Section 4.2 |
| CoNCERT | Preamble |
| CoNCERT Excluded Affiliates | Section 1.12 |
| CoNCERT Observer | Section 2.6 |
| CoNCERT Parties | Section 10.1 |
| CoNCERT Pre-Existing Affiliates | Section 1.12 |
| CoNCERT Sole Inventions | Section 7.1(b) |
| Confidential Information | Section 8.2 |
| Confidentiality Agreement | Section 8.2 |
| Courts | Section 12.1 |
| Effective Date | Preamble |
| Indemnified Party | Section 10.3(a) |
| Indemnifying Party | Section 10.3(a) |
| Infringement Claim | Section 7.3(a) |
| Joint Inventions | Section 7.1(c) |
| Joint Patent Rights | Section 7.2(b) |
| Late Payment Notice | Section 6.9 |
| Option | Section 2.1(a) |
| Option Exercise Date | Section 2.1(b) |
| Other API | Section 1.7 |
| Paragraph IV Claim | Section 7.8(a) |
| Product Liability Claim | Section 10.1(b) |
| Promet | Preamble |
| Promet Excluded Affiliates | Section 1.41 |
| Promet Parties | Section 10.2 |
| Promet Pre-Existing Affiliates | Section 1.41 |
| Promet Sole Inventions | Section 7.1(b) |
| Royalty Term | Section 6.3(b) |
| Sole Inventions | Section 7.1(b) |
| Sublicensee Intellectual Property | Section 2.2(c) |

| Definition: | Section: |
|---|---|
| Sublicensee Materials | Section 2.2(c) |
| Taxes | Section 6.6 |
| Term | Section 11.1 |
| Third Party Claims | Section 10.1 |
| Third Party Patent License | Section 6.3(c) |
| Transition Alliance Manager | Section 2.7 |

1.55 Captions; Certain Conventions; Construction. All headings and captions herein are for convenience only and shall not be interpreted as having any substantive meaning. The Schedules to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. Unless otherwise expressly provided herein or the context of this Agreement otherwise requires:

(a) words of any gender include each other gender;

(b) words such as "herein", "hereof" and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear;

(c) words using the singular shall include the plural, and vice versa;

(d) the words "include," "includes" and "including" shall be deemed to be followed by the phrase "but not limited to", "without limitation", "inter alia" or words of similar import;

(e) the word "or" shall be deemed to include the word "and" (*i.e.*, shall mean "and/or")

(f) references to "Article," "Section," "subsection", "paragraph", "clause" or other subdivision, or to a Schedule, without reference to a document, are to the specified provision or Schedule of this Agreement; and

(g) references to "$" or "dollars" shall be references to U.S. Dollars.

This Agreement shall be construed as if the Parties drafted it jointly.

## ARTICLE II
## GRANTS OF RIGHTS

2.1 Option.

(a) Grant. CoNCERT hereby grants to Promet the exclusive option, exercisable at Promet's sole discretion, to obtain the exclusive license set forth in Section 2.2(a) (the "Option").

(b) Option Exercise. Promet shall have the right to exercise the Option by written notice to CoNCERT solely during the Option Period; provided that Promet (i) has raised gross proceeds of at least Eight Million Dollars ($8,000,000) (such amounts raised shall include

any grants or other non-dilutive amounts received by Promet after the Effective Date) in one or more equity or other financings after the Effective Date, and (ii) has a post-money valuation, following the closing of its then most recent equity financing and based on the terms of such financing, of at least Forty Million Five Hundred Thousand Dollars ($40,500,000). The date on which Promet exercises the Option, if any, shall be the "Option Exercise Date."

(c) Expiration of the Option. If, for any reason (including a failure to meet the conditions in Sections 2.1(b)(i) and (ii) prior to the end of the Option Period), Promet does not exercise the Option within the Option Period, then (a) such Option shall terminate and be of no further force or effect as of the expiration of the Option Period and (b) this Agreement shall terminate in accordance with Section 11.2.

2.2 Licenses.

(a) Commercialization License. Subject to the terms of this Agreement, upon Promet's exercise of the Option pursuant to Section 2.1, CoNCERT shall, and hereby does, grant to Promet an exclusive (even as to CoNCERT and its Affiliates), royalty-bearing right and license, including the right to sublicense in accordance with Section 2.2(c), under the CoNCERT Intellectual Property and CoNCERT's interest in the Joint Intellectual Property, to Develop, Manufacture, use and Commercialize, including filing for, obtaining and maintaining Regulatory Approval for, Products in the Field in the Territory.

(b) Development License. Subject to the terms of this Agreement, CoNCERT hereby grants to Promet, for the duration of the Option Period, an exclusive (even as to CoNCERT and its Affiliates, but subject to the rights of CoNCERT and its Affiliates to Develop Compounds and Products as specifically set forth in this Agreement), right and license, including the right to sublicense in accordance with Section 2.2(c), under the CoNCERT Intellectual Property and CoNCERT's interest in the Joint Intellectual Property, to Develop Compounds and Products in the Field in the Territory.

(c) Sublicenses. From and after the Option Exercise Date, Promet shall have the right to grant sublicenses under the licenses to CoNCERT Intellectual Property and CoNCERT's interest in the Joint Intellectual Property granted to Promet under Section 2.2(a) and Section 2.2(b) to its Affiliates and to Third Parties without CoNCERT's prior written approval but with written notice to CoNCERT; provided, however, that any such sublicense shall be subject to all applicable terms and conditions of this Agreement. Promet shall use Commercially Reasonable Efforts to cause each agreement with each Sublicensee to include grants of rights sufficient to enable Promet to grant substantially the rights set forth in Sections 11.8(b) through 11.8(f) with respect to (i) all Know-How and Patent Rights (including all applicable pre-clinical and clinical data, including pharmacology and biology data; Manufacturing documents and materials; and Manufacturing technologies) Controlled by such Sublicensee during the Term and used by such Sublicensee in the Development, Manufacture or Commercialization of any Compound or Product (collectively, "Sublicensee Intellectual Property"); (ii) all filings with Regulatory Authorities in the Territory relating to Compounds and Products and Regulatory Approvals relating to Compounds and Products held by such Sublicensee, including related correspondence with Regulatory Authorities; (iii) all Manufacturing agreements to which such Sublicensee is a party that are related to Compounds or Products; (iv) all of such Sublicensee's

inventory of Compounds and Products existing as of the applicable date; and (v) all trademarks owned by such Sublicensee and used solely in connection with the Products, along with all associated goodwill ((i)-(v), collectively, "Sublicensee Materials").

2.3 Rights Retained by the Parties. Any rights of CoNCERT or Promet, as the case may be, not expressly granted to the other Party under the provisions of this Agreement shall be retained by such Party.

2.4 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement, including the licenses granted under Section 2.1, 2.2 or 11.8(e) to Patent Rights and Know-How (including any data included in the Know-How), are and will otherwise be deemed to be for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined in Section 101(35A) of the Bankruptcy Code. Each Party will retain and may fully exercise all of its respective rights and elections under the Bankruptcy Code. The Parties agree that each Party, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code or any other provisions of applicable Law outside the United States that provide similar protection for "intellectual property."

2.5 Transfer of CoNCERT Know-How. To the extent not addressed in the MTA, during the period beginning on the Effective Date and ending on the date that is three (3) months after the Option Exercise Date, CoNCERT shall transition CoNCERT Know-How to Promet and provide Promet with reasonable amounts of consultation regarding the transferred CoNCERT Know-How.

2.6 Board Observer. CoNCERT shall be entitled to have one representative of CoNCERT (the "CoNCERT Observer") attend all regularly held and special meetings of the Board of Directors of Promet (the "Board") in a nonvoting observer capacity and to receive notice of all meetings of the Board, and Promet shall give such CoNCERT Observer copies of all notices, minutes, consents and other material that it provides to its directors at or about the same time as delivered to such directors; provided, however, that the CoNCERT Observer shall agree to hold in confidence and trust and to act in a fiduciary manner with respect to all information and materials so provided and Promet reserves the right to exclude the CoNCERT Observer from any meeting or portion thereof of the Board or from access to any material or portion thereof if Promet reasonably believes that such exclusion or withholding of information with respect thereto is reasonably necessary to (a) preserve attorney-client privilege or (b) comply with the terms and conditions of confidentiality agreements with Third Parties or otherwise protect the confidential information of Promet to the extent there may be a conflict interest on the part of CoNCERT. CoNCERT's right under this Section 2.6 shall expire if and when CoNCERT's ownership interest in Promet first decreases below ten percent (10%) of the outstanding voting stock of Promet. CoNCERT shall bear any costs and expenses of performance of the CoNCERT Observer pursuant to this Agreement.

2.7 Transition Alliance Managers. CoNCERT and Promet each acknowledge and agree that it would be beneficial for each to have a representative with a general understanding of the Development, Manufacturing and Commercialization issues relating to the Compounds and Products to act as a transition alliance manager ("Transition Alliance Manager"), and each Party

will appoint such a person promptly after the Option Exercise Date. It is envisioned that the Transition Alliance Managers will serve as a single point of contact within each Party with responsibility for facilitating communication and collaboration between the Parties, including by aiding in the transfer of documents and materials between the Parties. Each Party may replace its Transition Alliance Manager with an alternative representative at any time with prior written notice to the other Party. A Party shall bear any costs and expenses of performance by its Transition Alliance Manager pursuant to this Agreement. Each Party's Alliance Manager and any substitute for an Alliance Manager shall be bound by obligations of confidentiality and non-use applicable to the other Party's Confidential Information that are at least as stringent as those set forth in ARTICLE VIII.

## ARTICLE III
## DEVELOPMENT

3.1 General. From and after the Effective Date, and subject to the terms of this Agreement, including the requirements of ARTICLE V, Promet (or its Affiliates or Sublicensees) shall control and be solely responsible for the Development of and regulatory activities with respect to Compounds and Products in the Field in the Territory, including all costs and expenses relating thereto; provided, however, that, prior to the Option Exercise Date, CoNCERT will reasonably cooperate with Promet, as Promet may reasonably request and at Promet's expense, to enable Promet to interact with FDA in order to discuss the Development of and regulatory activities with respect to Compounds and Products for the indications Promet desires to pursue with respect to such Compounds and Products. If Promet requests CoNCERT's cooperation as described above, the Parties shall mutually agree in advance on a budget therefor, and Promet shall reimburse CoNCERT for any expenses incurred by CoNCERT under this Section 3.1 within thirty (30) days after receiving an invoice therefor.

3.2 Exchange of Information Regarding Development. At least once each Calendar Year (or, from and after the date on which CoNCERT's right under Section 2.6 expires, at least once each six (6) months), beginning on the Effective Date and ending on the date on which Promet obtains the first Regulatory Approval for a Product in a Major Market, Promet shall provide CoNCERT with a reasonably detailed report describing Promet's Development activities and the summary results thereof with respect to all Compounds and Products.

## ARTICLE IV
## COMMERCIALIZATION

4.1 General. From and after the Option Exercise Date, and subject to the terms of this Agreement, including the requirements of ARTICLE V, Promet (or its Affiliates or Sublicensees) shall control and be solely responsible for the Commercialization of Products in the Field in the Territory, including all costs and expenses relating thereto.

4.2 Commercialization Plans. During the Royalty Term with respect to each Product, at least thirty (30) days prior to the commencement of each Calendar Year, Promet shall provide CoNCERT, for information purposes only, a summary of the planned Commercialization activities to be conducted by or on behalf of Promet and its Affiliates and Sublicensees with

respect to such Product in each country in the Territory during such Calendar Year (each such plan, a "Commercialization Plan").

## ARTICLE V
## DILIGENCE

5.1 Commercially Reasonable Efforts. During the Term, Promet shall, directly or through its Affiliates or Sublicensees, use Commercially Reasonable Efforts, from and after the Option Exercise Date, to (a) Develop and obtain Regulatory Approval for one (1) Product in the Field in the U.S. and at least one (1) other Major Market and (b) subject to obtaining Regulatory Approval in the applicable Major Market if required, Commercialize one (1) Product in the Field in the U.S. and at least one (1) other Major Market.

5.2 Termination for Failure to Meet Diligence Obligation. If, at any time during the Term, CoNCERT reasonably believes that Promet (itself and through its Affiliates and Sublicensees) has not complied with its obligations under Section 5.1 to Develop one (1) Compound or Product in the Field in the U.S. and at least one (1) other Major Market for any consecutive nine (9) month period following the Option Exercise Date, CoNCERT shall provide written notice to Promet specifying the nature of such reasonable belief, and CoNCERT may terminate this Agreement pursuant to Section 11.5.

## ARTICLE VI
## FINANCIAL PROVISIONS

6.1 Equity Investment. In partial consideration for the rights granted to Promet hereunder, if Promet exercises the Option pursuant to Section 2.1, within five (5) Business Days following the Option Exercise Date, pursuant to the terms of a customary stock purchase agreement between Promet and CoNCERT on mutually acceptable terms (which shall include a reasonable and customary lock up provision in connection with any public offering applicable to the Satisfactory Financing Round Securities on terms consistent with those applicable to the shares purchased by any other investor in the Satisfactory Financing Round), Promet shall issue to CoNCERT, for no additional consideration, shares of Satisfactory Financing Round Securities representing the lesser of (a) the number of shares determined by dividing Eight Million Dollars ($8,000,000) by the price per share paid by other investors in the Satisfactory Financing Round or (b) the number of shares rounded down to the nearest whole share equal to nineteen and nine tenths percent (19.9%) of the issued and outstanding shares of Promet immediately following the issuance of such shares to CoNCERT. Following the execution of such stock purchase agreement, CoNCERT shall be entitled to the same right to participate in future financing rounds of Promet (and subject to the same exceptions) as applicable to any investor in the Satisfactory Financing Round.

By way of example, if Promet has a pre-investment valuation of Eighty Million Dollars ($80,000,000) and Ten Million Shares are authorized pre-investment, the value per share pre-investment would be Eight Dollars per share ($8.00/share). If gross proceeds of Eight Million Dollars ($8,000,000) are raised, the new investor(s) would receive One Million shares (1,000,000) and CoNCERT would receive One Million shares (1,000,000) with a new total of authorized shares of Twelve Million shares (12,000,000) post-investment.

6.2 Development and Commercialization Costs. For clarity, following the Effective Date, Promet shall be solely responsible for all costs it incurs in Developing and Commercializing Compounds and Products, including all Manufacturing costs.

6.3 Product Royalties.

(a) Royalty Rate. Promet shall pay to CoNCERT royalties, on a Product-by-Product basis, on worldwide Net Sales of Products in the Territory during each Calendar Year during the applicable Royalty Term as follows:

| Worldwide Annual Net Sales of Products | Royalty Rate |
|---|---|
| For that portion less than or equal to One Hundred Million Dollars ($100,000,000) | 4% |
| For that portion greater than One Hundred Million Dollars ($100,000,000) and less than or equal to Five Hundred Million Dollars ($500,000,000) | 5% |
| For that portion greater than Five Hundred Million Dollars ($500,000,000) and less than or equal to One Billion Dollars ($1,000,000,000) | 6% |
| For that portion greater than One Billion Dollars ($1,000,000,000) | With respect to Net Sales made by Promet or any of its Affiliates, 10% of such Net Sales<br><br>With respect to Net Sales made by any Sublicensee, the greater of (i) 6% of such Net Sales or (ii) 50% of all payments received by Promet or any of its Affiliates with respect to such Net Sales |

For purposes of calculating royalties, in each Calendar Quarter in which cumulative Net Sales of Products for the applicable Calendar Year exceed One Billion Dollars ($1,000,000,000), the royalty shall first be calculated using the applicable royalty rates applied to Net Sales of Promet and its Affiliates and next using the applicable royalty rates applied to Net Sales of Sublicensees or fifty percent (50%) of payments received by Promet or any of its Affiliates with respect to such Net Sales, as applicable (as illustrated in the Q3 row of the table in the third example below).

By way of example, if worldwide Net Sales by Promet's Sublicensees in a Calendar Year are Two Billion Dollars ($2,000,000,000), neither Promet nor any of its Affiliates made any Net Sales in such Calendar Year, and Promet's Sublicensees are required to pay Promet and its Affiliates a royalty of eighteen percent (18%) of worldwide annual Net Sales made by such Sublicensees greater than One Billion Dollars ($1,000,000,000), then Promet will pay CoNCERT a royalty of One Hundred Forty-Four Million Dollars ($144,000,000), comprising Four Million Dollars ($4,000,000) on that portion of Net Sales that is less than or equal to One Hundred Million Dollars ($100,000,000), Twenty Million Dollars ($20,000,000) on that portion of Net Sales that is greater than One Hundred Million Dollars ($100,000,000) and less than or equal to Five Hundred Million Dollars ($500,000,000), Thirty Million Dollars ($30,000,000) on that portion of Net Sales that is greater than Five Hundred Million Dollars ($500,000,000) and less than or equal to One Billion Dollars ($1,000,000,000), and Ninety Million Dollars

($90,000,000) on that portion of Net Sales in excess of One Billion Dollars ($1,000,000,000) (which equals fifty percent (50%) of the One Hundred Eighty Million Dollars ($180,000,000) of royalties on Net Sales in excess of One Billion Dollars ($1,000,000,000) received by Promet from its Sublicensees).

By way of further example, if worldwide annual Net Sales by Promet's Sublicensees in a Calendar Year are Two Billion Dollars ($2,000,000,000), neither Promet nor any of its Affiliates made any Net Sales in such Calendar Year, and Promet's Sublicensees are required to pay Promet and its Affiliates a royalty of ten percent (10%) of worldwide annual Net Sales made by such Sublicensees greater than One Billion Dollars ($1,000,000,000), then Promet will pay CoNCERT a royalty of One Hundred Fourteen Million Dollars ($114,000,000), comprising Four Million Dollars ($4,000,000) on that portion of Net Sales that is less than or equal to One Hundred Million Dollars ($100,000,000), Twenty Million Dollars ($20,000,000) on that portion of Net Sales that is greater than One Hundred Million Dollars ($100,000,000) and less than or equal to Five Hundred Million Dollars ($500,000,000), Thirty Million Dollars ($30,000,000) on that portion of Net Sales that is greater than Five Hundred Million Dollars ($500,000,000) and less than or equal to One Billion Dollars ($1,000,000,000), and Sixty Million Dollars ($60,000,000) on that portion of Net Sales in excess of One Billion Dollars ($1,000,000,000) (which equals six percent (6%) of that portion of Net Sales in excess of One Billion Dollars ($1,000,000,000), because it is greater than fifty percent (50%) of the One Hundred Million Dollars ($100,000,000) of royalties on Net Sales in excess of One Billion Dollars ($1,000,000,000) received by Promet from its Sublicensees).

By way of further example, and as illustrated in the table below, if worldwide annual Net Sales are Three Billion Dollars ($3,000,000,000), of which Promet and its Affiliates made Net Sales of One Billion Five Hundred Fifty Million Dollars ($1,550,000,000) and Promet's Sublicensees made Net Sales of One Billion Four Hundred Fifty Million Dollars ($1,450,000,000) in such Calendar Year, and Promet's Sublicensees are required to pay Promet and its Affiliates a royalty of ten percent (10%) of worldwide annual Net Sales made by such Sublicensees, then Promet will pay CoNCERT a royalty of Two Hundred Six Million Dollars ($206,000,000), comprising Four Million Dollars ($4,000,000) on that portion of Net Sales that is less than or equal to One Hundred Million Dollars ($100,000,000), Twenty Million Dollars ($20,000,000) on that portion of Net Sales that is greater than One Hundred Million Dollars ($100,000,000) and less than or equal to Five Hundred Million Dollars ($500,000,000), Thirty Million Dollars ($30,000,000) on that portion of Net Sales that is greater than Five Hundred Million Dollars ($500,000,000) and less than or equal to One Billion Dollars ($1,000,000,000), Eighty Million Dollars ($80,000,000) on that portion of Net Sales made by Promet and its Affiliates in excess of One Billion Dollars ($1,000,000,000) and Seventy-Two Million Dollars ($72,000,000) on that portion of Net Sales made by Promet's Sublicensees in excess of One Billion Dollars ($1,000,000,000) (which equals six percent (6%) of that portion of Net Sales in excess of One Billion Dollars ($1,000,000,000), because it is greater than fifty percent (50%) of the One Hundred Twenty Million Dollars ($120,000,000) of royalties on Net Sales in excess of One Billion Dollars ($1,000,000,000) received by Promet from its Sublicensees).

| | Promet & Affiliates | Sublicensees |
|---|---|---|

| | Sales | Royalty % | Royalty Payment to CoNCERT | Sales | Royalty % | Royalty Payment to CoNCERT |
|---|---|---|---|---|---|---|
| Q1 | $50M | 4% | $2M | $50M | 4% | $2M |
| **Total Q1 Net Sales: $100M** | | | | | | |
| Q2 | $200M | 5% | $10M | $200M | 5% | $10M |
| **Total Q1 + Q2 Net Sales: $500M** | | | | | | |
| Q3 | $600M:<br>$500M<br>$100M | <br>6%<br>10% | <br>$30M<br>$10M | $500M | Greater of (i) 6% or (ii) 50% of all payments received by Promet or any of its Affiliates with respect to such Net Sales | $30M |
| **Total Q1 + Q2 +Q3 Net Sales: $1.6B** | | | | | | |
| Q4 | $700M | 10% | $70M | $700M | Greater of (i) 6% or (ii) 50% of all payments received by Promet or any of its Affiliates with respect to such Net Sales | $42M |
| Total Annual Promet Sales: $1.55B | | | | | | |
| Total Annual Sublicensee Sales: $1.45B | | | | | | |
| **Total Annual Net Sales: $3B** | | | | | | |
| Total Annual Royalty Payment to CoNCERT: $206M | | | | | | |

(b) Royalty Term and Adjustments. Promet's royalty obligations to CoNCERT under this Section 6.3 shall commence on a country-by-country and Product-by-Product basis on the Effective Date and shall expire on a country-by-country basis and Product-by-Product basis on the later of (i) expiration or invalidation of the last Valid Claim Covering

such Product in such country or (ii) the tenth ($10^{th}$) anniversary of the date of the First Commercial Sale by Promet or any of its Affiliates or Sublicensees to a non-Sublicensee Third Party of such Product in such country (the "Royalty Term"); provided that, during any period within the Royalty Term remaining after the expiration of all Valid Claims Covering such Product in such country and all Regulatory Exclusivity as to such Product in such country, the royalties payable as to such Product in such country under this Section 6.3 shall be reduced to fifty percent (50%) of the royalties otherwise payable as to such Product in such country pursuant to Section 6.3(a). Such royalty reduction will be calculated by determining the portion of total Net Sales of the relevant Product in a Calendar Quarter that is attributable to the applicable country in which such reduction applies, and by determining the total royalties without reduction, and then reducing by fifty percent (50%) the applicable portion (based on Net Sales) of total royalties attributable to the country in which such reduction applies.

(c) Third Party Payments. If, in order to Develop, Manufacture, use or Commercialize a Product in the Field in a country of the Territory, Promet or its Affiliate or Sublicensee is obligated to obtain a license or comparable grant of rights (*e.g.*, a covenant not to sue) under any Patent Rights from a Third Party ("Third Party Patent License") and pay a royalty under such Third Party Patent License with respect to such Product in such country, then, subject to Section 6.3(d), one hundred percent (100%) of such royalties actually paid by Promet, its Affiliates or Sublicensees shall be creditable against royalties payable to CoNCERT hereunder with respect to such Product in such country; provided that, if Promet is obligated to enter into any Third Party Patent License, Promet shall use Commercially Reasonable Efforts to minimize the royalties owed by Promet under such Third Party Patent License.

(d) Limitation on Royalty Reductions. Notwithstanding anything to the contrary in this Section 6.3, in no event shall the royalties payable under this Section 6.3 with respect to Net Sales of any Product in any country in any Calendar Quarter be reduced to less than fifty percent (50%) of the royalties payable under Section 6.3(a) with respect to Net Sales of such Product in such country in such Calendar Quarter; provided, however, that any amount which is entitled to be credited under Section 6.3(c) but is not credited as a result of the foregoing limitation in this Section 6.3(d) shall be carried over and applied against royalties payable to CoNCERT in respect of such Product in such country in subsequent periods of the Royalty Term until the full deduction is taken.

6.4 Reports; Payments. Within forty-five (45) days after the end of each Calendar Quarter during which there are Net Sales giving rise to a payment obligation under Section 6.3, Promet shall submit to CoNCERT a report identifying, for each Product, the gross sales, itemized deductions and Net Sales for such Product for each country in the Territory for such Calendar Quarter and the basis for any reduction in royalties pursuant to any subsection of Section 6.3. Concurrently with each such report, Promet shall pay to CoNCERT all royalties payable by it under Section 6.3.

6.5 Books and Records; Audit Rights. Promet shall keep complete and accurate records of the underlying revenue and expense data relating to the calculations of Net Sales and payments required by Section 6.3. CoNCERT shall have the right, once annually at its own expense, to have an independent, certified public accounting firm, selected by CoNCERT and reasonably acceptable to Promet, review any such records of Promet in the location(s) where

such records are maintained by Promet upon reasonable notice (which shall be no less than fourteen (14) days prior notice) and during regular business hours and under obligations of strict confidence, for the sole purpose of verifying the basis and accuracy of payments made under Section 6.3 within the thirty-six (36) month period preceding the date of the request for review. The report of such accounting firm shall be limited to a certificate stating whether any report made or payment submitted by Promet during such period is accurate or inaccurate and the actual amounts of Net Sales, and royalties due, for such period. Promet shall receive a copy of each such report concurrently with receipt by CoNCERT. Should such inspection lead to the discovery of a discrepancy to CoNCERT's detriment, Promet shall pay within five (5) Business Days after its receipt from the accounting firm of the certificate the amount of the discrepancy plus interest calculated in accordance with Section 6.9. CoNCERT shall pay the full cost of the review unless the underpayment of royalties is greater than five percent (5%) of the amount due for any applicable Calendar Year, in which case Promet shall pay the reasonable cost charged by such accounting firm for such review. Any overpayment by Promet revealed by an examination shall be fully creditable against future Payments.

6.6 Tax Matters. Except as expressly provided below, no payments to be made to CoNCERT by Promet hereunder shall be reduced by or on account of any taxes, levies, imposts, duties, charges, assessments or fees (collectively, "Taxes"). Notwithstanding the immediately preceding sentence, if any applicable Law requires (with due regard to any relief to which CoNCERT may be entitled) that Taxes be deducted and withheld from any payment made to CoNCERT by Promet under this Agreement, Promet shall (a) deduct those Taxes, together with any interest and penalties properly assessed thereon, from such payment or from any other payment owed by Promet hereunder; (b) transmit the amounts so deducted to the proper Governmental Authority; (c) send evidence of the requirement together with proof of due transmission of the amounts described in clause (b) to CoNCERT promptly following such payment; and (d) remit to CoNCERT the net amount of such payment after taking account of such deduction. In determining whether to deduct any amount hereunder, Promet shall take due account of all documentation supplied by CoNCERT, and of other facts known to Promet, supporting a reduction in any Tax otherwise required to be deducted, or a credit therefor or refund thereof. Promet will reasonably cooperate with CoNCERT in respect of Tax matters relating to payments made by Promet to CoNCERT under this Agreement and any disputes with a Governmental Authority regarding such matters, including without limitation: (y) complying with reasonable requests from CoNCERT to change the form, place or other circumstances of payments to be made to CoNCERT by Promet under this Agreement so as to reduce the incidence of Taxes on such payments or recover any Taxes imposed on such payments (any such recovery to be for the benefit of CoNCERT); and (z) in connection with any official or unofficial audit or contest relating to such payments.

6.7 Payment Method and Currency Conversion. All Payments shall be made in U.S. dollars in immediately available funds via either a bank wire transfer, an ACH (automated clearing house) mechanism, or any other means of electronic funds transfer, at Promet's election, to CoNCERT's bank account at Silicon Valley Bank, or to such other bank account as CoNCERT shall designate in a notice at least ten (10) days before the payment is due. CoNCERT's wiring instructions are set forth on Schedule 6.7. For the purposes of determining the amount of any royalties due for the relevant Calendar Quarter under Section 6.3, the amount of Net Sales in any foreign currency shall be converted into U.S. dollars in accordance with the

prevailing rates of exchange for the relevant month for converting such first currency into such other currency used by Promet's (or its Sublicensee's) internal accounting systems, which are independently audited on an annual basis. Upon request by CoNCERT, Promet shall disclose the bases for the rates of exchange used for purposes of assuring that such rates reflect prevailing rates of exchange.

6.8 Blocked Payments. If by reason of applicable Laws in any country in the Territory, it becomes impossible or illegal for Promet or any of its Affiliates or Sublicensees to transfer, or have transferred on its behalf royalties or other payments to CoNCERT or to Promet or its Affiliates or Sublicensees, Promet shall promptly notify CoNCERT of the conditions preventing such transfer. To the extent any payments to CoNCERT cannot be transferred pursuant to the preceding sentence, such amounts shall be deposited in local currency in the relevant country to the credit of CoNCERT in a recognized banking institution designated by CoNCERT or, if none is designated by CoNCERT within a period of thirty (30) days, in a recognized banking institution selected by Promet or its Affiliate or Sublicensee, as the case may be, and identified in a notice given to CoNCERT. If so deposited in a foreign country, Promet shall provide, or cause its Affiliate or Sublicensee to provide, reasonable cooperation to CoNCERT so as to allow CoNCERT to assume control over such deposit as promptly as practicable.

6.9 Late Payments. If a Party shall fail to make a timely payment pursuant to the terms of this Agreement, the other Party shall provide written notice of such failure to the non-paying Party (a "Late Payment Notice"), and interest shall accrue on the past due amount starting on the date of the Late Payment Notice at the thirty (30) day U.S. dollar London Interbank Offered Rate effective for the date that payment was due (as published in the Wall Street Journal) plus five percent (5%) per annum, computed for the actual number of days after the date of the Late Payment Notice that the payment was past due.

## ARTICLE VII
## INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION AND RELATED MATTERS

7.1 Ownership of Inventions.

(a) MTA. If, for any reason (including a failure to meet the conditions in Sections 2.1(b)(i) and 2.1(b)(ii) prior to end of the Option Period), Promet does not exercise the Option within the Option Period, all Promet Sole Inventions and Joint Inventions made after the Effective Date shall be governed by the terms of the MTA and Promet shall, and hereby does, assign the same to CoNCERT to the extent set forth the MTA upon the expiration of the Option Period; provided, however, that, notwithstanding the terms of the MTA, Promet shall not be required to assign such inventions to CoNCERT prior to the end the of Option Period. If Promet does exercise the Option within the Option Period, ownership of all Promet Sole Inventions and Joint Inventions made after the effective date of the MTA (*i.e.*, May 2, 2017) shall be governed by the terms of this Agreement.

(b) Sole Inventions. Subject to Section 7.1(a), each Party shall exclusively own all inventions relating to any Compound or Product or its manufacture or use made solely

by such Party, its employees, agents and consultants ("Sole Inventions"). Sole Inventions made solely by Promet, its employees, agents and consultants are referred to herein as "Promet Sole Inventions". Sole Inventions made solely by CoNCERT, its employees, agents and consultants are referred to herein as "CoNCERT Sole Inventions".

(c) Joint Inventions. Subject to Section 7.1(a), the Parties shall jointly own all inventions relating to any Compound or Product or its manufacture or use made jointly by employees, agents and consultants of Promet, on the one hand, and employees, agents and consultants of CoNCERT, on the other hand, on the basis of each Party having an undivided interest in the whole ("Joint Inventions"). Subject to the licenses and other provisions of this Agreement (including Section 7.1(a)), each Party shall have the unrestricted right to use and license Joint Inventions without obtaining consent from, or accounting to, the other Party.

(d) Inventorship. For purposes of determining whether an invention is a Promet Sole Invention, a CoNCERT Sole Invention or a Joint Invention, questions of inventorship shall be resolved in accordance with United States patent Laws.

(e) Further Assurances. Each Party shall execute such documents and take such actions as may be reasonably requested by the other Party to confirm and give further effect to the provisions of this Section 7.1.

7.2 Prosecution and Maintenance of Patent Rights.

(a) Prosecution of CoNCERT Patent Rights. With respect to CoNCERT Patent Rights, CoNCERT and Promet shall cooperate in good faith in connection with the continued prosecution and maintenance by CoNCERT of such CoNCERT Patent Rights. If Promet exercises the Option pursuant to Section 2.1, the out-of-pocket costs and expenses incurred by CoNCERT after the Option Exercise Date to obtain, prosecute and maintain CoNCERT Patent Rights shall be borne one hundred percent (100%) by Promet. CoNCERT shall notify Promet at least ninety (90) days prior to the deadline for entering into national phase with respect to any PCT application included in CoNCERT Patent Rights. No later than sixty (60) days prior to entry into national phase, Promet shall provide CoNCERT with a list of any countries in which Promet would like CoNCERT to file. CoNCERT shall file international patent applications, or designate for national filing and file, in all countries requested by Promet. CoNCERT shall promptly deliver to Promet copies of all official correspondence with the applicable patent and trademark offices in the Territory relating to the CoNCERT Patent Rights and, after the Option Exercise Date shall promptly provide Promet drafts of all proposed material filings and correspondence to any patent authority with respect to the CoNCERT Patent Rights for Promet's review and comment prior to the submission of such proposed filings and correspondences. CoNCERT shall keep Promet informed of the status of all pending patent applications that pertain to any Compound or Product. CoNCERT, its agents and attorneys shall not unreasonably decline to implement or incorporate any comments of Promet regarding any aspect of such patent prosecutions. CoNCERT shall not abandon any CoNCERT Patent Rights (the "Abandoned Patents") without at least ninety (90) days' prior notice to Promet. If CoNCERT decides to abandon any CoNCERT Patent Rights, Promet shall have the option to continue to prosecute and maintain the Abandoned Patents in CoNCERT's name.

(b) Prosecution of Joint Patent Rights. Promet shall be responsible for obtaining, prosecuting and/or maintaining patents and patent applications, in any countries in the Territory, Covering Joint Inventions ("Joint Patent Rights"). The out-of-pocket costs and expenses incurred to obtain, prosecute and maintain Joint Patent Rights shall be borne one-hundred percent (100%) by Promet. Promet shall keep CoNCERT informed of the status of all pending Joint Patent Rights. Promet, its agents and attorneys shall not unreasonably decline to implement or incorporate any comments of CoNCERT regarding any aspect of such patent prosecutions. Promet shall not abandon any Joint Patent Right without at least ninety (90) days' prior notice to CoNCERT. If Promet decides to abandon any Joint Patent Right, CoNCERT shall have the option to continue to prosecute and maintain such Joint Patent Right jointly in both Parties' names, at CoNCERT's sole expense.

(c) Prosecution of Promet Patent Rights. Promet has the sole right, but not the responsibility, to obtain, prosecute and/or maintain the Promet Patent Rights.

(d) Cooperation. Each Party agrees to cooperate fully in the preparation, filing, prosecution, and maintenance of CoNCERT Patent Rights and Joint Patent Rights pursuant to this Section 7.2 and in the obtaining and maintenance of any patent term extensions, supplementary protection certificates, pediatric extensions, and their equivalent with respect thereto. Such cooperation includes: (i) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, so as enable the other Party to apply for and to prosecute patent applications in any country as permitted by this Section 7.2; and (ii) promptly informing the other Party of any matters coming to such Party's attention that may affect the preparation, filing, prosecution, or maintenance of any such patent applications.

7.3 Third Party Infringement.

(a) Notice. Each Party shall promptly report in writing to the other Party during the Term any known or suspected (i) infringement of any of the CoNCERT Patent Rights or Joint Patent Rights, or (ii) unauthorized use or misappropriation of any of the CoNCERT Know-How or Joint Inventions, in the case of either clause (i) or clause (ii), that could reasonably be expected to impact the (A) Development, Manufacture, use or Commercialization of a Compound or Product in the Field in the Territory, or (B) scope of the rights licensed to Promet under ARTICLE II (an "Infringement Claim"), of which such Party becomes aware, and shall provide the other Party with all available evidence supporting such Infringement Claim.

(b) Initial Right to Enforce. Subject to Section 7.3(c), Promet (itself or through its Affiliate or Sublicensee) shall have the first right, but not the obligation, to initiate a suit, or take other appropriate action that it believes is reasonably required to protect (*i.e.*, prevent or abate actual or threatened infringement or misappropriation of) or otherwise enforce the CoNCERT Intellectual Property and Joint Intellectual Property with respect to an Infringement Claim; provided, however, that Promet shall (i) consult with CoNCERT in good faith with respect to any claim that any CoNCERT Patent Right or Joint Patent Right is invalid or unenforceable and (ii) implement any reasonable comment from CoNCERT regarding any aspect of defending against any such claim described in clause (i). Any such suit by Promet shall be brought either in the name of CoNCERT or its Affiliate, the name of Promet or its Affiliate, or the names of Promet, CoNCERT and their respective Affiliates, as may be required by the

Law of the forum. For this purpose, CoNCERT shall execute such legal papers and cooperate in the prosecution of such suit, including providing full access to documents, information and witnesses as reasonably requested by Promet in connection with such suit, as may be reasonably requested by Promet; provided that Promet shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by CoNCERT in connection with such cooperation. For clarity, as between CoNCERT and Promet, (A) CoNCERT shall have the sole right, but not the obligation, to protect CoNCERT Intellectual Property against any suspected misappropriation or infringement that does not constitute an Infringement Claim and (B) the Parties shall jointly determine by mutual agreement whether and how to protect Joint Intellectual Property against any suspected misappropriation or infringement that does not constitute an Infringement Claim, and the provisions of this ARTICLE VII shall not apply with respect thereto.

(c) Step-In Right. If Promet does not initiate a suit or take other appropriate action that it has the initial right to initiate or take with respect to an Infringement Claim pursuant to Section 7.3(b), then CoNCERT may, in its discretion, provide Promet with notice of CoNCERT's intent to initiate a suit or take other appropriate action. If CoNCERT provides such notice and Promet does not initiate a suit or take such other appropriate action within thirty (30) days after receipt of such notice from CoNCERT, then CoNCERT shall have the right to initiate a suit or take other appropriate action that it believes is reasonably required to protect the CoNCERT Intellectual Property. Any suit by CoNCERT shall be either in the name of CoNCERT or its Affiliate, the name of Promet or its Affiliate, or the names of Promet, CoNCERT and their respective Affiliates, as may be required by the Law of the forum. For this purpose, Promet shall execute such legal papers and cooperate in the prosecution of such suit, including providing full access to documents, information and witnesses as reasonably requested by CoNCERT in connection with such suit, as may be reasonably requested by CoNCERT; provided that CoNCERT shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by Promet in connection with such cooperation.

(d) Conduct of Certain Actions; Costs. The Party initiating suit or taking other action with respect to an Infringement Claim shall have the sole and exclusive right to select counsel for, and otherwise control, any suit or action initiated by it pursuant to Section 7.3(b) or 7.3(c). The initiating Party shall assume and pay all of its own out-of-pocket costs incurred in connection with any litigation or proceedings initiated by it pursuant to Sections 7.3(b) and 7.3(c), including the fees and expenses of the counsel selected by it. The other Party shall have the right to participate, but not control, and be represented in, any such suit by its own counsel at its own expense.

(e) Recoveries. Except as otherwise agreed by the Parties as part of a cost-sharing arrangement, any damages, settlements, accounts of profits, or other financial compensation recovered from a Third Party by the Party that assumes control over enforcing any Infringement Claim shall be allocated between the Parties as follows:

(i) first, to reimburse the Parties' actual out-of-pocket expenses (including reasonable counsel fees and expenses) incurred in pursuing such Infringement Claim; and

(ii) second, any remaining amount that represents compensatory damages relating to any Compound or Product (including lost sales or lost profits) shall be deemed Net Sales and paid to Promet, less an amount equal to royalty payments to CoNCERT on such deemed Net Sales in accordance with the royalty provisions of Section 6.3, which amount shall be paid to CoNCERT, and any remaining amount that represents punitive damages shall be shared equally by the Parties.

7.4 Patent Invalidity Claim. Each of the Parties shall promptly notify the other in the event of any legal or administrative action by any Third Party against a CoNCERT Patent Right or Joint Patent Right of which it becomes aware, including any nullity, revocation, reexamination or compulsory license proceeding. CoNCERT shall have the first right, but not the obligation, to defend against any such action involving a CoNCERT Patent Right, and the costs of any such defense shall be at CoNCERT's expense; provided, however, that, in the case of any *inter partes* review or similar post-grant matter before the Patent Trial and Appeal Board or similar administrative body that is based on the same subject matter as any claim or counterclaim in any Infringement Claim or Paragraph IV Claim, Promet shall have the first right, but not the obligation, to defend against any such action involving a CoNCERT Patent Right, and the costs of any such defense shall be at Promet's expense. Promet shall have the first right, but not the obligation, to defend against any such action involving a Joint Patent Right, and the costs of any such defense shall be at Promet's expense. If the Party that has the first right to defend against any such action involving such CoNCERT Patent Right or Joint Patent Right does not do so, then the other Party shall have the right, but not the obligation, to defend such action and any such defense shall be at such other Party's expense. Upon request of the Party that defends against any such action involving a CoNCERT Patent Right or Joint Patent Right, the other Party agrees to join in any such action and to cooperate reasonably with the defending Party, including providing full access to documents, information and witnesses as reasonably requested by the defending Party in connection with such action, provided that the defending Party shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by the other Party in connection with such cooperation.

7.5 Claimed Infringement. Each of the Parties shall promptly notify the other in the event a Party becomes aware that the practice by either Party of the CoNCERT Patent Rights infringes, or is suspected or alleged to infringe, the intellectual property rights of any Third Party in the Territory, and shall promptly provide the other Party with any notice it receives or has received from a Third Party related to such suspected, alleged or actual infringement.

7.6 Patent Term Extensions. Promet shall have the exclusive right and obligation to seek patent term extensions or supplemental patent protection, including supplementary protection certificates, in each country in the Territory in relation to the Products at Promet's expense. CoNCERT and Promet shall cooperate in connection with all such activities, and Promet, its agents and attorneys will give due consideration to all timely suggestions and comments of CoNCERT regarding any such activities; provided that all final decisions shall be made by Promet.

7.7 Patent Marking. Promet shall comply with the patent marking statutes in each country in the Territory in which any Product is sold by Promet, its Affiliates or its Sublicensees.

7.8 Certification under Drug Price Competition and Patent Restoration Act.

(a) Notice. If a Party becomes aware of any certification filed pursuant to 21 U.S.C. § 355(b)(2)(A) or 355(j)(2)(A)(vii)(IV) or its successor provisions, or any similar provision in any country in the Territory other than the U.S., claiming that any CoNCERT Patent Rights or Joint Patent Rights are invalid or otherwise unenforceable, or that infringement will not arise from the manufacture, use, import or sale of a product by a Third Party (a "Paragraph IV Claim"), such Party shall promptly notify the other Party in writing within five (5) Business Days after its receipt thereof.

(b) Control of Response; Recoveries. Promet shall have the first right, but not the obligation, to initiate and control patent infringement litigation for any Paragraph IV Claim; provided, however, that Promet shall (i) consult with CoNCERT in good faith with respect to any claim that any CoNCERT Patent Right or Joint Patent Right is invalid or unenforceable and (ii) implement any comment from CoNCERT regarding any aspect of defending against any such claim. Any suit by Promet shall be brought either in the name of CoNCERT or its Affiliate, the name of Promet or its Affiliate, or the names of Promet, CoNCERT and their respective Affiliates, as may be required by the Law of the forum. For this purpose, CoNCERT shall execute such legal papers and cooperate in the prosecution of such suit, including providing full access to documents, information and witnesses, as may be reasonably requested by Promet; provided that Promet shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by CoNCERT in connection with such cooperation. If Promet elects not to assume control over litigating any Paragraph IV Claim, Promet shall notify CoNCERT as soon as practicable but in any event not later than ten (10) days before the first action required to litigate such Paragraph IV Claim so that CoNCERT may, but shall not be required to, assume sole control over litigating such Paragraph IV Claim using counsel of its own choice. Any suit by CoNCERT shall be either in the name of CoNCERT or its Affiliate, the name of Promet or its Affiliate, or the names of Promet, CoNCERT and their respective Affiliates, as may be required by the Law of the forum. For this purpose, Promet shall execute such legal papers and cooperate in the prosecution of such suit, including providing full access to documents, information and witnesses, as may be reasonably requested by CoNCERT; provided that CoNCERT shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by Promet in connection with such cooperation. Any compensation recovered as a result of such litigation shall be allocated as set forth in Section 7.3(e) above.

7.9 Privileged Communications. In furtherance of this Agreement, it is expected that Promet and CoNCERT will, from time to time, disclose to one another privileged communications with counsel, including opinions, memoranda, letters and other written, electronic and verbal communications. Such disclosures are made with the understanding that they shall remain confidential, that they will not be deemed to waive any applicable attorney-client or attorney work product or other privilege and that they are made in connection with the shared community of legal interests existing between CoNCERT and Promet, including the community of legal interests in avoiding infringement of any valid, enforceable patents of Third Parties and maintaining the validity of CoNCERT Patent Rights, Promet Patent Rights and Joint Patent Rights.

7.10 Settlement. Neither Party shall unilaterally enter into any settlement or compromise of any suit, action or proceeding under this ARTICLE VII that would in any manner alter, diminish, or be in derogation of the other Party's rights under this Agreement without the prior written consent of such other Party, which shall not be unreasonably withheld.

## ARTICLE VIII
## CONFIDENTIAL INFORMATION

8.1 Treatment of Confidential Information. During the Term and for five (5) years thereafter, each Party shall maintain Confidential Information (as defined in Section 8.2) of the other Party in confidence, and shall not disclose, divulge or otherwise communicate such Confidential Information to others (except for agents, directors, officers, employees, consultants, subcontractors, licensees, sublicensees, partners, Affiliates and advisors who have a need to know such information to perform obligations or exercise rights under this Agreement on behalf of such Party (collectively, "Agents") under obligations of confidentiality no less stringent than those set forth in this ARTICLE VIII) or use it for any purpose other than in connection with the Development, Manufacture, use or Commercialization of Compounds or Products pursuant to this Agreement or otherwise to accomplish the purposes of this Agreement, including exercising its rights or performing its obligations hereunder, and each Party shall exercise Commercially Reasonable Efforts to prevent and restrain the unauthorized disclosure of such Confidential Information by any of its Agents, which efforts shall be at least as diligent as those generally used by such Party in protecting its own confidential and proprietary information, and in any event no less than reasonable efforts. Each Party will be responsible for any breach of this ARTICLE VIII by its Agents. Either receiving Party may disclose Confidential Information of the disclosing Party (a) to Governmental Authorities in order to comply with applicable Laws, respond to inquiries, requests or investigations by Governmental Authorities, including filing, prosecuting or maintaining Patent Rights as permitted by this Agreement; (b) to comply with the regulations or requirements of any stock exchange; (c) to the extent useful to Develop, Manufacture, use or Commercialize any Compound or Product, including making regulatory filings for any Compound or Product, in accordance with this Agreement; (d) to the extent necessary or useful in order to defend or prosecute litigation; and (e) to potential and actual *bona fide* investors, acquirors and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition or collaboration; provided that (x) with respect to any disclosure in accordance with Section 8.1(a), (b) or (d), the receiving Party shall promptly provide prior notice of such disclosure to the disclosing Party and use Commercially Reasonable Efforts to avoid or minimize the degree of such disclosure, (y) with respect to any disclosure in accordance with Section 8.1(a) or (d), the receiving Party will use efforts to secure confidential treatment of such Confidential Information at least as diligent as such Party would use to protect its own confidential information, but in no event less than reasonable efforts, and (z) with respect to any disclosure in accordance with Section 8.1(e),the receiving Party shall obtain the same confidentiality obligations from any Third Parties to which it discloses the Confidential Information of the disclosing Party as it obtains with respect to its own similar types of confidential information, and in any event such obligations shall be no less stringent than those set forth in this ARTICLE VIII.

8.2 Confidential Information. "Confidential Information" means all trade secrets or other proprietary information, including any proprietary data and materials (whether or not

patentable or protectable as a trade secret), that is disclosed by a Party to the other Party. All information disclosed prior to the Effective Date by CoNCERT to Promet pursuant to the Amended and Restated Nondisclosure Agreement by and between the Parties, dated as of February 2, 2017, as amended through the Effective Date (the "Confidentiality Agreement"), shall be deemed "Confidential Information" of CoNCERT. Notwithstanding the foregoing, there shall be excluded from the foregoing definition of Confidential Information any of the foregoing that:

(a) either before or after the date of the disclosure to the receiving Party is lawfully disclosed to the receiving Party by a Third Party without any violation of any obligation to the other Party; or

(b) either before or after the date of the disclosure to the receiving Party, becomes published or generally known to the public through no fault or omission on the part of the receiving Party or its Agents; or

(c) is independently developed by or for the receiving Party without reference to or reliance upon the disclosing Party's Confidential Information as demonstrated by contemporaneous written records of the receiving Party.

8.3 Publications. The Parties recognize the desirability of publishing and publicly disclosing the results of clinical trials of pharmaceutical products. Accordingly, subject to coordination through designated representatives of each Party, Promet shall be free to publicly disclose the results of clinical trials involving Compounds or Products, subject to prior review by CoNCERT for issues of patentability and protection of its Confidential Information, in a manner consistent with all Laws applicable to Promet and best industry practices. In addition, if Promet intends to publish articles in scientific or medical journals or to make presentations of the results of clinical trials involving Compounds or Products, Promet shall provide CoNCERT through the designated representatives of each Party at its earliest opportunity with any proposed abstracts, manuscripts or summaries of presentations that cover the results of Development of any Compound or Product. CoNCERT shall respond promptly through its designated representative, and in any event no later than fifteen (15) days after receipt of such proposed publication or presentation, or such shorter period as may be required by the publication. If timely requested by CoNCERT, Promet agrees to allow a reasonable period (not to exceed thirty (30) days) to permit filings for patent protection and to otherwise address issues of Confidential Information or related competitive harm to the reasonable satisfaction of CoNCERT. In addition, Promet will consider in good faith any comments furnished by CoNCERT to Promet during such period. Promet shall be responsible to assure that its Affiliates and licensees agree to, and comply with, equivalent undertakings in favor of CoNCERT. CoNCERT and its Affiliates may make any publication or public disclosure of any data concerning the Compounds or Products that existed as of the Effective Date, provided that CoNCERT provides Promet at least fifteen (15) days (or such shorter period as may be required by the publication) to review such publication or public disclosure, allows a reasonable period (not to exceed thirty (30) days) to permit filings for patent protection and to otherwise address issues of Confidential Information or related competitive harm to the reasonable satisfaction of Promet, and reasonably considers any timely comments provided by Promet with respect to such publication or public disclosure. CoNCERT shall not, and shall cause each of its Affiliates, licensees and sublicensees not to, make any other

publications or public disclosures regarding the Compounds or Products without Promet's prior written consent. If Promet consents to CoNCERT making such publications, CoNCERT shall provide Promet a reasonable opportunity to comment on any such publications and such comments shall not be unreasonably rejected. All publications involving Compounds or Products shall include appropriate acknowledgement consistent with standard scientific practice of any contributions of each Party to the results being publicly disclosed.

8.4 Press Releases and Other Disclosures. The Parties recognize that each Party may from time to time desire to issue press releases and make other public statements or disclosures regarding the subject matter of this Agreement. In such event, the Party desiring to issue a press release or make a public statement or disclosure shall provide the other Party with a copy of the proposed press release, statement or disclosure for review and approval in advance (except that neither Party shall have any obligation to disclose or approve the disclosure of Confidential Information except to the extent required or permitted pursuant to this ARTICLE VIII). No other public statement or disclosure concerning the existence or terms of this Agreement shall be made, either directly or indirectly, by either Party, without first obtaining the written approval of the other Party. Once any public statement or disclosure has been approved in accordance with this Section 8.4, then either Party may appropriately communicate information contained in such permitted statement or disclosure. Notwithstanding the foregoing provisions of this ARTICLE VIII, a Party may (a) disclose the existence and terms of this Agreement where required, as reasonably determined by the disclosing Party, by applicable Law, by applicable stock exchange regulation or by order or other ruling of a competent court and (b) disclose the existence and terms of this Agreement under obligations of confidentiality no less stringent than those set forth in this ARTICLE VIII to agents, advisors, contractors, licensees, sublicensees, and *bona fide* investors, acquirors and other financial or commercial partners, and to potential agents, advisors, contractors, licensees, sublicensees, and *bona fide* investors, acquirors and other financial or commercial partners. To the extent a Party determines in good faith that it is required by applicable Law to publicly file, register or notify this Agreement with a Governmental Authority, including public filings pursuant to securities Laws, it shall provide a proposed redacted form of the Agreement to the other Party a reasonable amount of time prior to filing for the other Party to review such draft and propose changes to such proposed redactions. The Party making such filing, registration or notification shall incorporate any proposed changes timely requested by the other Party, absent a reasonable basis for not making such changes, and shall use Commercially Reasonable Efforts to seek confidential treatment for any terms that the other Party timely requests be kept confidential, to the extent such confidential treatment is reasonably available consistent with applicable Law. Each Party shall be responsible for its own legal and other external costs in connection with any such filing, registration or notification.

8.5 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that a Party would suffer upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages would not be a sufficient remedy for any breach of this ARTICLE VIII. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this ARTICLE VIII.

## ARTICLE IX
## REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 CoNCERT's Representations. CoNCERT hereby represents and warrants as of the Effective Date as follows:

(a) CoNCERT has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder. The execution, delivery and performance of this Agreement has been duly and validly authorized and approved by all necessary corporate action on the part of CoNCERT. CoNCERT has taken all other action required by Law, its certificate of incorporation or by-laws or any agreement to which it is a party or by which it or its assets are bound, to authorize such execution, delivery and performance. Assuming due authorization, execution and delivery on the part of Promet, this Agreement constitutes a legal, valid and binding obligation of CoNCERT, enforceable against CoNCERT in accordance with its terms.

(b) The execution and delivery of this Agreement by CoNCERT will not violate any U.S. Law or, to CoNCERT's knowledge, any Law of any Governmental Authority outside the U.S.

(c) The execution and delivery of this Agreement by CoNCERT do not require CoNCERT to obtain any permit, authorization or consent from any Governmental Authority or from any other Person, and such execution and delivery by CoNCERT will not result in the breach of or give rise to any termination of, rescission, renegotiation or acceleration under or trigger any other rights under any agreement or contract to which CoNCERT may be a party that relates to the CoNCERT Patent Rights or the CoNCERT Know-How.

(d) Schedule 1.13 is a complete and correct list of all Patent Rights owned by CoNCERT as of the Effective Date that Cover any Compound or Product. No Patent Right that Covers any Compound or Product has been licensed to CoNCERT.

(e) CoNCERT is the legal and beneficial owner of all the Patent Rights identified on Schedule 1.13, free and clear of any liens, mortgages, security interests or other similar encumbrances. All assignments to CoNCERT of ownership rights relating to such Patent Rights are valid and enforceable. All of the Patent Rights listed identified on Schedule 1.13 that are issued patents are in full force and effect, and all applicable filing, maintenance and other fees required to be paid to a patent office with respect to the Patent Rights listed identified on Schedule 1.13 have been timely paid. CoNCERT has the right to grant the licenses granted by it in this Agreement and has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the CoNCERT Intellectual Property in a manner that conflicts with any rights granted to Promet hereunder.

(f) There is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to CoNCERT's knowledge, threatened against CoNCERT in connection with the Compounds or Products or any CoNCERT Patent Rights, CoNCERT Know-How or against or relating to the transactions contemplated by this

Agreement. CoNCERT has not received any written notice from a Third Party that the Development of any Compound or Product conducted by CoNCERT has infringed, or that any Development or Commercialization of any Compound or Product will infringe, any Patent Rights of any Third Party.

(g) No claim or action has been brought or, to CoNCERT's knowledge, threatened by any Third Party alleging that the CoNCERT Patent Rights are invalid or unenforceable, and no CoNCERT Patent Rights are the subject of any litigation, interference, post-grant review, opposition, cancellation or other proceeding challenging the validity or enforceability of the CoNCERT Patent Rights.

(h) Neither CoNCERT nor, to the knowledge of CoNCERT, any of its directors, officers, employees, agents or subcontractors has been convicted of any crime or engaged in any conduct that has resulted in, or would reasonably be expected to result, in debarment by the FDA under 21 U.S.C. § 335a or any similar state or foreign Law.

9.2 Promet's Representations. Promet hereby represents and warrants as of the Effective Date as follows:

(a) Promet has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder. The execution, delivery and performance of this Agreement has been duly and validly authorized and approved by all necessary corporate action on the part of Promet. Promet has taken all other action required by Law, its certificate of incorporation or by-laws or any agreement to which it is a party or by which it or its assets are bound to authorize such execution, delivery and (subject to obtaining all necessary governmental approvals with respect to the Development, Manufacture, use and Commercialization of Compounds and Products) performance. Assuming due authorization, execution and delivery on the part of CoNCERT, this Agreement constitutes a legal, valid and binding obligation of Promet, enforceable against Promet in accordance with its terms.

(b) The execution and delivery of this Agreement by Promet will not violate any U.S. Law or, to Promet's knowledge, any Law of any Governmental Authority outside the U.S.

(c) There is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to the knowledge of Promet, threatened against Promet in connection with or relating to the transactions contemplated by this Agreement.

(d) The execution and delivery of this Agreement do not require Promet to obtain any permit, authorization or consent from any Governmental Authority or from any other Person, and such execution and delivery by Promet will not result in the breach of or give rise to any termination of, rescission, renegotiation or acceleration under or trigger any other rights under any agreement or contract to which Promet may be a party that relates to the Products, Promet Patent Rights or Promet Know-How.

(e) Neither Promet nor, to the knowledge of Promet, any of its directors, officers, employees, agents or subcontractors has been convicted of any crime or engaged in any

conduct that has resulted in, or would reasonably be expected to result, in debarment by the FDA under 21 U.S.C. § 335a or any similar state or foreign Law.

9.3 CoNCERT Covenants. CoNCERT covenants and agrees during the Term that, subject to Promet's, its Affiliates' and Sublicensees' performance of their obligations under this Agreement:

(a) CoNCERT shall not grant to any Third Party any rights that would be inconsistent or conflict with Promet's rights hereunder.

(b) Subject to Section 12.7, CoNCERT shall not assign, transfer, convey or otherwise encumber its right, title and interest in the CoNCERT Intellectual Property in a manner that conflicts with any rights granted to Promet hereunder.

9.4 Promet Covenant. Promet shall conduct, and shall use Commercially Reasonable Efforts to cause its contractors and consultants to conduct, all of their activities contemplated under this Agreement in accordance with all applicable Laws of the country in which such activities are conducted, including applicable requirements of "good laboratory practices", "good clinical practices" and "good manufacturing practices", as applicable, as defined by the FDA.

9.5 No Warranty. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED. IN PARTICULAR, BUT WITHOUT LIMITATION, EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY CONCERNING WHETHER ANY OF THE COMPOUNDS OR PRODUCTS ARE FIT FOR ANY PARTICULAR PURPOSE OR SAFE FOR HUMAN CONSUMPTION.

## ARTICLE X
## INDEMNIFICATION

10.1 Indemnification in Favor of CoNCERT. Promet shall indemnify, defend and hold harmless the CoNCERT Parties from and against any and all Losses incurred, suffered or sustained by any of the CoNCERT Parties or to which any of the CoNCERT Parties becomes subject as a result of any Third Party claim, action, suit, proceeding, liability or obligation (which in no event includes any claim by any Promet Party or any CoNCERT Party) (collectively, "Third Party Claims") arising out of, relating to or resulting from:

(a) any misrepresentation or breach of any representation, warranty, covenant or agreement made by Promet in this Agreement; or

(b) the Development and, if the Option is exercised, Manufacture or Commercialization of Compounds or Products by Promet, its Affiliates or Sublicensees, including all Third Party Claims involving death or bodily injury caused or allegedly caused by the use of such a Compound or Product, and even if such a Compound or Product is altered for use for a purpose not intended (any and all such Third Party Claims "Product Liability Claims"); or

(c) any actual or alleged infringement of any trademark, Patent Right or other intellectual property right, or misappropriation of any trade secret, of any Third Party as a result of the Development, Manufacture or Commercialization of Compounds or Products by Promet, its Affiliates or Sublicensees; or

(d) the gross negligence or willful misconduct of any of the Promet Parties (as hereinafter defined) in connection with Promet's performance of this Agreement.

For purposes of this ARTICLE X, "CoNCERT Parties" means CoNCERT, its Affiliates and their respective agents, directors, officers, licensees, sublicensees and employees.

The indemnification obligations set forth in this Section 10.1 shall not apply to the extent that any Loss is the result of (i) a breach of any representation, warranty, covenant or agreement made by CoNCERT in this Agreement or (ii) the gross negligence or willful misconduct of any applicable CoNCERT Party.

10.2 Indemnification in Favor of Promet. CoNCERT shall indemnify, defend and hold harmless the Promet Parties from and against any and all Losses incurred, suffered or sustained by any of the Promet Parties or to which any of the Promet Parties becomes subject as a result of any Third Party Claim arising out of, relating to or resulting from:

(a) any misrepresentation or breach of any representation, warranty, covenant or agreement made by CoNCERT in this Agreement; or

(b) the Development, Manufacture or Commercialization of Compounds or Products by CoNCERT, its Affiliates, licensees (excluding Promet) or sublicensees after any termination of this Agreement, including all Product Liability Claims arising out of any such post-termination Development, Manufacture or Commercialization by CoNCERT, its Affiliates, licensees (excluding Promet) or sublicensees; or

(c) any actual or alleged infringement of any trademark, Patent Right or other intellectual property right, or misappropriation of any trade secret, of any Third Party as a result of the Development, Manufacture or Commercialization of Compounds or Products by CoNCERT, its Affiliates, licensees (excluding Promet) or sublicensees after any termination of this Agreement; or

(d) the gross negligence or willful misconduct of any of the CoNCERT Parties in connection with CoNCERT's performance of this Agreement.

For purposes of this ARTICLE X, "Promet Parties" means Promet, its Affiliates and their respective agents, directors, officers, licensees, sublicensees and employees.

The indemnification obligations set forth in this Section 10.2 shall not apply to the extent that any Loss is the result of (i) a breach of any representation, warranty, covenant or agreement made by Promet in this Agreement, or (ii) the gross negligence or willful misconduct of any applicable Promet Party.

10.3 General Indemnification Procedures.

(a) A CoNCERT Party or Promet Party seeking indemnification pursuant to this ARTICLE X (an "Indemnified Party") shall give prompt notice to the Party from whom such indemnification is sought (the "Indemnifying Party") of the commencement or assertion of any Third Party Claim in respect of which indemnity may be sought hereunder, shall give the Indemnifying Party such information with respect to any indemnified matter as the Indemnifying Party may reasonably request, and shall not make any admission concerning any Third Party Claim, unless such admission is required by applicable Law or legal process, including in response to questions presented in depositions or interrogatories. Any admission made by the Indemnified Party or the failure to give such notice shall relieve the Indemnifying Party of any liability hereunder only to the extent that the ability of the Indemnifying Party to defend such Third Party Claim is prejudiced thereby (and no admission required by applicable Law or legal process shall be deemed to result in prejudice). The Indemnifying Party shall assume and conduct the defense of such Third Party Claim, with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party. Subject to the initial and continuing satisfaction of the terms and conditions of this ARTICLE X by the Indemnifying Party, the Indemnifying Party shall have full control of such Third Party Claim, including settlement negotiations and any legal proceedings. If the Indemnifying Party does not assume the defense of such Third Party Claim in accordance with this Section 10.3, the Indemnified Party may defend the Third Party Claim. If both Parties are Indemnifying Parties with respect to the same Third Party Claim, the Parties shall determine by mutual agreement, within twenty (20) days following their receipt of notice of commencement or assertion of such Third Party Claim (or such lesser period of time as may be required to respond properly to such claim), which Party shall assume the lead role in the defense thereof. Should the Indemnifying Parties be unable to mutually agree on which of them shall assume the lead role in the defense of such Third Party Claim, both Indemnifying Parties shall be entitled to participate in such defense through counsel of their respective choosing.

(b) Any Indemnified Party or Indemnifying Party not managing the defense of a Third Party Claim shall have the right to participate in (but not control), at its own expense (subject to the immediately succeeding sentence), the defense. The Indemnifying Party managing the defense shall not be liable for any litigation cost or expense incurred, without its consent, by the Indemnified Party where the action or proceeding is under the control of such Indemnifying Party; provided, however, that, if the Indemnifying Party managing the defense fails to take reasonable steps necessary to defend such Third Party Claim, the Indemnified Party may assume its own defense, and the Indemnifying Party managing the defense will be liable for all reasonable costs or expenses paid or incurred in connection therewith.

(c) The Indemnifying Party shall not, except with the consent of the Indemnified Party, consent to a settlement of, or the entry of any judgment against, an Indemnified Party arising from any Third Party Claim to the extent such settlement or judgment involves equitable or other non-monetary relief from the Indemnified Party. No Party shall, without the prior written consent of the other Party or the Indemnified Party, enter into any compromise or settlement that commits the other Party or the Indemnified Party to take, or to forbear to take, any action.



(d) The Parties shall cooperate in the defense or prosecution of any Third Party Claim for which indemnity is sought hereunder and shall furnish such records, information and testimony, and attend such conferences, discovery proceedings, hearings, trials and appeals, as may be reasonably requested in connection therewith; provided, however, that the Indemnifying Party shall reimburse the Indemnified Party for any out-of-pocket expenses actually and reasonably incurred in connection with any such cooperation.

(e) Any indemnification hereunder shall be made net of any insurance proceeds actually recovered by the Indemnified Party from unaffiliated Third Parties; provided, however, that if, following the payment to the Indemnified Party of any amount under this ARTICLE X, such Indemnified Party recovers any such insurance proceeds in respect of the claim for which such indemnification payment was made, the Indemnified Party shall promptly pay an amount equal to the amount of such proceeds (but not exceeding the amount of such net indemnification payment) to the Indemnifying Party.

(f) The Parties agree and acknowledge that the provisions of this ARTICLE X represent the Indemnified Party's exclusive recourse with respect to any Losses for Third Party Claims for which indemnification is provided to the Indemnified Party under this ARTICLE X.

10.4 Insurance. During the Term, if the Option is exercised, and thereafter for so long as a Third Party Claim may be brought for which Promet must indemnify CoNCERT pursuant to Section 10.1, Promet shall obtain and maintain, at its sole cost and expense, product liability insurance in amounts that are reasonable and customary in the pharmaceutical industry, but in no event less than $5 million per occurrence or claim, and $10 million in the aggregate, or a comparable program of self-insurance. Such product liability insurance shall insure against all liability, including product liability and property damage arising out of the Development, use or Commercialization of Compounds and Products by Promet, its Affiliates or Sublicensees in the Territory. Without limiting the generality of the foregoing, Promet shall maintain comprehensive general liability insurance, including product liability insurance, to cover its activities and, unless its Affiliates and Sublicensees maintain comparable coverage, the activities of its Affiliates and Sublicensees, with respect to Compounds and Products. Promet shall provide satisfactory evidence of adequate insurance coverage to CoNCERT upon the request of CoNCERT prior to the Option Exercise Date and, upon the written request of CoNCERT, concurrent with any renewal or replacement of such coverage.

## ARTICLE XI
## TERM AND TERMINATION

11.1 Term. The term of this Agreement (the "Term") shall commence on the Effective Date and, unless earlier terminated as provided in this ARTICLE XI, shall continue in full force and effect until the expiration of the last Royalty Term. On a country-by-country and Product-by-Product basis, upon the expiration of the Royalty Term in such country with respect to such Product, Promet shall have a fully paid-up, perpetual, irrevocable license under the CoNCERT Intellectual Property and CoNCERT's interest in the Joint Intellectual Property with respect to such Product in such country.

11.2 Termination for Failure to Exercise Option. If, for any reason (including a failure to meet the conditions in Section 2.1(b)(i) and (ii) prior to end of the Option Period), Promet does not exercise the Option within the Option Period, then this Agreement shall automatically terminate in its entirety on the day after the last day of the Option Period.

11.3 Termination for Convenience. Promet shall have the right upon sixty (60) days prior written notice to CoNCERT to terminate this Agreement in its entirety for any reason.

11.4 Termination for Cause. In the event of a material breach of this Agreement by a Party, the other Party may give the Party in default notice requiring it to cure such default, which notice shall specify the nature of the breach. If such material breach is not cured within ninety (90) days after receipt of such notice (or within fifteen (15) days in the case of a payment breach), the notifying Party shall be entitled (without prejudice to any other rights conferred on it by this Agreement or under applicable Law) to terminate this Agreement by giving written notice to the defaulting Party. The right of either Party to terminate this Agreement as set forth in this Section 11.4 shall not be affected in any way by its waiver of, or failure to take action with respect to, any previous default.

11.5 Additional Termination by CoNCERT. In the event that CoNCERT has provided written notice to Promet pursuant to Section 5.2, if Promet does not respond to CoNCERT in writing within sixty (60) days of receipt of such notice from CoNCERT and reasonably demonstrate in such response compliance with Promet's obligations under Section 5.1, CoNCERT shall be entitled (without prejudice to any other rights conferred on it by this Agreement or under applicable Law) to terminate this Agreement by giving written notice to Promet.

11.6 Termination for Insolvency. This Agreement may be terminated by a Party upon written notice to the other Party if (a) the other Party shall make an assignment for the benefit of its creditors, file a petition in bankruptcy, petition or apply to any tribunal for the appointment of a custodian, receiver or trustee for it or a substantial part of its assets, or shall commence any proceeding under any bankruptcy, reorganization, readjustment of debt, dissolution or liquidation law or statute of any jurisdiction, whether now or hereafter in effect; or (b) if there shall have been filed against the other Party any such *bona fide* petition or application, or any such proceeding shall have been commenced against it, in which an order for relief is entered or that remains undismissed or unstayed for a period of ninety (90) days or more; or (c) if the other Party by any act or omission shall consent to, approve of or acquiesce in any such petition, application or proceeding or order for relief or the appointment of a custodian, receiver or trustee for it or any substantial part of its assets, or shall suffer any such custodianship, receivership or trusteeship to continue undischarged or unstayed for a period of ninety (90) days or more. Termination shall be effective upon the date specified in such notice.

11.7 Termination for Challenge of CoNCERT Patent Rights. If Promet or any of Promet's Affiliates or Sublicensees commences an action in any court or tribunal of competent jurisdiction that challenges, opposes or disputes the validity, enforceability or patentability of any CoNCERT Patent Rights, or any of the claims thereof, or supports or assists any Third Party that commences such an action in any such court or tribunal, CoNCERT shall have the right to terminate this Agreement upon notice to Promet; provided, however, that CoNCERT shall not

have a right to terminate if the challenge is brought by a Sublicensee, either directly or indirectly through any Third Party, and Promet or the Affiliate, as the case may be, terminates such Sublicensee's sublicense rights hereunder within thirty (30) days after becoming aware of such challenge.

11.8 Consequences of Termination. If this Agreement (w) terminates automatically pursuant to Section 11.2, (x) is terminated by CoNCERT under Section 11.4, 11.5, 11.6 or 11.7, (y) is terminated by Promet under Section 11.3, or (z) is terminated by Promet under Section 11.4 or 11.6, then the licenses granted to Promet in Section 2.2 and, except as provided in this Section 11.8 and Sections 11.9 and 11.10 (and any Articles and Sections referenced therein), all other rights and obligations of the Parties under this Agreement shall terminate. Upon a termination described in clause (x) (but not clause (w), (y) or (z)) of this Section 11.8, clause (a) shall apply, and, upon a termination described in clause (w), (x) or (y) (but not clause (z)), Promet shall grant, and shall cause any applicable Affiliate to grant, CoNCERT any combination of the following clauses (b) through (f) elected by CoNCERT, provided that (i) upon a termination described in clause (w), only clause (c) and, to the extent that any Promet Intellectual Property, Sublicensee Intellectual Property or Joint Intellectual Property exists as of such termination, clause (e) shall apply, and (ii) Promet shall only be required to grant CoNCERT rights to Sublicensee Materials to the extent permitted in the applicable sublicense agreement(s) with Sublicensee(s) to whom CoNCERT has not granted a direct license pursuant to Section 11.8(a):

(a) Sublicenses. CoNCERT hereby grants, effective automatically upon any termination of this Agreement by CoNCERT pursuant to Section 11.4, 11.5, 11.6 or 11.7, a direct license (subject to all applicable limitations and conditions set forth in this Agreement and the applicable sublicense) to each then-existing Sublicensee, provided that (i) such Sublicensee is not in breach under the applicable sublicense, (ii) such Sublicensee's failure to comply with the terms of its sublicense or other actions or omissions were not a basis for such termination, and (iii) such Sublicensee continues to satisfy all obligations under this Agreement applicable to such sublicense, including the diligence obligations set forth in ARTICLE V and all payments to CoNCERT required under Section 6.3, from and after the date that such direct license becomes effective.

(b) Regulatory Matters. Ownership of all filings with Regulatory Authorities in the Territory relating to Compounds and Products and Regulatory Approvals relating to . Compounds and Products held by Promet or its Affiliates or applicable Sublicensees, including related correspondence with Regulatory Authorities, and Promet shall provide copies thereof to CoNCERT;

(c) Pre-clinical and Clinical Matters. Possession of all pre-clinical and clinical data, including pharmacology and biology data, within the Promet Know-How and applicable Sublicensee Intellectual Property;

(d) Manufacturing Matters. At CoNCERT's option, to be exercised no later than the later of (x) thirty (30) days after the effective date of termination or (y) thirty (30) days after CoNCERT's receipt of the applicable Manufacturing agreements;

(i) use of Commercially Reasonable Efforts by Promet and its Affiliates to effect the assignment of each Manufacturing agreement (including any agreement to which any applicable Sublicensee is a party) specific and exclusive to Compounds or Products to CoNCERT, if such agreement is then in effect and such assignment is permitted under such agreement or by the applicable Third Party; provided that Promet and its applicable Affiliates and applicable Sublicensees shall be released to the extent the applicable Third Party will permit from any obligation arising out of such agreement following such assignment and CoNCERT shall execute such documentation reasonably satisfactory to Promet to effectuate such agreement; provided further that, (A) CoNCERT will bear any costs or expenses payable to the applicable Third Party in connection with assignment of any such agreement and (B) if any such agreement is specific but not exclusive to Compounds or Products, or is not assigned to CoNCERT for any reason, Promet will discuss in good faith with CoNCERT terms upon which Promet and its Affiliates shall use Commercially Reasonable Efforts to provide CoNCERT with the benefits of such agreement to the extent it relates to Compounds or Products for a limited period of time (not to exceed six (6) months) and upon payment of a reasonably acceptable fee to Promet;

(ii) for a period of up to six (6) months following the effective date of termination, (A) cooperation with CoNCERT in reasonable respects to transfer Manufacturing documents and materials within the Promet Know-How and applicable Sublicensee Intellectual Property that are used (at the time of the termination) by Promet or its Affiliates or applicable Sublicensees exclusively in the Manufacture of Compounds and Products to the extent such Manufacturing documents and materials are not obtained by CoNCERT pursuant to the assignment of agreements pursuant to paragraph (i) above, and (B) cooperation with CoNCERT to provide CoNCERT with reasonable access to and right to use such Manufacturing documents and materials in Promet's or its Affiliates' or applicable Sublicensees' possession or Control to the extent they relate to, but are not used exclusively in, the Manufacture of Compounds and Products, subject to appropriate confidentiality and limitation on use protections applicable to such Manufacturing documents and materials;

(iii) for a period of up to six (6) months following the effective date of termination, (A) cooperation with CoNCERT in reasonable respects to transfer Manufacturing technologies within the Promet Intellectual Property and applicable Sublicensee Intellectual Property that are used (at the time of the termination) by Promet or its Affiliates or applicable Sublicensees exclusively in the Manufacture of Compounds and Products, and (B) cooperation with CoNCERT to provide CoNCERT with reasonable access to and right to use such Manufacturing technologies Controlled by Promet or its Affiliates (other than Promet Excluded Affiliates) or applicable Sublicensees to the extent they relate to, but are not used exclusively in, the Manufacture of Compounds and Products and that Promet or such Affiliates or Sublicensees are permitted to provide such access to CoNCERT; provided that CoNCERT shall reimburse Promet for Promet's reasonable out-of-pocket expenses to provide such requested assistance, to the extent such Manufacturing technologies are not obtained by CoNCERT pursuant to the assignment of agreements pursuant to paragraph (i) above; and

(iv) sale of Promet's or its Affiliates' or applicable Sublicensees' then-existing inventory of Compounds and Products to CoNCERT, at Promet's or its applicable Affiliates' or applicable Sublicensees' cost of Manufacture, but only if the following conditions

have been met: (A) such Compounds and Products meet the applicable release specifications; and (B) Promet does not reasonably believe the continued use of such Compounds and Products causes safety concerns;

(e) License Grant. At CoNCERT's option, to be exercised by written notice to Promet no later than thirty (30) days after the effective date of termination, a license, with the right to sublicense, under the Promet Patent Rights, Promet Know-How, Promet's interest in the Joint Intellectual Property, and applicable Sublicensee Intellectual Property, solely to make, have made, use, sell, offer for sale and import Compounds and Products in the Field that were Developed or Commercialized prior to the effective date of termination, which license would be, at CoNCERT's election, either (i) non-exclusive, fully paid-up, non-royalty-bearing, irrevocable and perpetual or (ii) exclusive and royalty-bearing subject to mutual agreement by CoNCERT and Promet on commercially reasonable terms; provided that, notwithstanding the foregoing, with respect to any Promet Patent Rights or Promet Know-How that Promet acquired from a Third Party (by license or otherwise), or any applicable Sublicensee Intellectual Property that the applicable Sublicensee(s) acquired from a Third Party (by license or otherwise), Promet shall only be required to grant to CoNCERT a license to such Promet Patent Rights, Promet Know-How or Sublicensee Intellectual Property to the extent permitted under the applicable agreement with such Third Party, and CoNCERT shall pay Promet or such Third Party, as determined by Promet, any payment due to such Third Party relating to the Compounds and Products; provided further that CoNCERT shall execute such documentation reasonably satisfactory to Promet to effectuate such agreement; and if the license granted to CoNCERT is exclusive, CoNCERT shall have the same enforcement rights with respect to any Promet Patent Rights, Joint Patent Rights and Patent Rights within the Sublicensee Intellectual Property that exclusively Cover Products that are licensed to CoNCERT pursuant to this Section 11.8(e) as Promet has with respect to Infringement Claims pursuant to Section 7.3 (to the extent that Promet or the applicable Sublicensee(s) have such rights with respect to such Promet Patent Rights or Patent Rights within the Sublicensee Intellectual Property, as applicable), provided that any enforcement of Promet Patent Rights, Joint Patent Rights or Patent Rights within the Sublicensee Intellectual Property that Cover subject matter other than such Products shall be performed by CoNCERT only with the consultation and prior agreement of Promet or the applicable Sublicensee, which such agreement shall not unreasonably withheld, delayed or conditioned.

(f) Assignment of Trademarks. Assign to CoNCERT all of Promet's or its Affiliates' or applicable Sublicensees' right, title and interest in any trademark owned by Promet or its Affiliates or applicable Sublicensees and used solely in connection with the Products, along with all associated goodwill.

11.9 Effect of Termination or Expiration; Accrued Rights and Obligations. Termination or expiration of this Agreement for any reason shall not release either Party from any liability that, at the time of such termination or expiration, has already accrued or that is attributable to a period prior to such termination (including payment obligations accrued prior to the effective date of termination or expiration pursuant to ARTICLE VI) nor preclude either Party from pursuing any right or remedy it may have hereunder or at law or in equity with respect to any breach of this Agreement.

11.10 Survival. The rights and obligations set forth in this Agreement shall extend beyond the Term or termination or expiration of this Agreement only to the extent expressly provided for in this Agreement or to the extent required to give effect to a termination or expiration of this Agreement or the consequences of a termination or expiration of this Agreement as expressly provided for in this Agreement. Without limiting the generality of the foregoing, it is agreed that the provisions of ARTICLE I, Sections 2.3, 2.4, 6.1, 6.4 (only for thirty-six (36) months after expiration or termination), 6.5 (only for thirty-six (36) months after expiration or termination), 6.6, 6.7, 6.8, 6.9, 7.1, 7.9, 8.1, 8.2, 8.5, 9.5, ARTICLE X, and Sections 11.1 (last sentence as to any such license that became perpetual and irrevocable prior to expiration or termination), 11.8, 11.9, 11.10 and ARTICLE XII shall survive expiration or termination of this Agreement for any reason.

## ARTICLE XII
## MISCELLANEOUS

12.1 Governing Law; Jurisdiction. This Agreement shall be governed by and interpreted in accordance with the internal laws of the State of Delaware, without regard to its conflicts of laws rules. Each Party (a) irrevocably submits to the exclusive jurisdiction in the U.S. District Court for the Southern District of New York and any state court sitting New York, New York (collectively, the "Courts"), for purposes of any action, suit or other proceeding arising out of this Agreement, and (b) agrees not to raise any objection at any time to the laying or maintaining of the venue of any such action, suit or proceeding in any of the Courts, irrevocably waives any claim that such action, suit or other proceeding has been brought in an inconvenient forum and further irrevocably waives the right to object, with respect to such action, suit or other proceeding, that such Court does not have any jurisdiction over such Party. Either Party may serve any process required by such Courts by way of notice under this Agreement. Notwithstanding anything to the contrary in this Section 12.1, each Party shall have the right to institute judicial proceedings against the other Party or anyone acting by, through or under such other Party, in any court of competent jurisdiction, in order to enforce the instituting Party's rights hereunder through reformation of contract, specific performance, injunction or similar equitable relief.

12.2 Dispute Resolution. In the event of a dispute arising out of or relating to this Agreement, either Party shall provide written notice of the dispute to the other, in which event the dispute shall be referred to the Senior Executives of each Party, for attempted resolution by good faith negotiations within twenty (20) days after such notice is received. In the event the Senior Executives do not resolve such dispute within the allotted twenty (20) days, either Party may, after the expiration of the twenty (20) day period, seek to resolve the dispute in accordance with Section 12.1.

12.3 Waiver. Waiver by a Party of a breach hereunder by the other Party shall not be construed as a waiver of any succeeding breach of the same or any other provision. No delay or omission by a Party to exercise or avail itself of any right, power or privilege that it has or may have hereunder shall operate as a waiver of any right, power or privilege by such Party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.

12.4 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address specified in this Section 12.4 and shall be: (a) delivered personally; (b) sent by registered or certified mail, return receipt requested, postage prepaid; (c) sent via a reputable nationwide overnight courier service; or (d) sent by facsimile or other electronic transmission. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service, or when transmitted with confirmation of receipt, if transmitted by facsimile or other electronic transmission (if such transmission is on a Business Day; otherwise, on the next Business Day following such transmission).

Notices to Promet shall be addressed to:

Promet Therapeutics, LLC
7380 Coca Cola Drive, Suite 106
Hanover, MD 21076
Attn: Chief Executive Officer

Notices to CoNCERT shall be addressed to:

CoNCERT Pharmaceuticals, Inc.
99 Hayden Avenue, Suite 500
Lexington, MA 02421
Attn: Chief Executive Officer

With a copy to:

CoNCERT Pharmaceuticals, Inc.
99 Hayden Avenue, Suite 500
Lexington, MA 02421
Attn: General Counsel

Either Party may change its address by giving notice to the other Party in the manner provided above.

12.5 Entire Agreement. This Agreement (including Schedules) and, prior to the Option Exercise Date and subject to Section 7.1(a), the MTA, contain the complete understanding of the Parties with respect to the subject matter of this Agreement and the MTA and supersede all prior understandings and writings between the Parties relating to such subject matter.

12.6 Severability. If any provision of this Agreement is held unenforceable by a court or tribunal of competent jurisdiction because it is invalid or conflicts with any Law of any relevant jurisdiction, the validity of the remaining provisions shall not be affected. In such event,

the Parties shall negotiate a substitute provision that, to the extent possible, accomplishes the original business purpose.

12.7 Assignment. Neither this Agreement nor any right or obligation hereunder may be assigned or otherwise transferred by any Party without the consent of the other Party; provided, however, that any Party may, without such consent, assign this Agreement, in whole or in part: (a) to any of its respective Affiliates, provided that such Affiliate has acknowledged and confirmed in writing that, effective as of such assignment, such Affiliate shall be bound by this Agreement to the identical extent applicable to the assigning Party; or (b) to any successor in interest by way of merger, acquisition or sale of all or substantially all of its business or assets relating to the subject matter of this Agreement, provided that such successor (if the applicable Party is not the surviving entity in such transaction) agrees in writing to be bound by the terms of this Agreement to the identical extent applicable to the assigning Party. Any purported assignment in violation of this Section 12.7 shall be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement. Notwithstanding anything to the contrary in Section 2.1(b), if Promet assigns this Agreement to a Third Party pursuant to Section 12.7(b) and, at the time of such assignment, such Third Party has (y) cash and cash equivalents that exceed current liabilities by at least Eight Million Dollars ($8,000,000) and (z) a market capitalization or net worth (*i.e.*, total assets minus total liabilities) of at least Forty Million Five Hundred Thousand Dollars ($40,500,000), then such Third Party may exercise the Option at any time after such assignment and before the end of the Option Period.

12.8 Counterparts; Exchange by Facsimile. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and that together shall constitute one and the same instrument. Such counterparts may be exchanged by facsimile or PDF (provided that each executed counterpart is transmitted in one complete transmission or electronic mail message). Where there is an exchange of executed counterparts by facsimile or PDF, each Party shall be bound by the Agreement notwithstanding that original copies of the Agreement may not be exchanged immediately. The Parties shall cooperate after execution of the Agreement and exchange by facsimile or PDF to ensure that each Party obtains an original executed copy of this Agreement with reasonable promptness.

12.9 Force Majeure. No Party shall be liable for failure of or delay in performing obligations set forth in this Agreement, and no Party shall be deemed in breach of its obligations, if such failure or delay is due to a natural disaster, explosion, fire, flood, tornadoes, thunderstorms, earthquake, war, terrorism, riots, embargo, losses or shortages of power, labor stoppage, substance or material shortages, damage to or loss of product in transit not due to a failure by such Party or its Affiliates to exercise reasonable care, events caused by reason of Laws of any Governmental Authority, events caused by acts or omissions of a Third Party not induced or solicited by such Party or its Affiliates, or any other cause reasonably beyond the control of such Party or its Affiliates; provided that such Party uses Commercially Reasonable Efforts to overcome the difficulties created by such force majeure event and to resume performance of its obligations as soon as practicable.

12.10 Third-Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party other than a CoNCERT Party or a Promet Party, as applicable, that is an Indemnified Party under ARTICLE X, and no Third Party shall obtain

any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against either Party.

12.11 Relationship of the Parties. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other, except as expressly provided in this Agreement. Neither Party shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said other Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, the legal relationship under this Agreement of each Party to the other Party shall be that of independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint venturers between the Parties.

12.12 Performance by Affiliates. To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations.

12.13 No Consequential or Punitive Damages. NEITHER PARTY WILL BE LIABLE FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY OR PUNITIVE DAMAGES, INCLUDING LOST PROFITS, ARISING FROM OR RELATING TO THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTHING IN THIS SECTION 12.13 IS INTENDED TO LIMIT OR RESTRICT (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY UNDER THIS AGREEMENT WITH RESPECT TO THIRD PARTY CLAIMS, OR (B) DAMAGES TO WHICH A PARTY MAY BE ENTITLED FOR BREACH OF CONFIDENTIALITY AND LIMITATION ON USE OBLIGATIONS SET FORTH IN THIS AGREEMENT, OR (C) DAMAGES TO WHICH A PARTY MAY BE ENTITLED FOR THE WILLFUL MISCONDUCT, INTENTIONAL BREACH OR FRAUD OF THE OTHER PARTY.

*[Signature page follows]*

IN WITNESS WHEREOF, the Parties have signed this Agreement as of the Effective Date.

**PROMET THERAPEUTICS, LLC**

By: _____

Name: David Young

Title: Chief Executive Officer

**CoNCERT Pharmaceuticals, Inc.**

By: _____

Name: Roger Tung, President & CEO

Title: _____

**Schedule 1.13** Current as of [redacted], 2017

**Schedule 6.7**

**CoNCERT Wiring Instructions**

Beneficiary Bank: Silicon Valley Bank

Beneficiary Bank Address: 3003 Tasman Drive, Santa Clara, CA 95054

Routing & Transit: 121140399

Beneficiary Name: Concert Pharmaceuticals, Inc.

Beneficiary Account #: 3300530507

**EXECUTION COPY**

## Amendment to Option and License Agreement

**THIS AMENDMENT TO OPTION AND LICENSE AGREEMENT** (this "Amendment") is entered into as of this 19th day of March, 2018 (the "Amendment Effective Date"), by and between CoNCERT Pharmaceuticals, Inc., a corporation organized under the laws of Delaware, having a business address at 99 Hayden Avenue, Suite 500, Lexington, MA 02421 ("CoNCERT"), Promet Therapeutics, LLC, a limited liability company organized under the laws of Delaware, having a business address at 7380 Coca Cola Drive, Suite 106, Hanover, MD 21076 ("Promet") and Processa Pharmaceuticals, Inc., a corporation organized under the laws of Delaware, having a business address at 7380 Coca Cola Drive, Suite 106, Hanover, MD 21076 ("Processa").

WHEREAS, CoNCERT and Promet entered into an Option and License Agreement as of October 4, 2017 (the "Agreement"), pursuant to which CoNCERT granted to Promet an Option to obtain an exclusive license under CoNCERT Intellectual Property (the "Exclusive License");

WHEREAS, Promet will be assigning the Agreement to Processa; and

WHEREAS, the Parties wish to amend the Agreement to grant Processa the Exclusive License as of the Amendment Effective Date;

NOW, THEREFORE, the parties hereto, intending to be legally bound, hereby agree as follows:

1. Capitalized terms used in this Amendment that are not defined herein shall have the meanings ascribed to them in the Agreement.

2. Promet and Processa hereby notify CoNCERT that, as of the Amendment Effective Date, Promet assigned the Agreement, in its entirety, to Processa and Processa hereby agrees to be bound by the terms of the Agreement to the identical extent such terms are applicable to Promet.

3. The Parties hereby agree that Processa is hereby deemed to have exercised the Option effective as of the Amendment Effective Date.

4. Section 6.1 of the Agreement is hereby amended and restated in its entirety to read as follows:

   6.1 Equity Investment. On the Amendment Effective Date, CoNCERT, Promet and Processa are entering into a Securities Purchase Agreement pursuant to which Promet is selling and transferring to CoNCERT Two Million Ninety Thousand Three Hundred and One (2,090,301) shares of Processa's Common Stock, $0.0001 par value per share (the "Processa Common Stock").

5. Section 6.5 of the Agreement is hereby amended and restated in its entirety to read as follows:

6.5 Books and Records: Audit Rights. Processa shall keep complete and accurate records of the underlying revenue and expense data relating to the calculations of Net Sales and Payments required by Sections 6.3 and 6.10. CoNCERT shall have the right, once annually at its own expense, to have an independent, certified public accounting firm, selected by CoNCERT and reasonably acceptable to Processa, review any such records of Processa in the location(s) where such records are maintained by Processa upon reasonable notice (which shall be no less than fourteen (14) days prior notice) and during regular business hours and under obligations of strict confidence, for the sole purpose of verifying the basis and accuracy of reports and Payments made under Sections 6.3 and 6.10 within the thirty-six (36) month period preceding the date of the request for review. The report of such accounting firm shall be limited to a certificate stating whether any report made or Payment submitted by Processa during such period is accurate or inaccurate and the actual amounts of Net Sales, and Payments due, for such period. Processa shall receive a copy of each such report concurrently with receipt by CoNCERT. Should such inspection lead to the discovery of a discrepancy to CoNCERT's detriment, Processa shall pay within five (5) Business Days after its receipt from the accounting firm of the certificate the amount of the discrepancy plus interest calculated in accordance with Section 6.9. CoNCERT shall pay the full cost of the review unless the review reveals an underpayment greater than five percent (5%) of the amount due for any applicable Calendar Year, in which case Processa shall pay the reasonable cost charged by such accounting firm for such review. Any overpayment by Processa revealed by such review shall be fully creditable against future Payments.

6. A new Section 6.10 is hereby inserted in the Agreement immediately following Section 6.9 thereof as follows:

6.10 Sublicensing Revenues. If, prior to the earliest date following the Amendment Effective Date (as defined in the Amendment to this Agreement dated as of March 19, 2018) on which (a) Processa has raised gross proceeds of at least Eight Million Dollars ($8,000,000) (such amounts raised to include any grants or other non-dilutive amounts raised by Processa after the Effective Date) in one or more equity or other financings after the Effective Date and (b) CoNCERT can sell its shares of the Processa Common Stock without restriction pursuant to Paragraph b(1) of Rule 144 under the Securities Act of 1933, as amended, or any similar successor provision and the Leak-out provisions in the Sales and Transfer Agreement, Processa grants to any Third Party a sublicense under any of the CoNCERT Intellectual Property to Commercialize a Product in the Territory, Processa shall pay to CoNCERT, within forty-five (45) days after the end of each Calendar Quarter during the Term, fifteen percent (15%) of Sublicensing Revenues received by Processa or its Affiliates during such Calendar Quarter from such Sublicensee in consideration for such sublicense. For the purposes of this Section 6.10, "Sublicensing Revenues" means upfront payments, license fees, milestone payments, and any other payments other than royalties received by Processa or any of its Affiliates from a Sublicensee in consideration for a sublicense under any of the CoNCERT Intellectual Property to Develop, Manufacture, use or Commercialize a Product, but excludes (x) all royalties on sales of Products, (y) the portions of payments for debt or equity securities of Processa equal to the fair market value thereof and (z) funding or reimbursement for

actual costs of *bona fide* research and development activities performed by Processa or its Affiliates after the execution of, and pursuant to, such sublicense.

7. As amended by this Amendment, the Agreement remains in full force and effect.

8. This Amendment may be executed in two or more counterparts, including by facsimile or PDF signature pages, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument.

*[Signature page follows]*

IN WITNESS WHEREOF, CoNCERT, Promet and Processa have caused this Amendment to be executed by their duly authorized representatives as of the Amendment Effective Date.

**PROMET THERAPEUTICS, LLC**

By: _____

Name: David Young

Title: CEO

**CoNCERT PHARMACEUTICALS, INC.**

By: _____

Name: Nancy Stuart

Title: COO

**PROCESSA PHARMACEUTICALS, INC.**

By: _____

Name: David Young

Title: CEO

## SECURITIES PURCHASE AGREEMENT

This SECURITIES PURCHASE AGREEMENT (this "Agreement") is made and entered into as of March 19, 2018 by and among Processa Pharmaceuticals, Inc., a Delaware corporation (the "Company"), Promet Therapeutics, LLC, a Delaware limited liability company (the "Selling Stockholder"), and CoNCERT Pharmaceuticals, Inc., a Delaware corporation (the "Investor").

### RECITALS

A. The Selling Stockholder and the Investor are parties to an Option and License Agreement, dated as of October 4, 2017 (the "License Agreement"), pursuant to which the Investor granted to the Selling Stockholder an option to obtain an exclusive license under certain intellectual property of the Investor (the "Option");

B. The Selling Stockholder, the Company and the Investor intend to enter into an amendment to the License Agreement concurrently with entering into this Agreement to permit the Selling Stockholder to exercise the Option for consideration of 2,090,301 shares (the "Shares") of the Company's Common Stock, $0.0001 par value per share (the "Common Stock"), upon the terms and subject to the conditions stated in this Agreement; and

C. The Investor wishes to acquire from the Selling Stockholder, and the Selling Stockholder wishes to transfer to the Investor, the Shares, upon the terms and subject to the conditions stated in this Agreement, as consideration for the exercise of the Option;

In consideration of the mutual promises made herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Definitions. For the purposes of this Agreement, the following terms shall have the meanings set forth below:

"1933 Act" means the Securities Act of 1933, as amended, or any successor statute, and the rules and regulations promulgated thereunder.

"1934 Act" means the Securities Exchange Act of 1934, as amended, or any successor statute, and the rules and regulations promulgated thereunder.

"Affiliate" means, with respect to any Person, any other Person which directly or indirectly through one or more intermediaries Controls, is controlled by, or is under common Control with, such Person.

"Board" means the Board of Directors of the Company.

"Business Day" means a day, other than a Saturday or Sunday, on which banks in New York City are open for the general transaction of business.

"Closing" has the meaning set forth in Section 2.

"Common Stock" has the meaning ascribed to such term in the recitals to this Agreement.

"Company" has the meaning ascribed to such term in the preamble to this Agreement.

"Company Intellectual Property" has the meaning set forth in Section 4.13.

"Company's Knowledge", or "knowledge" with respect to the Company, means the actual knowledge of the executive officers (as defined in Rule 405 under the 1933 Act) of the Company, after reasonable due inquiry and investigation.

"Company Party" shall have the meaning set forth in Section 7.2(b).

"Control" (including the terms "controlling", "controlled by" or "under common control with") means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise.

"Damages" has the meaning set forth in Section 7.2(a).

"Derivative Securities" means any securities or rights convertible into, or exercisable or exchangeable for (in each case, directly or indirectly), Common Stock, including options and warrants.

"GAAP" has the meaning set forth in Section 4.8.

"Intellectual Property" means all of the following: (i) patents, patent applications, patent disclosures and inventions (whether or not patentable and whether or not reduced to practice); (ii) trademarks, service marks, trade dress, trade names, corporate names, logos, slogans and Internet domain names, together with all goodwill associated with each of the foregoing; (iii) copyrights and copyrightable works; (iv) registrations, applications and renewals for any of the foregoing; and (v) proprietary computer software (including, but not limited to, data, data bases and documentation).

"Investor" has the meaning ascribed to such term in the preamble to this Agreement.

"Investor Party" has the meaning set forth in Section 7.2(a).

"License Agreement" has the meaning ascribed to such term in the recitals to this Agreement.

"Material Adverse Effect" means a material adverse effect on (i) the assets, liabilities, results of operations, financial condition, business or prospects of the Company and its Subsidiaries taken as a whole, or (ii) the ability of the Company to perform its obligations under this Agreement.

"Material Contract" means any contract, instrument or other agreement to which the Company is a party or by which it is bound coming within the description of Item 601(b)(4) or Item 601(b)(10) of Regulation S-K as applied to the Company.

"New Securities" means, collectively, equity securities of the Company, whether or not currently authorized, as well as rights, options or warrants to purchase such equity securities, or securities of any type whatsoever that are, or may become, convertible or exchangeable into or exercisable for such equity securities.

"Offer Notice" has the meaning set forth in Section 6.4(a).

"Option" has the meaning ascribed to such term in the recitals to this Agreement.

"Person" means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.

"Public Reporting Company" means a Person subject to the reporting requirements set forth in Section 13(a) or Section 15(d) of the 1934 Act.

"ROFO Period" has the meaning set forth in Section 6.4(b).

"Rule 144" means Rule 144 under the 1933 Act or any successor rule thereto.

"SEC" means the U.S. Securities and Exchange Commission.

"SEC Filings" has the meaning set forth in Section 4.7.

"Selling Stockholder" has the meaning ascribed to such term in the preamble to this Agreement.

"Shares" has the meaning ascribed to such term in the recitals to this Agreement.

"Subsidiary" of any Person means another Person, an amount of the voting securities, other voting ownership or voting partnership interests of which is sufficient to elect at least a majority of its board of directors or other governing body (or, if there are no such voting interests, 50% or more of the equity interests of which) is owned directly or indirectly by such first Person.

2. Closing. Concurrently with the execution and delivery of this Agreement by all parties hereto, the Selling Stockholder will deliver, or cause to be delivered to the Investor, the Shares, registered in the name of the Investor, as consideration for the exercise of the Option (the "Closing").

3. Representations and Warranties of the Selling Stockholder. The Selling Stockholder hereby represents and warrants to the Investor that the statements contained in this Section 3 are complete and accurate:

3.1. Organization and Existence. The Selling Stockholder is a validly existing limited liability company and has all requisite limited liability company power and

authority to enter into and consummate the transactions contemplated by this Agreement and to carry out its obligations hereunder.

3.2. Authorization. The Selling Stockholder has taken all requisite action necessary for, and no further action on the part of the Selling Stockholder, its officers or members is necessary for (i) the authorization, execution and delivery of this Agreement and (ii) the authorization of the performance of all obligations of the Selling Stockholder hereunder.

3.3. Due Execution; Enforceability. This Agreement has been duly executed and delivered by the Selling Stockholder. This Agreement constitutes the valid and legally binding obligation of the Selling Stockholder, enforceable against the Selling Stockholder in accordance with its terms, subject to (i) applicable bankruptcy, insolvency, fraudulent transfer, moratorium, reorganization or other similar laws of general application relating to or affecting the enforcement of creditors' rights generally and (ii) general principles of equity.

3.4. Ownership of Shares. The Selling Stockholder has good and marketable title to all of the Shares, free and clear of any liens, encumbrances, equities and claims and, upon the delivery of the Shares pursuant to this Agreement, the Investor will acquire good and marketable title thereto, free and clear of any liens, encumbrances, equities and claims (other than those created by the Investor).

3.5. No Offers or Sales Requiring Registration. The offer, issuance and sale by the Company of the Shares to the Selling Stockholder were made in compliance with all applicable law and neither the Selling Stockholder nor any Person acting on its behalf has, directly or indirectly, made any offers or sales of any security or the right to purchase any security, or solicited any offers to buy any security or any such right, under circumstances that would require registration of the Shares under the 1933 Act.

3.6. Consents; No Conflict, Breach, Violation or Default. The execution, delivery and performance by the Selling Stockholder of its obligations under this Agreement require no consent of, action by or in respect of, or filing with, any Person, governmental body, agency or official. The execution, delivery and performance of this Agreement by the Selling Stockholder will not conflict with or result in a breach or violation of any of the terms and provisions of, or constitute a default under, the Selling Stockholder's organizational documents or any applicable statute, rule, regulation or order of any governmental agency or body or any court, domestic or foreign, having jurisdiction over the Selling Stockholder, or any of its assets or properties.

4. Representations and Warranties of the Company. The Company hereby represents and warrants to the Investor that, except as described in any disclosure schedule of the Company delivered to the Investor on or prior to the execution of this Agreement, the statements contained in this Section 4 are complete and accurate:

4.1. Organization, Good Standing and Qualification. Each of the Company and its Subsidiaries is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation and has all requisite corporate power and authority to carry on its business as now conducted and to own or lease its properties. Each of

the Company and its Subsidiaries is duly qualified to do business as a foreign corporation and is in good standing in each jurisdiction in which the conduct of its business or its ownership or leasing of property makes such qualification or leasing necessary unless the failure to so qualify has not had and would not reasonably be expected to have a Material Adverse Effect.

4.2. Authorization. The Company has the requisite corporate power and authority and has taken all requisite corporate action necessary for, and no further action on the part of the Company, its officers, directors and stockholders is necessary for (i) the authorization, execution and delivery of this Agreement and (ii) the authorization of the performance of all obligations of the Company hereunder. The Board has determined, at a duly convened meeting or pursuant to a unanimous written consent, that the consummation of the transactions contemplated this Agreement are in the best interest of the Company.

4.3. Due Execution; Enforceability. This Agreement has been duly executed and delivered by the Company and constitutes a valid and legally binding obligation of the Company, enforceable against the Company in accordance with its terms, subject to (i) applicable bankruptcy, insolvency, fraudulent transfer, moratorium, reorganization or other similar laws of general application relating to or affecting the enforcement of creditors' rights generally and (ii) general principles of equity.

4.4. Capitalization. The authorized capital of the Company consists of 350,000,000 shares of Common Stock, of which 35,272,558 shares are issued and outstanding, and 10,000,000 shares of Series D Preferred Stock $0.0001 par value per share, of which no shares are issued or outstanding. All of the outstanding shares of Common Stock have been duly authorized, are fully paid and nonassessable and were issued in compliance with all applicable federal and state securities laws. None of such shares were issued in violation of any pre-emptive rights and such shares were issued in compliance in all material respects with any rights of third parties. The Company does not have outstanding stockholder purchase rights or "poison pill" or any similar arrangement in effect giving any Person the right to purchase any equity interest in the Company upon the occurrence of certain events.

4.5. Valid Issuance. The Shares have been duly authorized and validly issued and are fully paid and nonassessable, and free and clear of any liens, encumbrances, equities and claims (other than those created by the Selling Stockholder).

4.6. Consents; No Conflict, Breach, Violation or Default. The execution, delivery and performance by the Company of its obligations under this Agreement require no consent of, action by or in respect of, or filing with, any Person, governmental body, agency or official. The execution, delivery and performance of this Agreement by the Company will not (i) conflict with or result in a breach or violation of (a) any of the terms and provisions of, or constitute a default under, the Company's Certificate of Incorporation or the Company's By-laws, both as in effect on the date hereof or (b) any applicable statute, rule, regulation or order of any governmental agency or body or any court, domestic or foreign, having jurisdiction over the Company, or any of its assets or properties, or (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any lien, encumbrance or other adverse claim upon any of the properties or assets of the Company or give to others any rights of termination, amendment, acceleration or cancellation

(with or without notice, lapse of time or both) of, any Material Contract, except, in the case of clauses (i)(b) and (ii) only, for such conflicts, breaches, violations and defaults as have not, and would not reasonably be expected to have a Material Adverse Effect.

4.7. SEC Filings. The Company has made all filings that would have been required to be made pursuant to the 1934 Act during the twelve months preceding the date hereof if the Company were a Public Reporting Company for the entirety of such period of time. At the times of filing thereof, the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2017 and the Company's Current Report on Form 8-K/A (Amendment No. 2) filed with the SEC on January 24, 2018 (including all exhibits and schedules thereto and the documents incorporated by reference) (collectively, the "SEC Filings") complied as to form in all material respects with the requirements of the 1934 Act that would have been applicable to the Company if it were a Public Reporting Company at the respective times of such filings and did not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements made therein, in the light of the circumstances under which they were made, not misleading.

4.8. Financial Statements. The financial statements included in each SEC Filing comply in all material respects with applicable accounting requirements and the rules and regulations of the SEC with respect thereto as in effect at the time of filing (or to the extent corrected by a subsequent restatement) that would have been applicable to the Company if it were a Public Reporting Company at the time of such filing and present fairly, in all material respects, the financial position of the Company as of the dates shown and its results of operations and cash flows for the periods shown, subject in the case of unaudited financial statements to normal, immaterial year-end audit adjustments, and such financial statements have been prepared in conformity with United States generally accepted accounting principles applied on a consistent basis during the periods involved ("GAAP"). Except as set forth in the financial statements of the Company included in the SEC Filings, the Company has not incurred any liabilities, contingent or otherwise, except those incurred in the ordinary course of business, consistent (as to amount and nature) with past practices since the date of such financial statements, none of which, individually or in the aggregate, have had or would reasonably be expected to have a Material Adverse Effect.

4.9. Absence of Changes. Since September 30, 2017, except as identified and described in the SEC Filings, there has not been:

(i) any change in the assets, liabilities, financial condition or operating results of the Company from that reflected in the financial statements included in the SEC Filings, except for changes in the ordinary course of business which have not had and would not reasonably be expected to have a Material Adverse Effect, individually or in the aggregate;

(ii) any declaration or payment by the Company of any dividend, or any authorization or payment by the Company of any distribution, on any of the capital stock of the Company, or any redemption or repurchase by the Company of any securities of the Company;

(iii) any material damage, destruction or loss, whether or not covered by insurance, to any assets or properties of the Company;

(iv) any satisfaction or discharge of any lien, claim or encumbrance or payment of any obligation by the Company, except in the ordinary course of business and which is not material to the assets, properties, financial condition, operating results or business of the Company (as such business is presently conducted);

(v) any change or amendment to the Company's Certificate of Incorporation or By-laws, or material change to any Material Contract or arrangement by which the Company is bound or to which any of its assets or properties is subject;

(vi) any material transaction entered into by the Company other than in the ordinary course of business;

(vii) any action taken by the by the Company or a Subsidiary of the Company to seek protection pursuant to any law or statute relating to bankruptcy, insolvency, reorganization, receivership, liquidation or winding up, nor does the Company have any knowledge that any of the creditors of the Company or a Subsidiary of the Company intend to initiate involuntary bankruptcy proceedings, nor has the Company or any Subsidiary of the Company received any notice from any such creditor threatening any such action; or

(viii) any other event or condition of any character that has had or would reasonably be expected to have a Material Adverse Effect.

4.10. Tax Matters. The Company and each Subsidiary of the Company has timely prepared and filed all tax returns required to have been filed by the Company or such Subsidiary of the Company with all appropriate governmental agencies and timely paid all taxes shown thereon or otherwise owed by it. The charges, accruals and reserves on the books of the Company in respect of taxes for all fiscal periods are adequate in all material respects, and there are no material unpaid assessments against the Company or any Subsidiary of the Company nor, to the Company's Knowledge, any basis for the assessment of any additional taxes, penalties or interest for any fiscal period or audits by any federal, state or local taxing authority except for any assessment which is not material to the Company. All taxes and other assessments and levies that the Company or any Subsidiary of the Company is required to withhold or to collect for payment have been duly withheld and collected and paid to the proper governmental entity or third party when due. There are no tax liens or claims pending or, to the Company's Knowledge, threatened against the Company or any Subsidiary of the Company or any of their respective assets or property. There are no outstanding tax sharing agreements or other such arrangements between the Company or any Subsidiary of the Company and any other corporation or entity.

4.11. Title to Properties. The Company and each Subsidiary of the Company (a) has good and marketable title to all real properties and all other properties and assets owned by it, in each case free from liens, encumbrances and defects that would materially affect the value thereof or materially interfere with the use made or currently planned to be made thereof by it and (b) holds any leased real or personal property under valid and enforceable leases with

no exceptions that would materially interfere with the use made or currently planned to be made thereof by it.

4.12. Certificates, Authorities and Permits. The Company and each Subsidiary of the Company possesses adequate certificates, authorities or permits issued by appropriate governmental agencies or bodies necessary to conduct the business now operated by it, and neither the Company nor any Subsidiary of the Company has received any notice of proceedings relating to the revocation or modification of any such certificate, authority or permit that would reasonably be expected to have a Material Adverse Effect, individually or in the aggregate, on the Company.

4.13. Intellectual Property. The Company, together with its Subsidiaries, owns, possesses, licenses or has other rights to use all material Intellectual Property as necessary for use in connection with its business (the "Company Intellectual Property"). There is no pending or, to the Company's Knowledge, threatened action, suit, proceeding or claim by any Person that the Company's business as now conducted infringes or otherwise violates any Intellectual Property rights of any third party or any confidentiality obligations owed to a third party. To the Company's Knowledge, there is no existing infringement by another Person of any of the Company Intellectual Property that would have or would reasonably be expected to have a Material Adverse Effect. The Company has taken reasonable security measures to protect the secrecy, confidentiality and value of all of the Company Intellectual Property, except where failure to do so would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

4.14. Legal Proceedings. There are no legal, governmental or regulatory investigations, actions, suits or proceedings pending to which the Company is a party or to which any property of the Company is subject that, individually or in the aggregate, would reasonably be expected to have a Material Adverse Effect and, to the Company's Knowledge, no such investigations, actions, suits or proceedings are threatened or contemplated by any governmental or regulatory authority or threatened by others. The SEC has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company under the 1933 Act or the 1934 Act and no stop order or suspension of trading has been imposed by any other governmental or regulatory body with respect to public trading in the Common Stock.

4.15. Transactions with Affiliates. None of the officers or directors of the Company and, to the Company's Knowledge, none of the employees of the Company is presently a party to any transaction with the Company or any Subsidiary of the Company (other than as holders of stock options and/or warrants, and for services as employees, officers and directors) within the description of Section 404 of Regulation S-K as applied to the Company.

4.16. Required Filings. No event or circumstance has occurred or information exists with respect to the Company or its business, properties, operations or financial condition, which, under applicable law, rule or regulation, requires public disclosure or announcement by the Company, or would require public disclosure or announcement by the Company if the Company were a Public Reporting Company, that has not been so publicly announced or disclosed.

4.17. No Offers or Sales Requiring Registration. The offer, issuance and sale by the Company of the Shares to the Selling Stockholder were made in compliance with all applicable law and neither the Company nor any Person acting on its behalf has, directly or indirectly, made any offers or sales of any security or the right to purchase any security, or solicited any offers to buy any security or any such right, under circumstances that would require registration under the 1933 Act of the disposition of the Shares by the Selling Stockholder to the Investor contemplated under this Agreement.

4.18. Exchange Listing. The Common Stock is listed for trading on the Pink Open Market of the OTC Markets Group and the Company is in compliance in all respects with the Company's obligations under the rules of such exchange.

5. Representations and Warranties of the Investor. The Investor hereby represents and warrants to the Selling Stockholder and the Company that the statements contained in this Section 5 are complete and accurate:

5.1. Organization, Good Standing and Qualification. The Investor is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation and has all requisite corporate power and authority to enter into and consummate the transactions contemplated by this Agreement and to carry out its obligations hereunder and thereunder.

5.2. Authorization. The Investor has the requisite corporate power and authority and has taken all requisite corporate action necessary for, and no further action on the part of the Investor, its officers, directors and stockholders is necessary for (i) the authorization, execution and delivery of this Agreement and (ii) the authorization of the performance of all obligations of the Investor hereunder.

5.3. Due Execution; Enforceability. This Agreement has been duly executed and delivered by the Investor and constitutes a valid and legally binding obligation of the Investor, enforceable against the Investor in accordance with its terms, subject to (i) applicable bankruptcy, insolvency, fraudulent transfer, moratorium, reorganization or other similar laws of general application relating to or affecting the enforcement of creditors' rights generally and (ii) general principles of equity.

5.4. Consents; No Conflict, Breach, Violation or Default. The execution, delivery and performance by the Investor of its obligations under this Agreement require no consent of, action by or in respect of, or filing with, any Person, governmental body, agency or official. The execution, delivery and performance of this Agreement by the Investor will not conflict with or result in a breach or violation of any of the terms and provisions of, or constitute a default under, the Investor's organizational documents or any applicable statute, rule, regulation or order of any governmental agency or body or any court, domestic or foreign, having jurisdiction over the Investor, or any of its assets or properties.

5.5. Acquisition Entirely for Own Account. The Shares are being acquired for the Investor's own account, not as nominee or agent, and not with a view to the resale or distribution of any part thereof in violation of the 1933 Act, and the Investor has no present

intention of selling, granting any participation in, or otherwise distributing the same in violation of the 1933 Act without prejudice, however, to the Investor's right at all times to sell or otherwise dispose of all or any part of the Shares in compliance with applicable federal and state securities laws. Nothing contained herein shall be deemed a representation or warranty by the Investor to hold the Shares for any period of time. The Investor is not a broker-dealer registered with the SEC under the 1934 Act or an entity engaged in a business that would require it to be so registered.

5.6. Investment Experience. The Investor acknowledges that it can bear the economic risk and complete loss of its investment in the Shares and has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment contemplated hereby.

5.7. Restricted Securities. The Investor understands that the Shares are characterized as "restricted securities" under the U.S. federal securities laws and that under such laws and applicable regulations such securities may be sold without registration under the 1933 Act only in certain limited circumstances.

5.8. Accredited Investor. The Investor is an "accredited investor" within the meaning of Rule 501 under the 1933 Act. The Investor has determined based on its own independent review and such professional advice as it deems appropriate that its acquisition of the Shares and participation in the transactions contemplated by this Agreement (i) comply and are consistent with all investment policies, guidelines and other restrictions applicable to the Investor and (ii) do not and will not violate or constitute a default under the Investor's charter, by-laws or other constituent document or under any law, rule, regulation, agreement or other obligation by which the Investor is bound.

5.9. Legends. It is understood that, except as provided below, certificates or book entry positions evidencing the Shares may bear the following or any similar legend:

> "The securities represented hereby have not been registered with the Securities and Exchange Commission or the securities commission of any state in reliance upon an exemption from registration under the Securities Act of 1933, as amended, and, accordingly, may not be transferred unless (i) such securities have been registered for sale pursuant to the Securities Act of 1933, as amended, (ii) such securities may be sold pursuant to Rule 144 or other applicable exemption from applicable securities laws. The Company may require an opinion of counsel to the holder of these securities, reasonably satisfactory to the Company, that such transfer may lawfully be made without registration under the Securities Act of 1933, as amended."

6. Further Covenants and Agreements.

6.1. Exchange Listing. Until such time as the Shares have been disposed of by the Company and its Affiliates, the Company will use its best efforts to continue the listing and trading of its Common Stock on the Pink Open Market of the OTC Markets Group (or in lieu thereof, any other exchange of the OTC Markets Group or any national securities exchange) and,

in accordance, therewith, will use its best efforts to comply in all respects with the Company's reporting, filing and other obligations under the bylaws or rules of such market or exchange, as applicable.

6.2. Current Public Information. With a view to making available to the Investor the benefits of Rule 144 (or its successor rule) and any other rule or regulation of the SEC that may at any time permit the Investor or its Affiliates to sell shares of Common Stock to the public without registration, the Company covenants and agrees to: (i) make and keep adequate current public information available, as such term is used in Rule 144, (ii) file with the SEC in a timely manner all reports and other documents that would be required of the Company under the 1934 Act if it were a Public Reporting Company and (iii) furnish to the Investor upon request (A) a written statement by the Company that it has complied with the reporting requirements of the 1934 Act that would be applicable to it if it were a Public Reporting Company, (B) a copy of the Company's most recent Annual Report on Form 10-K or Quarterly Report on Form 10-Q and (C) such other information as may be reasonably requested in order to avail the Investor and its Affiliates of any rule or regulation of the SEC that permits the selling of any of the Shares without registration. The covenant set forth in this Section 6.2 shall terminate as of the earlier of such time as the Shares (i) have been sold or transferred pursuant to an effective registration statement, (ii) have been sold pursuant to Rule 144 or (iii) are eligible for resale without restriction pursuant to paragraph (b)(1) of Rule 144 or any similar successor provision.

6.3. Removal of Legends. In connection with any sale or disposition of any Shares by the Investor pursuant to Rule 144 or pursuant to any other exemption under the 1933 Act, the Company shall use its best efforts to cause the transfer agent for the Common Stock to remove any restrictive legends related to the certificate evidencing, or the book entry account holding, such Shares and issue a new, unlegended certificate or book entry position for the Shares sold or disposed of within two trading days of the request of the Investor and receipt by the Company from the Investor of customary representations and other documentation reasonably acceptable to the Company in connection therewith. Subject to receipt by the Company of customary representations and other documentation reasonably acceptable to the Company in connection therewith, upon the earlier of such time as the Shares (i) have been sold or transferred pursuant to an effective registration statement, (ii) have been sold pursuant to Rule 144 or (iii) are eligible for resale without restriction pursuant to paragraph (b)(1) of Rule 144 or any similar successor provision, the Company shall (A) deliver to the transfer agent for the Common Stock irrevocable instructions that such transfer agent shall issue a new, unlegended certificate or book entry position for the Shares and (B) cause its counsel to deliver to the transfer agent for the Common Stock one or more opinions to the effect that the removal of such legends in such circumstances may be effected under the 1933 Act. The Company shall be responsible for the fees of the transfer agent for the Common Stock and all fees of The Depository Trust Company associated with such issuance.

6.4. Right of First Offer. Subject to the terms and conditions of this Section 6.4, if the Company proposes to offer or sell any New Securities, the Company shall first provide the Investor with the opportunity to purchase the portion of such New Securities specified in this Section 6.4. The Investor shall be entitled to apportion the right of first offer hereby granted to it in such proportions as it deems appropriate among itself and its Affiliates.

(a) Prior to any proposed offering of New Securities, the Company shall give notice (the "Offer Notice") to the Investor, stating (i) the Company's bona fide intention to offer such New Securities, (ii) the number of such New Securities to be offered and (iii) the price and terms, if any, upon which the Company proposes to offer such New Securities.

(b) By notification to the Company within fifteen (15) Business Days after the Offer Notice is given (the "ROFO Period"), the Investor may elect to purchase or otherwise acquire, at the price and on the terms specified in the Offer Notice, up to that portion of such New Securities that equals the proportion that the Common Stock then held by the Investor and its Affiliates (including all shares of Common Stock then issuable (directly or indirectly) upon conversion and/or exercise, as applicable, of any Derivative Securities then held by the Investor and its Affiliates) bears to the total Common Stock of the Company then outstanding (assuming full conversion and/or exercise, as applicable, of all Derivative Securities). The closing of any sale of New Securities that the Investor elects to purchase or otherwise acquire pursuant to this Section 6.4(b) shall occur concurrently with the earliest closing for the other New Securities offered by the Company.

(c) The Company may, during the sixty (60) days following the expiration of the ROFO Period, offer and sell the New Securities that the Investor (and its Affiliates) have not elected to purchase in such offering at a price not less than, and upon terms no more favorable to the offeree than, those specified in the Offer Notice. If the Company does not consummate the sale of such securities within such 30-day period, the right of first offer under this Section 6.4 shall be deemed to be revived and such New Securities shall not be offered unless the Investor shall have again been provided with a right of first offer with respect thereto in accordance with this Section 6.4.

(d) The right of first offer set forth in this Section 6.4 shall not be applicable to offers or sales of equity securities that are registered by the Company on Form S-8 under the 1933 Act.

(e) The right of first offer set forth in this Section 6.4 shall remain in effect as long as Investor and its Affiliates collectively own two percent (2%) or more of the outstanding Common Stock, with any shares of Common Stock that are issuable upon the exercise, conversion or exchange of any securities held by Investor or any of its Affiliates being considered to be outstanding shares of Common Stock for purposes of this sentence.

6.5. Leak-Out. Notwithstanding any other provision in this Agreement, the Investor will not, directly or indirectly:

(i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of any Shares or any securities convertible into or exercisable or exchangeable for Shares, owned by the Investor or with respect to which the Investor has the power of disposition, or

(ii) enter into any swap or other agreement, arrangement or transaction that transfers to another, in whole or in part, directly or indirectly, any of the

economic consequence of ownership of any Shares or any securities convertible into or exercisable or exchangeable for any Shares,

whether any transaction described in clause (i) or (ii) above is to be settled by delivery of Shares, other securities, in cash or otherwise, prior to July 2, 2018 unless: (a) the transaction price is in excess of $4.08 per share (subject to appropriate adjustment for any stock split, stock dividend, reclassification, recapitalization or other similar transaction affecting the Common Stock after the execution of this Agreement) of Common Stock and the number of Shares so sold prior to July 1, 2018 does not exceed 15% of the Shares; or (b) the transaction price is in excess of $5.10 per share (subject to appropriate adjustment for any stock split, stock dividend, reclassification, recapitalization or other similar transaction affecting the Common Stock after the execution of this Agreement) of Common Stock and the number of Shares so sold prior to July 2, 2018 does not exceed 40% of the Shares. In addition, Investor agrees that prior to July 2, 2018, Shares may only be sold at or above the lowest "offer" or "ask" prices stated by the relevant market maker for the Common Stock on the OTC Markets or any nationally recognized exchange on which the Common Stock is publicly traded. Investor further agrees that (a) no sales will be made at the "bid" prices for the Common Stock and that (b) it will not engage in any short selling of the Common Stock prior to July 2, 2018.

7. Survival, Indemnification and Remedies.

7.1. Survival. The representations, warranties, covenants, indemnities and agreements contained in this Agreement shall survive the Closing for the applicable statute of limitations.

7.2. Indemnification.

(a) Company and Selling Stockholder Indemnification of the Investor. In consideration of the Investor's execution and delivery of this Agreement and acquiring the Shares hereunder and in addition to all of the Company's and the Selling Stockholder's other obligations under this Agreement, subject to the provisions of this Section 7.2(a) and Section 7.3, the Company and the Selling Stockholder shall, severally and not jointly, indemnify and hold harmless the Investor, each of its directors, officers, shareholders, members, partners, employees, representatives, agents and advisors (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding the lack of such title or any other title), each Person, if any, who controls the Investor (within the meaning of Section 15 of the 1933 Act or Section 20(a) of the 1934 Act), and the respective directors, officers, shareholders, members, partners, employees, representatives, agents and advisors (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding the lack of such title or any other title) of such controlling Persons (each, an "Investor Party"), from and against all losses, liabilities, obligations, claims, damages, costs and expenses (including all judgments, amounts paid in settlement, court costs, reasonable attorneys' fees and costs of defense and investigation) (collectively, "Damages") that such Investor Party may suffer or incur as a result of or relating to any breach of any of the representations, warranties, covenants or agreements made by the Company or the Selling Stockholder in this Agreement; provided, however, that the foregoing indemnity shall not apply to any Damages to the extent, but only to the extent, that such

Damages resulted directly and primarily from a breach of any of the Investor's representations, warranties, covenants or agreements contained in this Agreement.

An Investor Party's right to indemnification or other remedies based upon the representations, warranties, covenants and agreements of the Company or the Selling Stockholder set forth in this Agreement shall not in any way be affected by any investigation or knowledge of such Investor Party. Such representations, warranties, covenants and agreements shall not be affected or deemed waived by reason of the fact that an Investor Party knew or should have known that any representation or warranty might be inaccurate or that the Company or the Selling Stockholder failed to comply with any agreement or covenant. Any investigation by such Investor Party shall be for its own protection only and shall not affect or impair any right or remedy hereunder.

To the extent that the foregoing undertakings by the Company and the Selling Stockholder set forth in this Section 7.2(a) may be unenforceable for any reason, the Company and the Selling Stockholder shall make the maximum contribution to the payment and satisfaction of each of the Damages which is permissible under applicable law.

(b) Investor Indemnification of the Company and the Selling Stockholder. In consideration of the Company's and the Selling Stockholder's execution and delivery of this Agreement and disposition of the Shares hereunder and in addition to all of the Investor's other obligations under this Agreement, subject to the provisions of this Section 7.2(b) and Section 7.3, the Investor shall indemnify and hold harmless the Company and the Selling Stockholder, each of their respective directors, officers, stockholders, employees, representatives, agents and advisors (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding the lack of such title or any other title), each Person, if any, who controls the Company or the Selling Stockholder (within the meaning of Section 15 of the 1933 Act or Section 20(a) of the 1934 Act), and the respective directors, officers, shareholders, members, partners, employees, representatives, agents and advisors (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding the lack of such title or any other title) of such controlling Persons (each, a "Company Party"), from and against all Damages that such Company Party may suffer or incur as a result of or relating to any breach of any of the representations, warranties, covenants or agreements made by the Investor in this Agreement; provided, however, that the foregoing indemnity shall not apply to any Damages to the extent, but only to the extent, that such Damages resulted directly and primarily from a breach of any of the representations, warranties, covenants or agreements of the Company or the Selling Stockholder contained in this Agreement.

A Company Party's right to indemnification or other remedies based upon the representations, warranties, covenants and agreements of the Investor set forth in this Agreement shall not in any way be affected by any investigation or knowledge of such Company Party. Such representations, warranties, covenants and agreements shall not be affected or deemed waived by reason of the fact that a Company Party knew or should have known that any representation or warranty might be inaccurate or that the Investor failed to comply with any agreement or covenant. Any investigation by such Company Party shall be for its own protection only and shall not affect or impair any right or remedy hereunder.

To the extent that the foregoing undertakings by the Investor set forth in this Section 7.2(b) may be unenforceable for any reason, the Investor shall make the maximum contribution to the payment and satisfaction of each of the Damages which is permissible under applicable law.

7.3. Conduct of Indemnification Proceedings. Any person entitled to indemnification hereunder shall (i) give prompt notice to the indemnifying party of any claim with respect to which it seeks indemnification and (ii) permit such indemnifying party to assume the defense of such claim with counsel reasonably satisfactory to the indemnified party; provided that any person entitled to indemnification hereunder shall have the right to employ separate counsel and to participate in the defense of such claim, but the fees and expenses of such counsel shall be at the expense of such person, unless (a) the indemnifying party has agreed to pay such fees or expenses, (b) the indemnifying party shall have failed to assume the defense of such claim and employ counsel reasonably satisfactory to such person or (c) in the reasonable judgment of any such person, based upon written advice of its counsel, a conflict of interest exists between such person and the indemnifying party with respect to such claims (in which case, if the person notifies the indemnifying party in writing that such person elects to employ separate counsel at the expense of the indemnifying party, the indemnifying party shall not have the right to assume the defense of such claim on behalf of such person); and provided, further, that the failure of any indemnified party to give notice as provided herein shall not relieve the indemnifying party of its obligations hereunder, except to the extent that such failure to give notice shall materially adversely affect the indemnifying party in the defense of any such claim or litigation. It is understood and agreed that the indemnifying party shall not, in connection with any proceeding in the same jurisdiction, be liable for fees or expenses of more than one separate firm of attorneys at any time for all such indemnified parties. No indemnifying party will, except with the consent of the indemnified party, consent to entry of any judgment or enter into any settlement that (i) does not include as an unconditional term thereof the giving by the claimant or plaintiff to such indemnified party of a release from all liability in respect of such claim or litigation or (ii) that includes the granting of any equitable relief or the admission by the indemnified party of its officers, directors, managers, partners or Affiliates of any legal, regulatory or ethical violations.

7.4. Remedies.

(a) The Investor shall have all rights and remedies set forth in this Agreement and all rights and remedies that the Investor has been granted at any time under any other agreement or contract and all of the rights that the Investor has under any law. The Company and the Selling Stockholder recognize that in the event that either of them fails to perform, observe or discharge any or all of its obligations under this Agreement, any remedy at law may prove to be inadequate relief to the Investor. The Company and the Selling Stockholder therefore each agree that the Investor shall be entitled to seek specific performance and/or temporary, preliminary and permanent injunctive or other equitable relief from any court of competent jurisdiction in any such case without the necessity of proving actual damages and without posting a bond or other security.

(b) The Company and the Selling Stockholder shall have all rights and remedies set forth in this Agreement and all rights and remedies that the Company and the

Selling Stockholder, respectively, have been granted at any time under any other agreement or contract and all of the rights which the Company and the Selling Stockholder, respectively, have under any law. The Investor recognizes that in the event that it fails to perform, observe or discharge any or all of its obligations under this Agreement, any remedy at law may prove to be inadequate relief to the Company or the Selling Stockholder. The Investor therefore agrees that the Company and the Selling Stockholder shall be entitled to seek specific performance and/or temporary, preliminary and permanent injunctive or other equitable relief from any court of competent jurisdiction in any such case without the necessity of proving actual damages and without posting a bond or other security.

8. Miscellaneous.

8.1. Successors and Assigns. This Agreement may not be assigned by a party hereto without the prior written consent of each other party hereto, provided, however, that, the Investor may, without the prior written consent of the Company or the Selling Stockholder, assign its rights and delegate its duties hereunder in whole or in part by operation of law, to an Affiliate or to a third party acquiring all or substantially all of its assets or securities in a transaction complying with applicable securities laws. The provisions of this Agreement shall inure to the benefit of and be binding upon the respective permitted successors and assigns of the parties. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective permitted successors and assigns any rights, remedies, obligations, or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement.

8.2. Counterparts; Faxes; E-mail. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may also be executed via facsimile or e-mail, which shall be deemed an original.

8.3. Titles and Subtitles. The titles and subtitles used in this Agreement are used for convenience only and are not to be considered in construing or interpreting this Agreement.

8.4. Notices. Unless otherwise provided, any notice required or permitted under this Agreement shall be given in writing and shall be deemed effectively given as hereinafter described (i) if given by personal delivery, then such notice shall be deemed given upon such delivery, (ii) if sent by electronic mail during normal business hours of the recipient, then notice shall be deemed given when sent, and if not sent during normal business hours, then notice shall be deemed given on the recipient's next Business Day, (iii) if given by facsimile, then such notice shall be deemed given upon receipt of confirmation of complete transmittal, (iv) if given by mail, then such notice shall be deemed given upon the earlier of (A) receipt of such notice by the recipient or (B) three days after such notice is deposited in first class mail, postage prepaid, and (v) if given by an internationally recognized overnight air courier, then such notice shall be deemed given one Business Day after delivery to such carrier. All notices shall be addressed to the party to be notified at the address as follows, or at such other address as such party may designate by ten days' advance written notice to the other party:

If to the Company or the Selling Stockholder:

Processa Pharmaceuticals, Inc.
7380 Coca Cola Drive, Suite 106,
Hanover, Maryland 21076
Attention: David Young, CEO
Fax: (443) 288-4420
E-mail: dyoung@processapharmaceuticals.com

With a copy to:

Foley & Lardner LLP
One Independent Drive
Suite 1300
Jacksonville, Florida 32202
Attention: John Wolfel
Fax: (904) 359-8700
E-mail: jwolfel@foley.com

If to the Investor:

CoNCERT Pharmaceuticals, Inc.
99 Hayden Avenue, Suite 500
Lexington, Massachusetts 02421
Attention: General Counsel
Fax: (781) 674-5310
E-mail: lherscha@concertpharma.com

With a copy to:

Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, Massachusetts 02109
Attention: Steven D. Barrett
Fax: (617) 526-5000
E-mail: steven.barrett@wilmerhale.com

8.5. Amendments and Waivers. Any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively), only with the written consent of each of the parties hereto.

8.6. Publicity. No public release or announcement concerning the transactions contemplated hereby shall be issued by any party hereto without the prior consent of each of the other parties hereto, except as such release or announcement may be required by law or the applicable rules or regulations of any securities exchange or securities market, in which case the releasing or announcing party shall allow each other party hereto, to the extent

reasonably practicable in the circumstances, reasonable time to comment on such release or announcement in advance of such issuance.

8.7. Severability. Any provision of this Agreement that is prohibited or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof but shall be interpreted as if it were written so as to be enforceable to the maximum extent permitted by applicable law, and any such prohibition or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction. To the extent permitted by applicable law, the parties hereby waive any provision of law which renders any provision hereof prohibited or unenforceable in any respect.

8.8. Entire Agreement. This Agreement and the License Agreement constitute the entire agreement among the parties hereof with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, both oral and written, between the parties with respect to the subject matter hereof and thereof.

8.9. Further Assurances. The parties shall execute and deliver all such further instruments and documents and take all such other actions as may reasonably be required to carry out the transactions contemplated hereby and to evidence the fulfillment of the agreements herein contained.

8.10. Governing Law; Consent to Jurisdiction. This Agreement shall be governed by, and construed in accordance with, the internal laws of the Commonwealth of Massachusetts without regard to the choice of law principles thereof. Each of the parties hereto irrevocably submits to the exclusive jurisdiction of the courts of the Commonwealth of Massachusetts located in Suffolk County and the United States District Court for the District of Massachusetts for the purpose of any suit, action, proceeding or judgment relating to or arising out of this Agreement and the transactions contemplated hereby. Service of process in connection with any such suit, action or proceeding may be served on each party hereto anywhere in the world by the same methods as are specified for the giving of notices under this Agreement. Each of the parties hereto irrevocably consents to the jurisdiction of any such court in any such suit, action or proceeding and to the laying of venue in such court. Each party hereto irrevocably waives any objection to the laying of venue of any such suit, action or proceeding brought in such courts and irrevocably waives any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum.

[remainder of page intentionally left blank]

IN WITNESS WHEREOF, the parties have executed this Agreement or caused their duly authorized officers to execute this Agreement as of the date first above written.

COMPANY:

PROCESSA PHARMACEUTICALS, INC.

By: _____
Name: David Young
Title: CEO

SELLING STOCKHOLDER:

PROMET THERAPEUTICS, LLC

By: _____
Name: David Young
Title: CEO

INVESTOR:

CONCERT PHARMACEUTICALS, INC.

By: _____
Name: Davy Stout
Title: COO

**Exhibit 10.4**

PROCESSA PHARMACEUTICALS INC.
EMPLOYMENT AGREEMENT
SEPTEMBER 1, 2018

This Employment Agreement is entered into as of the date of the last signature affixed hereto, by and between Processa Pharmaceuticals Inc., a Delaware corporation ("Processa"), and James Stanker, ("Employee").

In consideration of the mutual promises and covenants set forth herein, and other good and valuable consideration, the sufficiency of which is hereby acknowledged, Processa and Employee hereby agree as follows:

1. Position of Employment. Processa will employ the Employee in the position of Chief Financial Officer ("CFO") and, as CFO, Employee will report to the Chief Executive Officer ("CEO"). Processa retains the right to change Employee's title, duties, and reporting relationships as may be determined to be in the best interests of Processa; provided, however, that any such change in Employee's duties shall be consistent with Employee's training, experience, and qualifications.

   The terms and conditions of the Employee's employment shall, to the extent not addressed or described in this Employment Agreement, be governed by Processa's Policies and Procedures Manual and existing practices. In the event of a conflict between this Employment Agreement and the Policies and Procedures Manual or existing practices, the terms of this Agreement shall govern.

2. Term of Employment. Employee's employment with Processa shall begin on September 1, 2018 and shall continue until December 31, 2018, after which time continued employment shall be on an "at will" basis, unless:

   a. Employee's employment is terminated by either party in accordance with the terms of Section 5 of this Employment Agreement; or

   b. Such term of employment is extended or shortened by a subsequent agreement duly executed by each of the parties to this Employment Agreement, in which case such employment shall be subject to the terms and conditions contained in the subsequent written agreement.

3. Compensation and Benefits.

   a. Base Salary. Employee shall receive an initial base annual salary of $87,500, subject to review and adjustment from time to time by the Company in its sole discretion. The annual salary is based on a 50% level of effort.

   b. Stock Options. Subject to approval by the Processa's Board of Directors (the "Board"), and pursuant to the Processa's 2017 Stock Plan (the "Plan"), Processa shall grant Employee an option to purchase 316,400 shares of Processa's common stock at the fair market value as determined by the Board as of the date of grant (the "Option") with a 10-year term. The option shall be an incentive stock option to the extent permissible under Section 422 of the Internal Revenue Code. The Option shall vest over a period of 4 years as follows: 25% of the shares vesting on September 1, 2019 and 1/48$^{th}$ of total shares subject to the Option shall vest monthly thereafter over the remaining three years of the vesting period, subject to Employee's continuous service as of each applicable date. In the event of the Employee's termination without cause or termination for Good Reason prior to September 1, 2019, then 25% of the then-unvested Option shall immediately vest. In addition, in the event of a Change of Control, subject to Employee's continuous service as of the closing of such Sale Event, all of Employee's then-unvested Option shall immediately and automatically vest as of the Closing of such Change of Control Event.

      Employee shall also receive an option to purchase 18,000 shares of Processa's common stock at the exercise price as determined by the Board. 9,000 of these shares will vest on March 1, 2019 and 9,000 will vest on September 1, 2019. The specifics of the stock options will be described in the Stock Option Agreement and Stock Option Award provided to the Employee.

   c. Incentive and Deferred Compensation. Employee shall be eligible to participate in all incentive and deferred compensation programs available to other executives or officers of Processa, such participation to be in the same form, under the same terms, and to the same extent that such programs are made available to other such executives or officers. Nothing in this Employment Agreement shall be deemed to require the payment of bonuses, awards, or incentive compensation to Employee if such payment would not otherwise be required under the terms of Processa's incentive compensation programs.

d. Employee Benefits. Employee shall be eligible to participate in all employee benefit plans, policies, programs, or perquisites in which other Processa executive or officers participate, including the Processa Stock Option program. The terms and conditions of Employee's participation in Processa's employee benefit plans, policies, programs, or perquisites shall be governed by the terms of each such plan, policy, or program.

4. Duties and Performance. The Employee acknowledges and agrees that he is being offered a position of employment by Processa with the understanding that the Employee possesses a unique set of skills, abilities, and experiences which will benefit Processa, and he agrees that his continued employment with Processa, whether during the term of this Employment Agreement or thereafter, is contingent upon his successful performance of his duties in his position as noted above, or in such other position to which he may be assigned.

   a. General Duties.

      1. Employee shall render to the best of the Employee's ability, on behalf of the Processa, services to and on behalf of the Processa, and shall undertake diligently all duties assigned to him by the Processa.

      2. Employee shall devote his time, energy and skill to the performance of the services in which Processa is engaged, at such time and place as Processa may direct. The Employee shall not serve on any board of directors of a company or perform any other activities with a company that presents a conflict of interest and/or would interfere with Employee's responsibilities and the performance of Employee's duties hereunder. Employees will notify the CEO of service on boards of directors of companies that are not competitive with the Company, do not otherwise present a conflict of interest and would not otherwise interfere with Employee's responsibilities and the performance of Employee's duties hereunder. The Employee is not prohibited from preforming other activities, for compensation or otherwise, that would not interfere with Employee's responsibilities and the performance of Employee's duties hereunder or present a conflict of interest.

      3. Employee shall faithfully and industriously assume and perform with skill, care, diligence and attention all responsibilities and duties connected with his employment on behalf of Processa.

      4. Employee shall have no authority to enter into any contracts binding upon Processa, or to deliberately create any obligations on the part of Processa, except as may be specifically authorized by the Board of Directors of Processa.

   b. Specific Duties.

   c. To the best of the Employees ability, he will:

      1. provide leadership in the development for the continuous evaluation of short and long-term strategic financial objectives.

      2. ensure credibility of the Accounting and Finance group by providing timely and accurate analysis of budgets, financial trends and forecasts.

      3. direct and oversee all aspects of the finance & Accounting functions of the organization.

      4. evaluate and advises on the impact of long-range planning, introduction of new programs/strategies and regulatory action.

      5. manage processes for financial forecasting, budgets and consolidation and reporting to the Company.

      6. provide executive management with advice on the financial implications of business activities.

      7. provide recommendations to strategically enhance financial performance and business opportunities.

      8. develop, design and implement effective internal controls over financial reporting to comply with the requirement of the Sarbanes Oxley Act of 2002.

      9. understand and mitigate key elements of the company's risk profile.

      10. report risk issues to the CEO and audit committee of the Board of Directors.

      11. oversee the SEC financial reporting process.

      12. other duties as assigned.

5. Termination of Employment. Employee's employment with Processa may be terminated, prior to the expiration of the term of this Employment Agreement, in accordance with any of the following provisions:

   a. Termination by Employee. The Employee may terminate his employment at any time during the course of this agreement by giving 4 weeks' notice in writing to the Board of Directors of Processa. During the notice period, Employee must fulfill all his duties and responsibilities set forth above and use his best efforts to train and support his replacement, if any. Failure to comply with this requirement may result in Termination for Cause described below, but otherwise Employee's salary and benefits will remain unchanged during the notification period.

   b. Termination by Employee for Good Reason. The Employee may terminate employment with the Company for Good Reason. "Good Reason" shall mean the occurrence without Employee's written consent, of one or more of the following events: (i) the Company reduces Employee's base salary by more than 25%, (ii) the Company materially decreases Employee's responsibilities, (iii) the Company relocates Employee's principal place of work to a location more than fifty (50) miles from the location of Employee's principal place of work on the date of this Agreement, or (iv) the Company materially breaches the terms of this Agreement; provided that no such event shall constitute Good Reason hereunder unless (a) Employee shall have given written notice to the Company of Employee's intent to resign for Good Reason within 30 days after Employee becomes aware of the occurrence of any such event (specifying in detail the nature and scope of the event), (b) such event or occurrence shall not have been cured within 30 days of the Company's receipt of such notice, (c) any Termination by Employee for Good Reason following such 30 day cure period must occur no later than the date that is 30 days following the expiration of such 30 day cure period. Employee's Termination for Good Reason shall be treated as involuntary.

   c. Termination by Processa without Cause. Processa may terminate Employee's employment at any time during the course of this agreement by giving 4 weeks' notice in writing to the Employee. During the notice period, Employee must fulfill all of Employee's duties and responsibilities set forth above and use Employee's best efforts to train and support Employee's replacement, if any. Failure of Employee to comply with this requirement may result in Termination for Cause described below, but otherwise Employee's salary and benefits will remain unchanged during the notification period. Processa, in its sole discretion, may give Employee severance pay in the amount of the remaining notice period in lieu of actual employment, and nothing herein shall require Processa to maintain employee in active employment for the duration of the notice period.

   d. Termination by Processa for Cause. Processa may, at any time and without notice, terminate the Employee for "cause". Termination by Processa of the Employee for "cause" shall include but not be limited to termination based on any of the following grounds: (a) conduct by Employee that demonstrates Employee's gross unfitness to serve under circumstances that materially and adversely affect the Company; (b) fraud, misappropriation, embezzlement or acts of similar dishonesty; (c) conviction of a felony involving moral turpitude; (d) illegal use of drugs or excessive use of alcohol in the workplace; (e) intentional and willful misconduct that may subject Processa to criminal or civil liability; (f) breach of the Employee's duty of loyalty, including the diversion or usurpation of corporate opportunities properly belonging to Processa; (g) willful disregard of Processa policies and procedures; and (h) breach of any of the material terms of this Agreement.

   e. Termination by Death or Disability. The Employee's employment and rights to compensation under this Employment Agreement shall terminate if the Employee is unable to perform the duties of his position due to death or disability lasting more than 90 days, and the Employee's heirs, beneficiaries, successors, or assigns shall not be entitled to any of the compensation or benefits to which Employee is entitled under this Agreement, except: (a) to the extent specifically provided in this Employment Agreement; (b) to the extent required by law; or (c) to the extent that such benefit plans or policies under which Employee is covered provide a benefit to the Employee's heirs, beneficiaries, successors, or assigns.

   f. Termination of Employment without Cause or for Good Reason Involving a Change of Control. Employee's employment with Processa may be terminated in the event that a Change in Control occurs which is also a Cash Severance Change in Control (as defined below), and Employee's employment with the Company is terminated by the Company Without Cause or by Employee for Good Reason at any time within the three (3) month period before the date of such Cash Severance Change in Control or during the twelve (12) month period following the date of such Cash Severance Change in Control, Employee will receive severance compensation equal to six months' of the highest Base Salary in the calendar year in which the Cash Severance Change in Control occurs.

For purposes of this Section, "**Cash Severance Change in Control**" shall mean and include:

i. Acquisition by any "Person" or "Group" of securities entitled to vote generally in the election of directors ( "voting securities" ) of the Company that represent 50% or more of the combined voting power of the Company's then outstanding voting securities;

ii. A change in the composition of the Board occurring within a twelve (12) month period, as a result of which a majority of the incumbent directors are replaced by directors whose appointment or election is not endorsed by a majority of the incumbent directors before the date of the appointment or election;

iii. Merger or consolidation in which the seller's shareholders no longer control the surviving entity;

iv. Sale of substantially all assets to an unrelated entity.

6. Confidentiality. Employee agrees that at all times during Employee's employment and following the conclusion of Employee's employment, whether voluntary or involuntary, Employee will hold in strictest confidence and not disclose Confidential Information (as defined below) to anyone who is not also an employee of Processa or to any employee of Processa.

a. "Confidential Information" shall mean any trade secrets or Processa proprietary information, including but not limited to manufacturing techniques, processes, formulas, customer lists, inventions, experimental developments, research projects, operating methods, cost, pricing, financial data, business plans and proposals, data and information Processa receives in confidence from any other party, or any other secret or confidential matters of Processa. Additionally, Employee will not use any Confidential Information for Employee's own benefit or to the detriment of Processa during Employee's employment or thereafter. Employee also certifies that employment with Processa does not and will not breach any agreement or duty that Employee has to anyone concerning confidential information belonging to others.

b. "Immunity from Liability for Confidential Disclosure of a Trade Secret to the Government or in a Court Filing:

(1) Immunity—An individual shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that—(A) is made—(i) in confidence to a federal, state or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

(2) Use of Trade Secret Information in Anti-Retaliation Lawsuit—An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual—(A) files any document containing the trade secret under seal; and (B) does not disclose the trade secret, except pursuant to court order."

7. Expenses. Processa shall pay or reimburse Employee for any expenses reasonably incurred by him in furtherance of his duties hereunder, including expenses for entertainment, travel, meals and hotel accommodations, upon submission by him of vouchers or receipts maintained and provided to Processa in compliance with such rules and policies relating thereto as Processa may from time to time adopt.

8. General Provisions.

a. Notices. All notices and other communications required or permitted by this Agreement to be delivered by Processa or Employee to the other party shall be delivered in writing to the address shown below, either personally, by facsimile transmission or by registered, certified or express mail, return receipt requested, postage prepaid, shall be sent to the Company at its primary office location and to Employee at Employee's address as listed on the Company Payroll, or at such other address as the Company or Employee may designate by ten days advance written notice to the other, and shall be deemed given and received as of actual personal delivery, on the first business day after the date of delivery shown on any such facsimile transmission or upon the date or actual receipt shown on any return receipt if registered, certified or express mail is used, as the case may be.

b. Amendments and Termination; Entire Agreement. This Agreement may not be amended or terminated except by a writing executed by all of the parties hereto. This Agreement constitutes the entire agreement of Processa and Employee relating to the subject matter hereof and supersedes all prior oral and written understandings and agreements relating to such subject matter.

c. Successors and Assigns. The rights and obligations of the parties hereunder are not assignable to another person without prior written consent; provided, however, that Processa, without obtaining Employee's consent, may assign its rights and obligations hereunder to a wholly-owned subsidiary and provided further that any post-employment restrictions shall be assignable by Processa to any entity which purchases all or substantially all of Processa's assets.

d. Severability; Provisions Subject to Applicable Law. All provisions of this Agreement shall be applicable only to the extent that they do not violate any applicable law, and are intended to be limited to the extent necessary so that they will not render this Agreement invalid, illegal or unenforceable under any applicable law. If any provision of this Agreement or any application thereof shall be held to be invalid, illegal or unenforceable, the validity, legality and enforceability of other provisions of this Agreement or of any other application of such provision shall in no way be affected thereby.

e. Waiver of Rights. No waiver by Processa or Employee of a right or remedy hereunder shall be deemed to be a waiver of any other right or remedy or of any subsequent right or remedy of the same kind.

f. Definitions; Headings; and Number. A term defined in any part of this Employment Agreement shall have the defined meaning wherever such term is used herein. The headings contained in this Agreement are for reference purposes only and shall not affect in any manner the meaning or interpretation of this Employment Agreement. Where appropriate to the context of this Agreement, use of the singular shall be deemed also to refer to the plural, and use of the plural to the singular.

g. Counterparts. This Agreement may be executed in separate counterparts, each of which shall be deemed an original but both of which taken together shall constitute but one and the same instrument.

h. Governing Laws and Forum. This Agreement shall be governed by, construed, and enforced in accordance with the laws of Maryland. The parties hereto further agree that any action brought to enforce any right or obligation under this Agreement shall be subject to the exclusive jurisdiction of the courts of Maryland.

i. Indemnification. The Employee shall be entitled to indemnification to the maximum extent permitted by applicable law and the Company's Bylaws with terms no less favorable than provided to any other Company executive officer and subject to the terms of any separate written indemnification agreement. At all times during the Employee's employment, the Company shall maintain in effect a directors and officers liability insurance policy with the Employee as a covered officer.

All terms in this offer are dependent on the approval of the Processa Board of Directors. IN WITNESS WHEREOF, Processa Pharmaceuticals, Inc. and Employee have executed and delivered this Agreement as of the date written below.

Processa Pharmaceuticals, Inc.

James Stanker

By: _____

Name: _____

Title: _____

ANNEX A

**PROCESSA PHARMACEUTICALS, INC.**
**2019 OMNIBUS INCENTIVE PLAN**

**1. Purposes, History and Effective Date.**

(a) *Purpose*. The Processa Pharmaceuticals, Inc. 2019 Omnibus Incentive Plan has two complementary purposes: (i) to attract and retain outstanding individuals to serve as officers, directors, employees and consultants and (ii) to increase stockholder value by providing Participants incentives to increase stockholder value by offering the opportunity to acquire shares of the Company's Stock, receive monetary payments based on the value of such Stock, or receive other incentive compensation, on the potentially favorable terms that this Plan provides.

(b) *Effective Date.* This Plan will become effective, and Awards may be granted under this Plan, on and after the Effective Date. This Plan will terminate as provided in Section 14.

(c) *History*. Prior to the Effective Date, the Company had in effect the Heatwurx 2011 Amended and Restated Equity Incentive Plan (the "Prior Plan"). Upon the Effective Date, the Prior Plan will terminate, and no new awards will be granted under the Prior Plan, although awards previously granted under the Prior Plan and still outstanding will continue to be subject to all terms and conditions of the Prior Plan.

**2. Definitions.** Capitalized terms used and not otherwise defined in this Plan or in any Award agreement have the following meanings:

(a) "Act" means the Securities Act of 1933, as amended from time to time. Any reference to a specific provision of the Act shall include any successor provision thereto and the rules and regulations promulgated under such provision.

(b) "Administrator" means the Board or the Committee;*provided* that, to the extent the Board or the Committee has delegated authority and responsibility as an Administrator of the Plan to one or more committees or officers of the Company as permitted by Section 3(b), the term "Administrator" shall also mean such committee(s) and/or officer(s) to the extent of such delegation.

(c) "Affiliate" has the meaning ascribed to such term in Rule 12b-2 under the Exchange Act. Notwithstanding the foregoing, for purposes of determining those individuals to whom an Option or a Stock Appreciation Right that is exempt from Code Section 409A may be granted, the term "Affiliate" means any entity that, directly or through one or more intermediaries, is controlled by or is under common control with, the Company within the meaning of Code Sections 414(b) or (c); *provided* that, in applying such provisions, the phrase "at least 20 percent" shall be used in place of "at least 80 percent" each place it appears therein.

(d) "Award" means a grant of Options, Stock Appreciation Rights, Performance Units, Stock, Restricted Stock, Restricted Stock Units, a Cash Incentive Award, Dividend Equivalent Units or any other type of award permitted under this Plan.

(e) "Beneficial Owner" means a Person, with respect to any securities which:

(i) such Person or any of such Person's Affiliates has the right to acquire (whether such right is exercisable immediately or only after the passage of time) pursuant to any agreement, arrangement or understanding, or upon the exercise of conversion rights, exchange rights, rights, warrants or options, or otherwise; *provided, however*, that a Person shall not be deemed the Beneficial Owner of, or to beneficially own, securities tendered pursuant to a tender or exchange offer made by or on behalf of such Person or any of such Person's Affiliates until such tendered securities are accepted for purchase; or

(ii) such Person or any of such Person's Affiliates, directly or indirectly, has the right to vote or dispose of or has "beneficial ownership" of (as determined pursuant to Rule 13d-3 of the General Rules and Regulations under the Act), including pursuant to any agreement, arrangement or understanding; *provided, however*, that a Person shall not be deemed the Beneficial Owner of, or to beneficially own, any security under this clause (ii) as a result of an agreement, arrangement or understanding to vote such security if the agreement, arrangement or understanding: (A) arises solely from a revocable proxy or consent given to such Person in response to a public proxy or consent solicitation made pursuant to, and in accordance with, the applicable rules and regulations under the Act and (B) is not also then reportable on a Schedule 13D under the Act (or any comparable or successor report); or

(iii) are beneficially owned, directly or indirectly, by any other Person with which such Person or any of such Person's Affiliates has any agreement, arrangement or understanding for the purpose of acquiring, holding, voting (except pursuant to a revocable proxy as described in clause (ii) above) or disposing of any voting securities of the Company.

(f) "Board" means the Board of Directors of the Company.

(g) "Cash Incentive Award" means the right to receive a cash payment to the extent Performance Goals are achieved as described in Section 10.

(h) "Cause" has the meaning given in a Participant's employment, retention, change of control, severance, Award agreement or similar agreement with the Company or any Affiliate, or if no such agreement is in effect or does not include a definition of "Cause," then (i) if the determination of Cause is being made prior to a Change of Control, Cause has the meaning given in the Company's employment policies as in effect at the time of the determination or (ii) if the determination of Cause is being made following a Change of Control, Cause has the meaning given in the Company's employment policies as in effect immediately prior to the Change of Control.

(i) "Change of Control" means, unless specified otherwise in an Award agreement, the first to occur of any of the following with respect to the Company or any upstream holding company (which, for purposes of this definition, shall be included in references to the Company):

(i) any Person (but excluding the Company, any trustee or other fiduciary holding securities under an employee benefit plan of the Company, or any corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company) is or becomes the Beneficial Owner, directly or indirectly, of securities of the Company representing thirty-five percent (35%) or more of the combined voting power of the Company's then outstanding securities; or

(ii) the Company is merged or consolidated with any other corporation or other entity, other than: (A) a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the combined voting power of the voting securities of the Company or such surviving entity outstanding immediately after such merger or consolidation; or (B) the Company engages in a merger or consolidation effected to implement a recapitalization of the Company (or similar transaction) in which no Person acquires thirty-five percent (35%) or more of the combined voting power of the Company's then outstanding securities. Notwithstanding the foregoing, a merger or consolidation involving the Company shall not be considered a "Change of Control" if the Company is the surviving corporation and the shares of Stock are not converted into or exchanged for stock or securities of any other corporation, cash or any other thing of value, unless Persons who Beneficially Owned the Shares outstanding immediately prior to such transaction Beneficially Own less than a majority of the outstanding voting securities of the Company immediately following the merger or consolidation;

(iii) the sale or disposition of all or substantially all of the Company's assets (in one transaction or a series of related transactions within any period of 24 consecutive months) other than a sale or distribution of all or substantially all of the Company's assets to any entity of which at least seventy-five percent (75%) of the combined voting power of the voting securities are owned by Persons in substantially the same proportions as their ownership of the Company immediately prior to such sale;

(iv) the Company dissolves and liquidates substantially all of its assets; or

(v) at any time after the Effective Date, the "Continuing Directors" cease to constitute a majority of the Board. For this purpose, a "Continuing Director" shall mean: (A) the individuals who, at the Effective Date, constitute the Board; and (B) any new Directors (other than Directors designated by a person who has entered into an agreement with the Company to effect a transaction described in clause (i), (ii), or (iii) of this definition) whose appointment to the Board or nomination for election by Company stockholders was approved by a vote of at least two-thirds of the then-serving Continuing Directors.

Notwithstanding the foregoing, in order to ensure compliance with Code Section 409A when applicable, the foregoing definition shall be deemed amended to the minimum extent necessary to comply with Code Section 409A.

(j) "Code" means the Internal Revenue Code of 1986, as amended. Any reference to a specific provision of the Code includes any successor provision and the regulations promulgated under such provision.

(k) "Committee" means the Compensation Committee of the Board, any successor committee thereto or such other committee of the Board that is designated by the Board with the same or similar authority. The Committee shall consist only of Non-Employee Directors (not fewer than two (2)) who, to the extent necessary for the Plan to comply with Rule 16b-3 promulgated under the Exchange Act, meet the requirements of a "non-employee director" as defined in Rule 16b-3.

(l) "Company" means Processa Pharmaceuticals, Inc., a Delaware corporation, or any successor thereto.

(m) "Director" means a member of the Board.

(n) "Dividend Equivalent Unit" means the right granted in connection with Restricted Stock Units or Performance Units, to receive a payment, in cash or Shares, equal to the cash dividends or other cash distributions paid with respect to a Share.

(o) "Effective Date" means the date the Company's stockholders approve this Plan.

(p) "Exchange Act" means the Securities Exchange Act of 1934, as amended. Any reference to a specific provision of the Exchange Act includes any successor provision and the regulations and rules promulgated under such provision.

(q) "Fair Market Value" means, unless otherwise determined by the Administrator, per Share on a particular date:

(i) if the Stock is listed on any established stock exchange or traded on any established market, the closing sales price of a Share as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Stock) on such date, as reported in such source as the Administrator deems reliable. Unless otherwise provided by the Administrator, if there is no closing sales price for the Stock on the date of determination, then the Fair Market Value will be the closing sales price (or closing bid if no sales were reported) on the last preceding date for which such quotation exists; or

(ii) if the Stock is not listed on any exchange or traded on any established market, then the Fair Market Value will be determined by the Administrator in compliance with Code Section 409A and, in the case of an incentive stock option, in compliance with Code Section 422.

Notwithstanding the foregoing, in the case of a sale of Shares, the actual sale price shall be the Fair Market Value of such Shares.

(r) "Good Reason" has the meaning given in a Participant's employment, retention, change of control, severance, Award agreement or similar agreement with the Company or any Affiliate, or if no such agreement is in effect or does not include a definition of "Good Reason," then the occurrence of any of the following events, without the Participant's advance written consent:

(i) a material reduction in the Participant's base salary or cash bonus opportunity;

(ii) a material adverse change in the Participant's duties, responsibilities, authority, title, status or reporting structure; or

(iii) a geographical relocation of the Participant's principal office location by more than fifty (50) miles that increases the distance of the Participant's commute.

A Participant's Termination shall not be considered to have occurred for "Good Reason" unless (A) within ninety (90) days following the occurrence of one of the events listed above the Participant provides written notice to the Company setting forth the specific event constituting Good Reason, (B) the Company fails to remedy the event constituting Good Reason within thirty (30) days following its receipt of the Participant's notice, and (C) the Participant actually terminates his or her employment with the Company and its Affiliates within thirty (30) days following the end of the Company's remedy period.

(s) "Non-Employee Director" means a Director who is not also an employee of the Company or its Subsidiaries.

(t) "Option" means the right to purchase Shares at a stated price for a specified period of time.

(u) "Participant" means an individual selected by the Administrator to receive an Award.

(v) "Performance Goals" means any objective or subjective goals selected by the Administrator to measure the level of performance and determine the payout or vesting of an Award. Performance Goals may include, but are not limited to, the performance of the Company or any one or more of its Subsidiaries, Affiliates or other business units with respect to the following measures (singly or in combination): net sales; cost of sales; revenue; gross income; net income; operating income; income from continuing operations; earnings (including before taxes, and/or interest and/or depreciation and amortization); earnings per share (including diluted earnings per share); price per share; cash flow; net cash provided by operating activities; net cash provided by operating activities less net cash used in investing activities; net operating profit; ratio of debt to debt plus equity; return on stockholder equity; return on capital; return on assets; operating working capital; average accounts receivable; economic value added; total stockholder return; customer satisfaction; operating margin; profit margin; sales performance; sales quota attainment; new sales; cross/integrated sales; customer engagement; internal revenue growth; client retention; the achievement of research, production, or regulatory approval milestones; achievement of merger or acquisition milestones (including but not limited to identification of acquisition candidates). Performance goals may also relate to a Participant's individual performance.

The Administrator reserves the right to adjust Performance Goals, or modify the manner of measuring or evaluating a Performance Goal, for any reason the Administrator determines is appropriate, including but not limited to: (i) by excluding the effects of charges for reorganizing and restructuring; discontinued operations; asset write-downs; gains or losses on the disposition of a business; or mergers, acquisitions or dispositions; and extraordinary, unusual and/or non-recurring items of gain or loss; (ii) excluding the costs of litigation, claims, judgments or settlements; (iii) excluding the effects of changes in laws or regulations affecting reported results, or changes in tax or accounting principles, regulations or law; and (iv) excluding any accruals of amounts related to payments under the Plan or any other compensation arrangement maintained by the Company or an Affiliate.

The inclusion in an Award agreement of specific adjustments or modifications shall not be deemed to preclude the Administrator from making other adjustments or modifications, in its discretion, as described herein, unless the Award agreement provides that the adjustments or modifications described in such agreement shall be the sole adjustments or modifications.

(w) "Performance Unit" means the right to receive a cash payment and/or Shares valued in relation to a unit that has a designated dollar value or the value of which is equal to the Fair Market Value of one or more Shares, to the extent Performance Goals are achieved (and the other requirements described in the Award agreement, if any, are met).

(x) "Person" has the meaning given in Section 3(a)(9) of the Exchange Act as modified and used in Section 13(d) and 14(d) thereof, or any group of Persons acting in concert.

(y) "Plan" means this Processa Pharmaceuticals 2019 Omnibus Incentive Plan, as it may be amended from time to time.

(z) "Restricted Stock" means Shares that are subject to a risk of forfeiture or restrictions on transfer, or both, which may lapse upon the achievement or partial achievement of Performance Goals or upon the completion of a period of service, or both.

(aa) "Restricted Stock Unit" means the right to receive a Share or a cash payment, the value of which is equal to the Fair Market Value of one Share.

(bb) "Section 16 Participants" means Participants who are subject to the provisions of Section 16 of the Exchange Act.

(cc) "Share" means a share of Stock.

(dd) "Stock" means the common stock of the Company, par value $0.0001 per share.

(ee) "Stock Appreciation Right" or "SAR" means the right to receive a cash payment, and/or Shares with a Fair Market Value, equal to the appreciation of the Fair Market Value of a Share during a specified period of time.

(ff) "Subsidiary" means any corporation, limited liability company or other limited liability entity in an unbroken chain of entities beginning with the Company if each of the entities (other than the last entities in the chain) owns the stock or equity interest possessing more than fifty percent (50%) of the total combined voting power of all classes of stock or other equity interests in one of the other entities in the chain.

(gg) "Termination" means cessation of employment by, or service to, the Company or an Affiliate for any reason. Unless determined otherwise by the Administrator, for purposes of the Plan and all Awards, the following rules shall apply:

(i) the date of a Participant's Termination shall be the date the Participant ceases to perform services for the Company or an Affiliate, without regard to whether the Participant thereafter continues to receive any compensatory payments or is paid salary in lieu of notice of Termination, and shall disregard any notice or severance period that the Participant may be entitled to receive;

(ii) a Participant who transfers employment between the Company and its Affiliates, or between Affiliates, will not be considered to have experienced a Termination;

(iii) a Participant who ceases to be a Non-Employee Director because he or she becomes an employee of the Company or an Affiliate shall not be considered to have ceased service as a Director with respect to any Award until such Participant's Termination with the Company and its Affiliates;

(iv) a Participant who ceases to be employed by the Company or an Affiliate and immediately thereafter becomes a Non-Employee Director, a non-employee director of an Affiliate, or a consultant to the Company or any Affiliate shall not be considered to have experienced a Termination until such Participant's service as a director of, or consultant to, the Company and its Affiliates has ceased; and

(v) a Participant employed by an Affiliate will be considered to have experienced a Termination when such entity ceases to be an Affiliate.

Notwithstanding the foregoing, for purposes of an Award that is subject to Code Section 409A, if a Participant's Termination triggers the payment of compensation under such Award, then the Participant will be deemed to have experienced a Termination upon their "separation from service" within the meaning of Code Section 409A. Notwithstanding any other provision in this Plan or an Award to the contrary, if any Participant is a "specified employee" within the meaning of Code Section 409A as of the date of their "separation from service" within the meaning of Code Section 409A, then, to the extent required by Code Section 409A, any payment made to the Participant on account of such separation from service shall not be made before a date that is six months after the date of the separation from service.

**3. Administration**.

(a) *Administration*. In addition to the authority specifically granted to the Administrator in this Plan, the Administrator has full discretionary authority to administer this Plan, including but not limited to the authority to: (i) interpret the provisions of this Plan or any agreement covering an Award; (ii) prescribe, amend and rescind rules and regulations relating to this Plan; (iii) correct any defect, supply any omission, or reconcile any inconsistency in the Plan, any Award or any agreement covering an Award in the manner and to the extent it deems desirable to carry this Plan or such Award into effect; and (iv) make all other determinations necessary or advisable for the administration of this Plan. All Administrator determinations shall be made in the sole discretion of the Administrator and are final and binding on all interested parties.

(b) *Delegation to Other Committees or Officers.* To the extent applicable law permits, the Board may delegate to another committee of the Board, or the Committee may delegate to either a subcommittee consisting of one or more Committee members or to one or more officers of the Company, any or all of their respective authority and responsibility as an Administrator of the Plan; *provided* that no such delegation is permitted with respect to Stock-based Awards made to Section 16 Participants at the time any such delegated authority or responsibility is exercised unless the delegation is to another committee of the Board or sub-committee of the Committee consisting entirely of Non-Employee Directors who also qualify as "non-employee directors" within the meaning of Rule 16b-3 of the Exchange Act. If the Board or the Committee has made such a delegation, then all references to the Administrator in this Plan include such other committee or one or more officers to the extent of such delegation.

(c) *No Liability; Indemnification.* No member of the Board or the Committee, and no officer or member of any other committee to whom a delegation under Section 3(b) has been made, will be liable for any act done, or determination made, by the individual in good faith with respect to the Plan or any Award. The Company will indemnify and hold harmless each such individual as to any acts or omissions, or determinations made, in each case done or made in good faith, with respect to this Plan or any Award to the maximum extent that the law and the Company's By-Laws permit.

**4. Eligibility**. The Administrator may designate any of the following as a Participant from time to time, to the extent of the Administrator's authority: any officer or other employee of the Company or its Affiliates; any individual that the Company or an Affiliate has engaged to become an officer or employee; any consultant or advisor who provides services to the Company or its Affiliates; or any Director, including a Non-Employee Director. The Administrator's designation of, or granting of an Award to, a Participant will not require the Administrator to designate such individual as a Participant or grant an Award to such individual at any future time. The Administrator's granting of a particular type of Award to a Participant will not require the Administrator to grant any other type of Award to such individual.

**5. Types of Awards**. Subject to the terms of this Plan, the Administrator may grant any type of Award to any Participant it selects, but only employees of the Company or a Subsidiary may receive grants of incentive stock options within the meaning of Code Section 422. Awards may be granted alone or in addition to, in tandem with, or (subject to the prohibition on repricing set forth in Section 14(e)) in substitution for any other Award (or any other award granted under another plan of the Company or any Affiliate, including the plan of an acquired entity).

**6. Shares Reserved under this Plan**.

(a) *Plan Reserve*. Subject to adjustment as provided in Section 16, an aggregate of 3,500,000 Shares are reserved for issuance under this Plan, all of which may be issued pursuant to the exercise of incentive stock options. The Shares reserved for issuance may be either authorized and unissued Shares or Shares reacquired at any time and now or hereafter held as treasury stock.

(b) *Depletion of Reserve.* The aggregate number of Shares reserved under Section 6(a) shall be depleted on the date of grant of an Award by the maximum number of Shares, if any, that may become payable with respect to such Award. For the sake of clarity, an Award that may be settled solely in cash shall not cause any depletion of the Plan's Share reserve at the time such Award is granted.

(c) ***Replenishment of Reserve***. If (i) an Award lapses, expires, terminates or is cancelled without the issuance of Shares under the Award (whether due currently or on a deferred basis) or is settled in cash, (ii) it is determined during or at the conclusion of the term of an Award that all or some portion of the Shares with respect to which the Award was granted will not be issuable on the basis that the conditions for such issuance will not be satisfied, (iii) Shares are forfeited under an Award, or (iv) Shares are issued under any Award and the Company subsequently reacquires them pursuant to rights reserved upon the issuance of the Shares, then such Shares shall be recredited to the Plan's reserve and may again be used for new Awards under this Plan, but Shares recredited to the Plan's reserve pursuant to clause (iv) may not be issued pursuant to incentive stock options. Notwithstanding the foregoing, in no event shall the following Shares be recredited to the Plan's reserve: (A) Shares purchased by the Company using proceeds from Option exercises; (B) Shares tendered or withheld in payment of the exercise price of an Option or as a result of the net settlement of an outstanding Stock Appreciation Right; or (C) Shares tendered or withheld to satisfy federal, state or local tax withholding obligations.

**7. Options**. Subject to the terms of this Plan, the Administrator will determine all terms and conditions of each Option, including but not limited to: (a) whether the Option is an "incentive stock option" which meets the requirements of Code Section 422, or a "nonqualified stock option" which does not meet the requirements of Code Section 422; (b) the grant date, which may not be any day prior to the date that the Administrator approves the grant; (c) the number of Shares subject to the Option; (d) the exercise price, which may never be less than the Fair Market Value of the Shares subject to the Option as determined on the date of grant; (e) the terms and conditions of vesting and exercise; (f) the term, except that an Option must terminate no later than ten (10) years after the date of grant; and (g) the manner of payment of the exercise price. In all other respects, the terms of any incentive stock option should comply with the provisions of Code Section 422 except to the extent the Administrator determines otherwise. If an Option that is intended to be an incentive stock option fails to meet the requirements thereof, the Option shall automatically be treated as a nonqualified stock option to the extent of such failure. To the extent permitted by the Administrator, and subject to such procedures as the Administrator may specify, the payment of the exercise price of Options may be made by (w) delivery of cash or other Shares or other securities of the Company (including by attestation) having a then Fair Market Value equal to the purchase price of such Shares, (x) by delivery to the Company or its designated agent of an executed irrevocable option exercise form together with irrevocable instructions to a broker-dealer to sell or margin a sufficient portion of the Shares and deliver the sale or margin loan proceeds directly to the Company to pay for the exercise price, (y) by surrendering the right to receive Shares otherwise deliverable to the Participant upon exercise of the Award having a Fair Market Value at the time of exercise equal to the total exercise price, or (z) by any combination of (w), (x) and/or (y). Except to the extent otherwise set forth in an Award agreement, a Participant shall have no rights as a holder of Stock as a result of the grant of an Option until the Option is exercised, the exercise price and applicable withholding taxes are paid and the Shares subject to the Option are issued thereunder.

**8. Stock Appreciation Rights**. Subject to the terms of this Plan, the Administrator will determine all terms and conditions of each SAR, including but not limited to: (a) the grant date, which may not be any day prior to the date that the Administrator approves the grant; (b) the number of Shares to which the SAR relates; (c) the grant price, which may never be less than the Fair Market Value of the Shares subject to the SAR as determined on the date of grant; (d) the terms and conditions of exercise or maturity, including vesting; (e) the term, *provided* that an SAR must terminate no later than ten (10) years after the date of grant; and (f) whether the SAR will be settled in cash, Shares or a combination thereof.

**9. Performance and Stock Awards**. Subject to the terms of this Plan, the Administrator will determine all terms and conditions of each award of Shares, Restricted Stock, Restricted Stock Units or Performance Units, including but not limited to: (a) the number of Shares and/or units to which such Award relates; (b) whether, as a condition for the Participant to realize all or a portion of the benefit provided under the Award, one or more Performance Goals must be achieved during such period as the Administrator specifies; (c) the length of the vesting and/or performance period and, if different, the date on which payment of the benefit provided under the Award will be made; (d) with respect to Performance Units, whether to measure the value of each unit in relation to a designated dollar value or the Fair Market Value of one or more Shares; and (e) with respect to Restricted Stock Units and Performance Units, whether to settle such Awards in cash, in Shares (including Restricted Stock), or in a combination of cash and Shares.

**10. Cash Incentive Awards**. Subject to the terms of this Plan, the Administrator will determine all terms and conditions of a Cash Incentive Award, including but not limited to the Performance Goals, performance period, the potential amount payable, and the timing of payment.

**11. Dividends and Dividend Equivalent Units**.

(a) Subject to the terms of this Plan, the Administrator will determine all terms and conditions of each award of Dividend Equivalent Units, including but not limited to whether: (i) payment of the Award will be made concurrently with dividend payments or credited to an account for the Participant which provides for the deferral of such amounts until a stated time; (ii) the Award will be settled in cash or Shares; and (iii) as a condition for the Participant to realize all or a portion of the benefit provided under the Award, the same vesting or performance requirements applicable to the related Award must be achieved.

(b) Notwithstanding anything in the Plan or an Award to the contrary, no dividends or Dividend Equivalent Units may be paid with respect to an Award that is subject to Performance Goals unless and until such Performance Goals have been satisfied.

**12. Other Stock-Based Awards**. Subject to the terms of this Plan, the Administrator may grant to a Participant other Stock-based Awards, including shares of unrestricted Stock, as replacement for other compensation to which the Participant is entitled, such as in payment of director fees, in lieu of cash compensation, in exchange for cancellation of a compensation right, or as a bonus.

**13. Transferability**. Awards are not transferable other than by will or the laws of descent and distribution, unless and to the extent the Administrator allows a Participant to: (a) designate in writing a beneficiary to exercise the Award or receive payment under the Award after the Participant's death; (b) transfer an Award to the former spouse of the Participant as required by a domestic relations order incident to a divorce; or (c) otherwise transfer an Award; *provided, however*, that with respect to clause (c) above the Participant may not receive consideration for transferring the Award.

**14. Termination and Amendment of Plan; Amendment, Modification or Cancellation of Awards**

(a) *Term of Plan*. Unless the Board earlier terminates this Plan pursuant to Section 14(b), this Plan will terminate when all Shares reserved for issuance have been issued. If the term of this Plan extends beyond ten (10) years from the Effective Date, no incentive stock options may be granted after such time unless the stockholders of the Company have approved an extension of this Plan for such purpose.

(b) *Termination and Amendment*. The Board or the Administrator may amend, alter, suspend, discontinue or terminate this Plan at any time, subject to the following limitations:

(i) the Board must approve any amendment of this Plan to the extent the Company determines such approval is required by: (A) prior action of the Board, (B) applicable corporate law, or (C) any other applicable law; and

(ii) stockholders must approve any amendment of this Plan to the extent the Company determines such approval is required by: (A) Section 16 of the Exchange Act, (B) the Code, (C) the listing requirements of any principal securities exchange or market on which the Shares are then traded, or (D) any other applicable law. Such amendments include, but are not limited to, an amendment to materially increase the number of Shares reserved under Section 6(a) (except as permitted by Section 16) or an amendment that would diminish the protections afforded by Section 14(e).

(c) *Amendment, Modification, Cancellation and Disgorgement of Awards.*

(i) Except as provided in Section 14(e) and subject to the requirements of this Plan, the Administrator may modify, amend or cancel any Award, or waive any restrictions or conditions applicable to any Award or the exercise of the Award; *provided* that, except as otherwise provided in the Plan or the Award agreement, any modification or amendment that materially diminishes the rights of the Participant, or the cancellation of an Award, shall be effective only if agreed to by the Participant or any other person(s) as may then have an interest in such Award, but the Administrator need not obtain Participant (or other interested party) consent for the modification, amendment or cancellation of an Award pursuant to the provisions of subsection (ii) or Section 16 or as follows: (A) to the extent the Administrator deems such action necessary to comply with any applicable law or the listing requirements of any principal securities exchange or market on which the Shares are then traded; (B) to the extent the Administrator deems necessary to preserve favorable accounting or tax treatment of any Award for the Company; or (C) to the extent the Administrator determines that such action does not materially and adversely affect the value of an Award or that such action is in the best interest of the affected Participant (or any other person(s) as may then have an interest in the Award). Notwithstanding the foregoing, unless determined otherwise by the Administrator, any such amendment shall be made in a manner that will enable an Award intended to be exempt from Code Section 409A to continue to be so exempt, or to enable an Award intended to comply with Code Section 409A to continue to so comply.

(ii) Notwithstanding anything to the contrary in an Award agreement, the Administrator shall have full power and authority to terminate or cause the Participant to forfeit the Award, and require the Participant to disgorge to the Company any gains attributable to the Award, if the Participant engages in any action constituting, as determined by the Administrator in its discretion, Cause for Termination, or a breach of any Award agreement or any other agreement between the Participant and the Company or an Affiliate concerning noncompetition, nonsolicitation, confidentiality, trade secrets, intellectual property, nondisparagement or similar obligations.

(iii) Any Awards granted pursuant to this Plan, and any Stock issued or cash paid pursuant to an Award, shall be subject to any recoupment or clawback policy that is adopted by, or any recoupment or similar requirement otherwise made applicable by law, regulation or listing standards to, the Company from time to time.

(d) *Survival of Authority and Awards.* Notwithstanding the foregoing, the authority of the Board and the Administrator under this Section 14 and to otherwise administer the Plan with respect to then-outstanding Awards will extend beyond the date of this Plan's termination. In addition, termination of this Plan will not affect the rights of Participants with respect to Awards previously granted to them, and all unexpired Awards will continue in force and effect after termination of this Plan except as they may lapse or be terminated by their own terms and conditions.

(e) *Repricing and Backdating Prohibited.* Notwithstanding anything in this Plan to the contrary, and except for the adjustments provided for in Section 16, neither the Administrator nor any other person may (i) amend the terms of outstanding Options or SARs to reduce the exercise or grant price of such outstanding Options or SARs; (ii) cancel outstanding Options or SARs in exchange for Options or SARs with an exercise or grant price that is less than the exercise or grant price of the original Options or SARs; or (iii) cancel outstanding Options or SARs with an exercise or grant price above the current Fair Market Value of a Share in exchange for cash or other securities. In addition, the Administrator may not make a grant of an Option or SAR with a grant date that is effective prior to the date the Administrator takes action to approve such Award.

(f) *Foreign Participation.* To assure the viability of Awards granted to Participants employed or residing in foreign countries, the Administrator may provide for such special terms as it may consider necessary or appropriate to accommodate differences in local law, tax policy, accounting or custom. Moreover, the Administrator may approve such supplements to, or amendments, restatements or alternative versions of, this Plan as it determines is necessary or appropriate for such purposes. Any such amendment, restatement or alternative versions that the Administrator approves for purposes of using this Plan in a foreign country will not affect the terms of this Plan for any other country. In addition, all such supplements, amendments, restatements or alternative versions must comply with the provisions of Section 14(b)(ii).

**15. Taxes**

(a) *Withholding.* In the event the Company or one of its Affiliates is required to withhold any Federal, state or local taxes or other amounts in respect of any income recognized by a Participant as a result of the grant, vesting, payment or settlement of an Award or disposition of any Shares acquired under an Award, the Company may satisfy such obligation by:

(i) if cash is payable under an Award, deducting (or requiring an Affiliate to deduct) from such cash payment the amount needed to satisfy such obligation;

(ii) if Shares are issuable under an Award, then to the extent previously approved by the Administrator (which approval may be set forth in an Award agreement or in administrative rules) (A) withholding Shares having a Fair Market Value equal to such obligations; or (B) allowing the Participant to elect to (1) have the Company or its Affiliate withhold Shares otherwise issuable under the Award, (2) tender back Shares received in connection with such Award or (3) deliver other previously owned Shares, in each case having a Fair Market Value equal to the amount to be withheld; provided that the amount to be withheld under this clause (ii) may not exceed the total maximum statutory tax withholding obligations associated with the transaction to the extent needed for the Company and its Affiliates to avoid an accounting charge. If an election is provided, the election must be made on or before the date as of which the amount of tax to be withheld is determined and otherwise as the Administrator requires; or

(iii) deducting (or requiring an Affiliate to deduct) the amount needed to satisfy such obligation from any wages or other payments owed to the Participant, requiring such Participant to pay to the Company or its Affiliate, in cash, promptly on demand, or make other arrangements satisfactory to the Company or its Affiliate regarding the payment to the Company or its Affiliate of the amount needed to satisfy such obligation.

(b) *No Guarantee of Tax Treatment.* Notwithstanding any provisions of this Plan to the contrary, the Company does not guarantee to any Participant or any other Person with an interest in an Award that (i) any Award intended to be exempt from Code Section 409A shall be so exempt, (ii) any Award intended to comply with Code Section 409A or Code Section 422 shall so comply, or (iii) any Award shall otherwise receive a specific tax treatment under any other applicable tax law, nor in any such case will the Company or any Affiliate be required to indemnify, defend or hold harmless any individual with respect to the tax consequences of any Award.

**16. Adjustment and Change of Control Provisions**.

(a) *Adjustment of Shares.* If (i) the Company shall at any time be involved in a merger or other transaction in which the Shares are changed or exchanged; (ii) the Company shall subdivide or combine the Shares or the Company shall declare a dividend payable in Shares, other securities (other than stock purchase rights issued pursuant to a stockholder rights agreement) or other property; (iii) the Company shall effect a cash dividend the amount of which, on a per Share basis, exceeds ten percent (10%) of the Fair Market Value of a Share at the time the dividend is declared, or the Company shall effect any other dividend or other distribution on the Shares in the form of cash, or a repurchase of Shares, that the Board determines by resolution is special or extraordinary in nature or that is in connection with a transaction that the Company characterizes publicly as a recapitalization or reorganization involving the Shares; or (iv) any other event shall occur, which, in the case of this clause (iv), in the judgment of the Administrator necessitates an adjustment to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under this Plan, then the Administrator shall, in such manner as it may deem equitable to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under this Plan, adjust any or all of: (A) the number and type of Shares subject to this Plan (as described in Section 6(a)) and which may after the event be made the subject of Awards; (B) the number and type of Shares subject to outstanding Awards; (C) the grant, purchase, or exercise price with respect to any Award; and (D) the Performance Goals of an Award. In any such case, the Administrator may also (or in lieu of the foregoing) make provision for a cash payment to the holder of an outstanding Award in exchange for the cancellation of all or a portion of the Award (without the consent of the holder of an Award) in an amount determined by the Administrator effective at such time as the Administrator specifies (which may be the time such transaction or event is effective). However, in each case, with respect to Awards of incentive stock options, no such adjustment may be authorized to the extent that such authority would cause this Plan to violate Code Section 422(b). Further, the number of Shares subject to any Award payable or denominated in Shares must always be a whole number. In any event, previously granted Options or SARs are subject to only such adjustments as are necessary to maintain the relative proportionate interest the Options and SARs represented immediately prior to any such event and to preserve, without exceeding, the value of such Options or SARs.

Without limitation, in the event of any reorganization, merger, consolidation, combination or other similar corporate transaction or event, whether or not constituting a Change of Control (other than any such transaction in which the Company is the continuing corporation and in which the outstanding Stock is not being converted into or exchanged for different securities, cash or other property, or any combination thereof), the Administrator may substitute, on an equitable basis as the Administrator determines, for each Share then subject to an Award and the Shares subject to this Plan (if the Plan will continue in effect), the number and kind of shares of stock, other securities, cash or other property to which holders of Stock are or will be entitled in respect of each Share pursuant to the transaction.

Notwithstanding the foregoing, in the case of a stock dividend (other than a stock dividend declared in lieu of an ordinary cash dividend) or subdivision or combination of the Shares (including a reverse stock split), if no action is taken by the Administrator, adjustments contemplated by this subsection that are proportionate shall nevertheless automatically be made as of the date of such stock dividend or subdivision or combination of the Shares.

(b) *Issuance or Assumption*. Notwithstanding any other provision of this Plan, and without affecting the number of Shares otherwise reserved or available under this Plan, in connection with any merger, consolidation, acquisition of property or stock, or reorganization, the Administrator may authorize the issuance or assumption of awards under this Plan upon such terms and conditions as it may deem appropriate.

(c) *Effect of a Change of Control.* To the extent a Participant has in effect an employment, retention, change of control, severance or similar agreement with the Company or any Affiliate that discusses the effect of a Change of Control on the Participant's Awards, such agreement shall control. In all other cases, unless provided otherwise in an Award agreement or by the Administrator prior to the date of the Change of Control, in the event of a Change of Control:

(i) If the purchaser, successor or surviving entity (or parent thereof) so agrees, some or all outstanding Awards shall be assumed, or replaced with the same type of award with similar terms and conditions, by the purchaser, successor or surviving entity (or parent thereof) in the Change of Control transaction. If applicable, each Award which is assumed by the purchaser, successor or surviving entity (or parent thereof) shall be appropriately adjusted, immediately after such Change of Control, to apply to the number and class of securities which would have been issuable to the Participant upon the consummation of such Change of Control had the Award been exercised, vested or earned immediately prior to such Change of Control, and other appropriate adjustments in the terms and conditions of the Award shall be made. Upon the Participant's Termination by the successor or surviving entity without Cause, or by the Participant for Good Reason, in either case within twenty-four (24) months following the Change of Control, all of the Participant's Awards that are in effect as of the date of such Termination shall be vested in full or deemed earned in full (assuming target performance goals provided under such Award were met, if applicable) effective on the date of such Termination.

(ii) To the extent the purchaser, successor or surviving entity (or parent thereof) in the Change of Control transaction does not assume the Awards or issue replacement awards as provided in clause (i), then immediately prior to the date of the Change of Control:

(A) each Option or SAR that is then held by a Participant who is employed by or in the service of the Company or an Affiliate shall become immediately and fully vested, and, unless otherwise determined by the Board or Committee, all Options and SARs shall be cancelled on the date of the Change of Control in exchange for a cash payment equal to the excess of the Change of Control Price of the Shares covered by the Option or SAR that is so cancelled over the purchase or grant price of such Shares under the Award (or for no payment, if there is no such excess);

(B) Restricted Stock, Restricted Stock Units (and any related Dividend Equivalent Units) and Shares that are not then vested shall vest;

(C) all Performance Units (and any related Dividend Equivalent Units) that are earned but not yet paid shall be paid in an amount equal to the value of the Performance Unit, and all Performance Units for which the performance period has not expired shall be cancelled in exchange for a payment equal to the product of: (1) the value of the Performance Units that would have been earned if the Performance Goals (as measured at the time of the Change of Control) were to continue to be achieved at the same rate through the end of the performance period, or if higher, assuming the target Performance Goals had been met at the time of such Change of Control; and (2) a fraction, the numerator of which is the number of whole months that have elapsed from the beginning of the performance period to which the Award is subject to the date of the Change of Control and the denominator of which is the number of whole months in the performance period;

(D) all Cash Incentive Awards that are earned but not yet paid shall be paid, and all Cash Incentive Awards that are not yet earned shall be cancelled in exchange for a cash payment in an amount determined by taking the product of: (1) the amount that would have been due under such Award(s) if the Performance Goals (as measured at the time of the Change of Control) were to continue to be achieved at the same rate through the end of the performance period, or if higher, assuming the target Performance Goals had been met at the time of such Change of Control; and (2) a fraction, the numerator of which is the number of whole months that have elapsed from the beginning of the performance period to which the Award is subject to the date of the Change of Control and the denominator of which is the number of whole months in the performance period; and

(E) all other Awards not described above that are not vested shall vest and if an amount is payable under such vested Award, such amount shall be paid in cash based on the value of the Award.

(d) If the value of an Award is based on the Fair Market Value of a Share, Fair Market Value shall be deemed to mean the per share Change of Control Price. The Change of Control Price shall equal the price paid or deemed paid per Share in the Change of Control transaction as determined by the Administrator. Notwithstanding anything to the contrary in this Section 16(d), the terms of any Awards that are subject to Code Section 409A shall govern the treatment of such Awards upon a Change of Control, and the terms of this Section 16(d) shall not apply, to the extent required for such Awards to remain compliant with Code Section 409A, as applicable.

(e) *Application of Limits on Payments.* Except to the extent the Participant has in effect an employment or similar agreement with the Company or any Affiliate or is subject to a policy that provides for a more favorable result to the Participant upon a Change of Control, in the event that the Company's legal counsel or accountants determine that any payment, benefit or transfer by the Company under this Plan or any other plan, agreement, or arrangement to or for the benefit of the Participant (in the aggregate, the "Total Payments") to be subject to the tax ("Excise Tax") imposed by Code Section 4999 but for this Section 16(e), then, notwithstanding any other provision of this Plan to the contrary, the Total Payments shall be delivered either (i) in full or (ii) in an amount such that the value of the aggregate Total Payments that the Participant is entitled to receive shall be One Dollar ($1.00) less than the maximum amount that the Participant may receive without being subject to the Excise Tax, whichever of (i) or (ii) results in the receipt by the Participant of the greatest benefit on an after-tax basis (taking into account applicable federal, state and local income taxes and the Excise Tax). In the event that (ii) results in a greater after-tax benefit to the Participants, payments or benefits included in the Total Payments shall be reduced or eliminated by applying the following principles, in order: (A) the payment or benefit with the higher ratio of the parachute payment value to present economic value (determined using reasonable actuarial assumptions) shall be reduced or eliminated before a payment or benefit with a lower ratio; (B) the payment or benefit with the later possible payment date shall be reduced or eliminated before a payment or benefit with an earlier payment date; and (C) cash payments shall be reduced prior to non-cash benefits; provided that if the foregoing order of reduction or elimination would violate Code Section 409A, then the reduction shall be made pro rata among the payments or benefits included in the Total Payments (on the basis of the relative present value of the parachute payments).

**17. Miscellaneous.**

(a) *Other Terms and Conditions.* The Administrator may provide in any Award agreement such other provisions (whether or not applicable to the Award granted to any other Participant) as the Administrator determines appropriate to the extent not otherwise prohibited by the terms of the Plan. No provision in an Award agreement shall limit the Administrator's discretion hereunder unless such provision specifically so provides for such limitation.

(b) *Employment and Service*. The issuance of an Award shall not confer upon a Participant any right with respect to continued employment or service with the Company or any Affiliate, or the right to continue as a Director.

(c) *No Fractional Shares.* No fractional Shares or other securities may be issued or delivered pursuant to this Plan. Unless otherwise determined by the Administrator or otherwise provided in any Award agreement, all fractional Shares that would otherwise be issuable under the Plan shall be canceled for no consideration.

(d) *Unfunded Plan; Awards Not Includable for Benefits Purposes.* This Plan is unfunded and does not create, and should not be construed to create, a trust or separate fund with respect to this Plan's benefits. This Plan does not establish any fiduciary relationship between the Company and any Participant or other person. To the extent any person holds any rights by virtue of an Award granted under this Plan, such rights are no greater than the rights of the Company's general unsecured creditors. Income recognized by a Participant pursuant to an Award shall not be included in the determination of benefits under any employee pension benefit plan (as such term is defined in Section 3(2) of the Employee Retirement Income Security Act of 1974, as amended) or group insurance or other benefit plans applicable to the Participant which are maintained by the Company or any Affiliate, except as may be provided under the terms of such plans or determined by resolution of the Board.

(e) *Requirements of Law and Securities Exchange.* The granting of Awards and the issuance of Shares in connection with an Award are subject to all applicable laws, rules and regulations and to such approvals by any governmental agencies or national securities exchanges as may be required. Notwithstanding any other provision of this Plan or any award agreement, the Company has no liability to deliver any Shares under this Plan or make any payment unless such delivery or payment would comply with all applicable laws and the applicable requirements of any securities exchange or similar entity, and unless and until the Participant has taken all actions required by the Company in connection therewith. The Company may impose such restrictions on any Shares issued under the Plan as the Company determines necessary or desirable to comply with all applicable laws, rules and regulations or the requirements of any national securities exchanges.

(f) *Code Section 409A.* Any Award granted under this Plan shall be provided or made in such manner and at such time as to either make the Award exempt from, or comply with, the provisions of Code Section 409A, and the provisions of Code Section 409A are incorporated into this Plan to the extent necessary for any Award that is subject to Code Section 409A to comply therewith.

(g) *Governing Law; Venue*. This Plan, and all agreements under this Plan, will be construed in accordance with and governed by the laws of the State of Maryland, without reference to any conflict of law principles. Any legal action or proceeding with respect to this Plan, any Award or any award agreement, or for recognition and enforcement of any judgment in respect of this Plan, any Award or any award agreement, may only be brought and determined in a court sitting in the County of Howard in the State of Maryland.

(h) *Limitations on Actions.* Any legal action or proceeding with respect to this Plan, any Award or any award agreement, must be brought within one year (365 days) after the day the complaining party first knew or should have known of the events giving rise to the complaint.

(i) *Construction*. Whenever any words are used herein in the masculine, they shall be construed as though they were used in the feminine in all cases where they would so apply; and wherever any words are used in the singular or plural, they shall be construed as though they were used in the plural or singular, as the case may be, in all cases where they would so apply. Titles of sections are for general information only, and this Plan is not to be construed with reference to such titles.

(j) *Severability*. If any provision of this Plan or any award agreement or any Award (a) is or becomes or is deemed to be invalid, illegal or unenforceable in any jurisdiction, or as to any person or Award, or (b) would cause this Plan, any award agreement or any Award to violate or be disqualified under any law the Administrator deems applicable, then such provision should be construed or deemed amended to conform to applicable laws, or if it cannot be so construed or deemed amended without, in the determination of the Administrator, materially altering the intent of this Plan, award agreement or Award, then such provision should be stricken as to such jurisdiction, person or Award, and the remainder of this Plan, such award agreement and such Award will remain in full force and effect.

# LINE OF CREDIT AGREEMENT

This LINE OF CREDIT AGREEMENT is made this 20th day of September 2019 ("**Line of Credit Agreement**"), by and among **Processa Pharmaceuticals, Inc., (Borrower)** a Delaware Corporation and **DKBK ENTERPRISE, LLC**, (**Lender**) a Delaware Corporation. A line of credit is hereby established in the amount of Seven Hundred Thousand Dollars ($700,000) for the benefit of the Borrower; provided however, that the lender may terminate the Borrower's privilege to request advances hereunder or lower said amount. This line of credit will be subject to the following terms and conditions.

1. The Lender hereby establishes a revolving line of credit in Borrower's favor in the amount of Seven Hundred Thousand Dollars ($700,000), provided however, that no provision of this agreement shall be deemed to require the lender to advance any sum of money at any time. At any time that the Borrower desires the Lender to advance any sum of money hereunder, the Borrower may request the same, and the Lender for any or no reason may deny such request.

2. The loan made hereunder will bear interest at the rate as determined pursuant to a certain promissory note (the "Note"), a copy of which is attached hereto and made a part of hereof as Exhibit A.

3. The occurrence of one or more of the following (herein called a "**Default**" or an "**Event of Default**"" shall constitute a default by the Borrower hereunder, and under the Note, in addition to but not in limitation of any events which would cause a default under the terms and conditions of the note:

(a) Default in the payment or performance of any liability or obligation of Borrower to the Lender or any covenant or liability contained or referred to herein, in the Note, or in any other note, instrument, document or agreement evidencing any obligation.

(b) Any representation or warranty of the Borrower in connection with this Line of Credit Agreement or any document executed in accordance herewith, or in pursuance hereof, shall be false on the date on which made.

(c) The failure of Borrower to pay, when due, any amount due under the Note or the failure by the Borrower to pay, when due, any obligation of Borrower to Lender.

(d) Borrower's insolvency, appointment of a receiver for all or part of Borrower's property, the making of any assignment by Borrower for the benefit of creditors or commencement of any proceeding under any bankruptcy or insolvency laws by or against Borrower or upon the issuing of any writ of attachment by trustee process or otherwise or a restraining order or injunction affecting any of the Borrower's property; provider, however, if any such proceeding is commenced against the Borrower, the Borrower shall have thirty (30) days in which to cause such proceeding to be dismissed.

(e) The insolvency of any guarantor of this Line of Credit Agreement and/or the Note or any obligation of any Borrower to the Lender.

(f) The death, dissolution, termination of existence, declared insolvency; or failure in the business of the Borrower of any guarantor of this Line of Credit or the Note.

(g) The admission in writing of a Borrower's insolvency or inability to pay debts generally as they become due, or upon any deterioration of the financial condition of the Borrower, any endorser or guarantor of this Line of Credit Agreement or the Note, which results in the Lender deeming itself, in good faith, insecure.

(h) Ninety (90) days after DEMAND is made pursuant to the Note, unless the Borrower has satisfied the Note in full.

Any such event caused by, or occurring with regard to, any one or more persons constituting the "Borrower" shall be deemed to be so caused by (or occurring with regard to) the "Borrower".

If any Event of Default occurs, all obligations outstanding from the Borrower to the lender, including obligations pursuant to this Line of Credit Agreement and/or the Note, shall immediately become due and payable without demand, presentment, protest or other notice of any kind, all of which are hereby expressly waived. In the event of such Event of Default, the Lender may proceed to enforce the payment of all obligations of Borrower to Lender and to exercise any and all rights and remedies afforded to Lender by law or under the terms of this Line of Credit Agreement or otherwise.

4. Borrower agrees to furnish to the Lender, upon demand, but not more than semi-annually, so long as indebtedness under the Line of Credit Agreement and the Note remains unpaid, a certified financial statement prepared by an independent accountant setting forth in reasonable detail the assets, liabilities, and net worth of the Borrower and certified to under oath by an officer of the Borrower, Such financial statements shall be sent to the Lender at its address listed above and shall be the sole and cost and expense of the Borrower.

5. This Line of Credit is supplementary to each and every other agreement between Borrower and Lender and shall not be construed as to limit or otherwise derogate from any of the rights or remedies of Lender of any of the liabilities, obligations or undertakings of Borrower under any such agreement, nor shall any contemporaneous or subsequent agreement Borrower and Lender be construed to limit or otherwise derogate from any of the rights or remedies of Lender or any of the liabilities, obligations or undertakings of Borrower hereunder unless such other agreement specifically refers to this Line of Credit Agreement and expressly so provides.

6. This Line of Credit Agreement and the convents and agreements herein contained shall continue in full force and effect until all such obligations, liabilities and undertakings have been paid or otherwise satisfied in full. No delay or omission on the part of Lender in exercising any right hereunder shall operate as a waiver of such rights or any other right and waiver on any one or more occasions shall not be construed as to bar to or waiver of any right or remedy of Lender on any future occasion. This Line of Credit Agreement is intended to take effect as a sealed instrument, shall be governed by and construed in accordance with the laws of the Delaware, shall be binding upon Borrower's legal representatives, successors and assigns, and shall inure to the benefit of Lender's successors and assigns.

7. The Borrower does hereby certify that any all necessary resolutions that may be required to effectuate and validate the terms of this Line of Credit Agreement and the Note, have been duly made and adopted by the Borrower.

[The remainder of this page intentionally left blank; signature page follows]

IN WITNESS WHEREOF, the undersigned have caused this Agreement to be duly executed as of the date first above written.

**BORROWER:**

PROCESSA PHARMACEUTICALS, INC.

DocuSigned by:
By: Wendy Guy
Name: Wendy Guy
Title: Chief Administrative Officer

**LENDER:**

DKBK ENTERPRISE, LLC

DocuSigned by:
By: David Young
2CC6C188EE8A407...
Name: David Young
Title: Managing Member

## EXHIBIT A

## PROMISSORY NOTE

FOR EVERY DOLLAR WITHDRAWN, the DEBTOR promises to pay to the CREDITOR, or its permitted assigns, all money borrowed under this Line of Credit Agreement at an 8% annual interest rate prorated monthly from the date money has been borrowed to the money has been paid back The DEBTOR may borrow any portion or pay back any portion during the life of the Line of Credit.

The CREDITOR also has the right to convert all or any portion of the debt and interest into Processa common shares at the terms defined in the July 2019 Bridge Subscription Agreement.

There will be no cost if the Line of Credit is not used.

# LINE OF CREDIT AGREEMENT

This LINE OF CREDIT AGREEMENT is made this 20th day of September 2019 ("**Line of Credit Agreement**"), by and among **Processa Pharmaceuticals, Inc., (Borrower)** a Delaware Corporation and **CorLyst, LLC**, (**Lender**) a Delaware Corporation. A line of credit is hereby established in the amount of Seven Hundred Thousand Dollars ($700,000) for the benefit of the Borrower; provided however, that the lender may terminate the Borrower's privilege to request advances hereunder or lower said amount. This line of credit will be subject to the following terms and conditions.

1. The Lender hereby establishes a revolving line of credit in Borrower's favor in the amount of Seven Hundred Thousand Dollars ($700,000), provided however, that no provision of this agreement shall be deemed to require the lender to advance any sum of money at any time. At any time that the Borrower desires the Lender to advance any sum of money hereunder, the Borrower may request the same, and the Lender for any or no reason may deny such request.

2. The loan made hereunder will bear interest at the rate as determined pursuant to a certain promissory note (the "Note"), a copy of which is attached hereto and made a part of hereof as Exhibit A.

3. The occurrence of one or more of the following (herein called a "**Default**" or an "**Event of Default**"" shall constitute a default by the Borrower hereunder, and under the Note, in addition to but not in limitation of any events which would cause a default under the terms and conditions of the note:

(a) Default in the payment or performance of any liability or obligation of Borrower to the Lender or any covenant or liability contained or referred to herein, in the Note, or in any other note, instrument, document or agreement evidencing any obligation.

(b) Any representation or warranty of the Borrower in connection with this Line of Credit Agreement or any document executed in accordance herewith, or in pursuance hereof, shall be false on the date on which made.

(c) The failure of Borrower to pay, when due, any amount due under the Note or the failure by the Borrower to pay, when due, any obligation of Borrower to Lender.

(d) Borrower's insolvency, appointment of a receiver for all or part of Borrower's property, the making of any assignment by Borrower for the benefit of creditors or commencement of any proceeding under any bankruptcy or insolvency laws by or against Borrower or upon the issuing of any writ of attachment by trustee process or otherwise or a restraining order or injunction affecting any of the Borrower's property; provider, however, if any such proceeding is commenced against the Borrower, the Borrower shall have thirty (30) days in which to cause such proceeding to be dismissed.

(e) The insolvency of any guarantor of this Line of Credit Agreement and/or the Note or any obligation of any Borrower to the Lender.

(f) The death, dissolution, termination of existence, declared insolvency; or failure in the business of the Borrower of any guarantor of this Line of Credit or the Note.

(g) The admission in writing of a Borrower's insolvency or inability to pay debts generally as they become due, or upon any deterioration of the financial condition of the Borrower, any endorser or guarantor of this Line of Credit Agreement or the Note, which results in the Lender deeming itself, in good faith, insecure.

(h) Ninety (90) days after DEMAND is made pursuant to the Note, unless the Borrower has satisfied the Note in full.

Any such event caused by, or occurring with regard to, any one or more persons constituting the "Borrower" shall be deemed to be so caused by (or occurring with regard to) the "Borrower".

If any Event of Default occurs, all obligations outstanding from the Borrower to the lender, including obligations pursuant to this Line of Credit Agreement and/or the Note, shall immediately become due and payable without demand, presentment, protest or other notice of any kind, all of which are hereby expressly waived. In the event of such Event of Default, the Lender may proceed to enforce the payment of all obligations of Borrower to Lender and to exercise any and all rights and remedies afforded to Lender by law or under the terms of this Line of Credit Agreement or otherwise.

4. Borrower agrees to furnish to the Lender, upon demand, but not more than semi-annually, so long as indebtedness under the Line of Credit Agreement and the Note remains unpaid, a certified financial statement prepared by an independent accountant setting forth in reasonable detail the assets, liabilities, and net worth of the Borrower and certified to under oath by an officer of the Borrower, Such financial statements shall be sent to the Lender at its address listed above and shall be the sole and cost and expense of the Borrower.

5. This Line of Credit is supplementary to each and every other agreement between Borrower and Lender and shall not be construed as to limit or otherwise derogate from any of the rights or remedies of Lender of any of the liabilities, obligations or undertakings of Borrower under any such agreement, nor shall any contemporaneous or subsequent agreement Borrower and Lender be construed to limit or otherwise derogate from any of the rights or remedies of Lender or any of the liabilities, obligations or undertakings of Borrower hereunder unless such other agreement specifically refers to this Line of Credit Agreement and expressly so provides.

6. This Line of Credit Agreement and the convents and agreements herein contained shall continue in full force and effect until all such obligations, liabilities and undertakings have been paid or otherwise satisfied in full. No delay or omission on the part of Lender in exercising any right hereunder shall operate as a waiver of such rights or any other right and waiver on any one or more occasions shall not be construed as to bar to or waiver of any right or remedy of Lender on any future occasion. This Line of Credit Agreement is intended to take effect as a sealed instrument, shall be governed by and construed in accordance with the laws of the Delaware, shall be binding upon Borrower's legal representatives, successors and assigns, and shall inure to the benefit of Lender's successors and assigns.

7. The Borrower does hereby certify that any all necessary resolutions that may be required to effectuate and validate the terms of this Line of Credit Agreement and the Note, have been duly made and adopted by the Borrower.

[The remainder of this page intentionally left blank; signature page follows]

IN WITNESS WHEREOF, the undersigned have caused this Agreement to be duly executed as of the date first above written.

**BORROWER:**

PROCESSA PHARMACEUTICALS, INC.

DocuSigned by:
By: David Young
3CC6C188EE8A407...
Name: David Young
Title: Chief Executive Officer

**LENDER:**

CORLYST, LLC

DocuSigned by:
By: Wendy Guy
Name: Wendy Guy
Title: Chief Management Officer

## EXHIBIT A

## PROMISSORY NOTE

FOR EVERY DOLLAR WITHDRAWN, the DEBTOR promises to pay to the CREDITOR, or its permitted assigns, all money borrowed under this Line of Credit Agreement at an 8% annual interest rate prorated monthly from the date money has been borrowed to the money has been paid back The DEBTOR may borrow any portion or pay back any portion during the life of the Line of Credit.

The CREDITOR also has the right to convert all or any portion of the debt and interest into Processa common shares at the terms defined in the July 2019 Bridge Subscription Agreement.

There will be no cost if the Line of Credit is not used.

**Confidential**

**[Execution Copy]**

# LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this "**Agreement**") dated as of August 29, 2019 (the "**Effective Date**"), is entered into by and between AKASHI THERAPEUTICS, INC., a Delaware corporation ("**Akashi**"), and PROCESSA PHARMACEUTICALS, INC., a Delaware corporation ("**Processa**"). Each of Akashi and Processa may be referred to herein as a "**Party**", or jointly as the "**Parties**".

WHEREAS, Akashi owns or controls rights in and to its proprietary product, known as HT-100, an orally available small molecule drug candidate being developed to reduce fibrosis and inflammation; and

WHEREAS, Processa desires to obtain an exclusive worldwide license to develop and commercialize products comprising or containing HT-100 and Akashi is willing to grant such a license on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, the Parties agree as follows:

1. DEFINITIONS

1.1 "**Affiliate**" means, with respect to any Person, any other Person which directly or indirectly controls, is controlled by, or is under common control with, such Person. A Person shall be regarded as in control of another Person if it owns, or directly or indirectly controls, more than fifty percent (50%) of the voting stock or other ownership interest of the other Person, or if it directly or indirectly possesses the power to direct or cause the direction of the management and policies of the other Person by any means whatsoever.

1.2 "**Annual Net Sales**" means aggregate Net Sales of all Licensed Products realized in the Territory in a given calendar year.

1.3 "**Commercially Reasonable Efforts**" means, with respect to the efforts and resources to be expended by a Party, efforts and resources commensurate with the efforts and resources commonly used in the pharmaceutical or biotechnology industry by a company of comparable size in connection with the development or commercialization of pharmaceutical or biotechnology products that are of similar status, taking into account the proprietary position of the product (including intellectual property scope, subject matter and coverage), safety and efficacy, product profile, competitiveness of the marketplace, the regulatory status and approval process, anticipated or approved labeling, present and future market potential, the probable profitability of the applicable product (including pricing and reimbursement status achieved or likely to be achieved) and other relevant factors such as technical, legal, scientific or medical factors. Notwithstanding the foregoing, the factors to be taken into consideration in determining whether Commercially Reasonable Efforts are being or have been used shall not include any obligation to make any payment hereunder or the existence of any of potentially competitive program of such Party or its Affiliates.

1.4 "**Confidential Information**" means, with respect to a Party ("**Discloser**"), all information of any kind whatsoever, and all tangible and intangible embodiments thereof of any kind whatsoever, which is or was disclosed by or on behalf of such Party to the other Party ("**Recipient**") in connection with this Agreement or the Confidentiality Agreement. Notwithstanding the foregoing, Confidential Information of a Party shall not include information which Recipient can establish: (a) to have been publicly known prior to disclosure of such information by Discloser to Recipient; (b) to have become publicly known, without breach of this Agreement or the Confidentiality Agreement on the part of Recipient, subsequent to disclosure of such information by Discloser to Recipient; (c) to have been received by Recipient on a non-confidential basis at any time from a source, other than Discloser, rightfully having possession of and the right to disclose such information without restriction; (d) to have been otherwise known by Recipient prior to disclosure of such information by Discloser to Recipient; or (e) to have been independently developed by or on behalf of Recipient without access to or use of such information disclosed by Discloser to Recipient, as demonstrated by contemporaneous written records.

1.5 "**Confidentiality Agreement**" means the Mutual Confidentiality Agreement between the Parties dated June 13, 2018.

1.6 "**Control**", "**Controls**" or "**Controlled**" means, with respect to any know-how, patents, proprietary information or trade secrets, or other intellectual property rights (collectively, "**Rights**"), the legal authority or right (whether by ownership, license or otherwise) of a Party to grant a license or a sublicense of or under such Rights to the other Party, or to otherwise disclose such proprietary information or trade secrets to the other Party, without breaching the terms of any agreement with a Third Party, misappropriating the proprietary information or trade secrets of a Third Party, or being required to make a payment to a Third Party.

1.7 "**Cover**" means, with respect to a Patent and a product, that such Patent would (absent a license thereunder or ownership thereof) be infringed by the manufacture, use, offer for sale, sale or import of such product, provided, however, that in determining whether a claim of a pending Patent application would be infringed, it shall be treated as if issued in the form then currently being prosecuted. Cognates of the word "Cover" shall have correlative meanings.

1.8 "**Development Plan**" has the meaning set forth in Section 2.1.2.

1.9 "**DMD**" means Duchenne Muscular Dystrophy.

1.10 "**Exploit**" (or "**Exploitation**") means, with respect to HT-100 or Licensed Product (as applicable), to use, have used, manufacture, have manufactured, sell, have sold, offer for sale, have offered for sale, import, and have imported, or otherwise exploit HT-100 or Licensed Product.

1.11 "**FDA**" means the United States Food and Drug Administration or any successor agency thereto.

1.12 "**FD&C Act**" means the United States Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.), as amended, and the rules and regulations promulgated thereunder, and any successor legislation thereto.

1.13 "**Field**" means all therapeutic uses.

1.14 "**First Commercial Sale**" means, with respect to a product in any country, the first sale for end use or consumption by the general public of such product in such country after marketing approval for such product has been granted in such country. First Commercial Sale excludes any sale or other distribution of a product for use in a clinical trial or other development activity, promotional use (including samples) prior to marketing approval or for compassionate use or on a named patient basis.

1.15 "**Foreground IP**" has the meaning set forth in Section 7.1.

1.16 "**Foreground Patent**" has the meaning set forth in Section 7.1.

1.17 "**HT-100**" means the product specified in Exhibit D**.**

1.18 "**IND**" means an investigational new drug application, as defined in the FD&C Act, which is required to be filed with the FDA before beginning clinical testing of a Licensed Product in human subjects, or an equivalent foreign filing.

1.19 "**Indication**" means a separate and distinct disease or medical condition in humans.

1.20 **"Initiation"** of a human clinical trial means, except as otherwise provided in Section 1.31(b), the first dosing of the first subject in such trial.

1.21 "**Know-How**" means all information and data that is not generally known (including, but not limited to, information and data regarding formulae, procedures, protocols, techniques, pharmacological, toxicological and clinical data and results and other results of experimentation and testing), and all rights therein and thereto.

1.22 "**Licensed IP**" means, collectively, the Licensed Patents and the Licensed Know-How.

1.23 "**Licensed Know-How**" means all Know-How which is Controlled by Akashi as of the Effective Date and which is necessary or specifically useful for Processa and its Affiliates and Sublicensees to make, use, develop, sell, or seek regulatory approval to market or otherwise Exploit HT-100, including without limitation the information and data described on Exhibit A attached hereto and any Product Records/Filings provided to Processa in accordance with Section 2.2. Licensed Know-How specifically excludes any Know-How that is owned or licensed by any acquiror or merger partner of Akashi or of any of its Affiliates (other than the Know-How which is Controlled by Akashi as of the Effective Date and is transferred to any such acquiror or merger partner of Akashi or of any of its Affiliates after the Effective Date).

1.24 "**Licensed Patents**" means (a) all Patents listed on Exhibit B; (b) any Patent filed after the Effective Date claiming priority to any Patent set forth in Exhibit B, solely to the extent the claims thereof Cover HT-100 or Licensed Product; and (c) any counterparts of a Patent described in subclause (a) or (b), solely to the extent the claims thereof Cover a Licensed Product. Licensed Patents specifically exclude any Patents that are owned or licensed by any acquiror or

merger partner of Akashi or of any of its Affiliates (other than Patents which are Controlled by Akashi as of the Effective Date and are transferred to any such acquiror or merger partner of Akashi or of any of its Affiliates after the Effective Date).

1.25 "**Licensed Product**" means any product utilizing, containing, comprising or consisting of HT-100 or any derivative, fragment, combination or conjugate thereof.

1.26 "**NDA**" means a new drug application or product license application or its equivalent filed with and accepted by the FDA to obtain marketing approval for any Licensed Product, or any comparable application filed with and accepted by the Regulatory Authority of a country other than the United States.

1.27 "**Net Sales**" means, with respect to any Licensed Product, the gross invoice price of such Licensed Product sold by or on behalf of Processa, its Affiliates or its Sublicensees to Third Parties in bona fide, arms-length transactions after deduction of all of the following (reasonably documented):

(a) normal and customary cash, trade and quantity discounts, actually paid or incurred;

(b) discounts, refunds, rebates, chargebacks, retroactive price adjustments, and any other allowances actually made which effectively reduce the net selling price, including any institutional rebate or discount for government subsidy or reimbursement programs such as Medicare or Medicaid provided in the United States or any similar organization elsewhere in the world, and Processa's discount programs;

(c) credits and allowances for returned Licensed Products actually made and actually taken (for financial reporting purposes) and for recalls, retroactive price reductions, and billing corrections;

(d) freight, packing, shipping, handling and insurance fees, but solely to the extent separately stated on the invoice and included in the gross invoice price;

(e) tariffs, duties, exercise taxes and all other taxes, including value added taxes and sales taxes, but excluding taxes based on the Processa's, its Affiliates' or Sublicensees' income; and

(f) amounts actually credited for uncollectible amounts on previously sold Licensed Products;

all as determined in accordance with U.S. generally accepted accounting principles.

Amounts invoiced between Processa and its Affiliates for quantities of the Licensed Products for use in clinical trials or for resale, or by Processa or its Affiliates to permitted Sublicensees for resale, shall not be included in the calculation of Net Sales.

Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales but which are separately charged to Third Parties shall not be deducted from the invoice price in the calculation of Net Sales.

Net Sales of any Licensed Product sold by or on behalf of Processa, its Affiliates or its Sublicensees as part of a product that, in addition to Licensed Product, contains one or more active pharmaceutical ingredients (a "**Combination Product**"), shall be calculated as follows:

(x) The Net Sales for the purpose of determining royalty payments and sales milestones payments on sales of the Combination Product shall be calculated by multiplying Net Sales of such Combination Product by the fraction A/(A+B) where A is either: (i) the weighted average price (by sales volume) to Third Party end users of the Licensed Product component of the Combination Product when sold separately, should Licensed Products be sold separately in the applicable country; or (ii) the weighted average fair market value (by sales volume) of the portion of the Combination Product containing the Licensed Product included in such Combination Product, as such fair market value is determined in good faith by the Parties, if Licensed Products are not sold separately in the applicable country, and B is either (i) the weighted average price (by sales volume) to Third Party end users of product containing the other active ingredients of the Combination Product when sold separately, should such active ingredients be sold separately in the applicable country; or (ii) the weighted average fair market value (by sales volume) of the portion of the Combination Product containing the other active ingredients, as such fair market value is determined in good faith by the Parties, should such active ingredients not be sold separately in the applicable country.

(y) Regarding prices comprised in the weighted average price when sold separately referred to in paragraph (x) above, if these are available for different dosages of the Licensed Product and the other active ingredients from the dosage that are included in the Combination Product, then Processa shall be entitled to make a proportional adjustment to such prices in calculating the Net Sales of the Combination Product, with written notice of such adjustment to be provided to Akashi.

1.28 "**Patents**" means all patents and provisional and non-provisional patent applications (including inventor's certificates and applications for certificates of invention), including all divisionals, continuations, substitutions, continuations-in-part, re-examinations, reissues, additions, renewals, revalidations, extensions, registrations, patent term extensions, patent term adjustments, and supplemental protection certificates and the like of any such patents and patent applications, and any and all foreign equivalents of the foregoing.

1.29 "**Person**" means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.

1.30 "**Phase 1 or 2 Trial**" means a human clinical trial of a Licensed Product other than a Pivotal Trial that is designed to demonstrate safety, clinical efficacy or biological activity/proof of concept, and that is generally consistent with 21 CFR 312.21(a) or 21 CFR 312.21(b) for the United States, or a similar clinical study prescribed by the Regulatory Authorities in a foreign country.

1.31 "**Pivotal Trial**" means:

(a) a Phase 3 clinical trial; or

(b) any other human clinical trial that the applicable Regulatory Authority has agreed, whether before first dosing of the first patient in such trial (e.g., pursuant to a special protocol assessment agreement with the FDA) or after first dosing of the first patient in such trial (e.g., based on an interim data analysis), is sufficient to form the primary basis of an efficacy claim in an NDA submission, regardless of whether the sponsor of such trial characterizes or refers to such trial as a "Phase 3," "Phase 2b" or "Phase 2b/3" trial (or otherwise) in the applicable protocol, on clinicaltrials.gov, or in any other context. If a human clinical trial does not constitute a Pivotal Trial at the time of first dosing of the first patient in such trial, but is later determined by the applicable Regulatory Authority to be sufficient to form the primary basis of an efficacy claim in an NDA submission, then, for purposes of Section 4.2, "Initiation" of such Pivotal Trial shall be deemed to have occurred on the date of such determination by the applicable Regulatory Authority.

1.32 "**Prior IND**" has the meaning set forth in Section 2.2.2.

1.33 "**Product Infringement**" has the meaning set forth in Section 10.2.1.

1.34 "**Product Records/Filing**" means (a) any clinical records (including clinical protocol, study, clinical data or result used in or resulting from any clinical trial) and manufacturing records of HT-100 or Licensed Product, or (b) subject to Section 2.2.2, any IND, application for Regulatory Approval, Regulatory Approval or other regulatory filing regarding HT-100 or Licensed Product and data referenced therein.

1.35 "**Regulatory Approval**" means any license, registration, authorization or approval (including, without limitation, any approval of an NDA, supplement or amendment, pre- and post- approval, pricing approval, or labeling approval) of any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, necessary for the commercial manufacture, distribution, marketing, promotion, offer for sale, use, import, export and sale of a Licensed Product in a regulatory jurisdiction.

1.36 "**Regulatory Authority**" means any national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity in each country of the world involved in the granting of Regulatory Approval for the Licensed Product.

1.37 "**Right of Reference**" means a "Right of Reference," as that term is defined in 21 C.F.R. § 314.3(b) and any comparable right existing under the laws or regulations of any foreign country.

1.38 "**Rights**" has the meaning set forth in Section 1.6.

1.39 "**Royalty Term**" means, with respect to each Licensed Product in each country, the later of (a) the expiration of the last to expire Valid Claim that Covers such Licensed Product in such country, or (b) ten (10) years from the date of the First Commercial Sale of such Licensed Product in such country.

1.40 "**Sublicensee**" means any Third Party to whom Processa has sublicensed rights with respect to the development, commercialization or other Exploitation of Licensed Product in accordance with Section 3.2.2.

1.41 "**Territory**" means the entire world.

1.42 "**Third Party**" means any Person other than Akashi, Processa and their respective Affiliates.

1.43 "**Valid Claim**" means either (a) a claim of an issued and unexpired Patent within the Licensed Patents, which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise; or (b) a claim of a pending Patent application within the Licensed Patents, provided that if such claim shall not have issued within seven (7) years after the earliest filing date from which such claim takes priority, such claim shall not constitute a Valid Claim for the purposes of this Agreement unless and until such claim issues.

## 2. PRODUCT DEVELOPMENT AND COMMERCIALIZATION

### 2.1 Research and Development Efforts.

2.1.1 Processa shall use Commercially Reasonable Efforts to research, develop and commercialize Licensed Products in one or more countries in the Territory. The efforts of Processa's Affiliates and Sublicensees shall be treated as the efforts of Processa when evaluating Processa's compliance with the foregoing diligence obligations. Without limiting the generality of the foregoing, Processa will be responsible for conducting all necessary studies, including safety studies and clinical trials that are necessary in connection with seeking Regulatory Approvals to market the Licensed Product in the Territory, at Processa's own cost and discretion.

2.1.2 Development Plan. Processa shall provide to Akashi a written research and development plan (the **"Development Plan"**) setting forth in reasonable detail planned activities to research and develop HT-100 and the Licensed Products and the estimated timelines for such activities. The Development Plan may be amended from time to time by Processa. The initial Development Plan as of the Effective Date will be provided to Akashi and attached as Exhibit C within six (6) months of the Effective Date. As used herein, the term "Development Plan" shall mean the Development Plan as then in effect, including all updates and amendments thereto.

2.1.3 Reporting. Processa shall provide Akashi with written reports detailing the activities of Processa, its Affiliates and Sublicensees with respect to the research and development of and pre-commercial launch activities for Licensed Products in the Field in the Territory, both as to activities conducted during the prior period and planned activities for HT-100 and Licensed Products, in sufficient detail to enable Akashi to reasonably assess Processa's compliance with its diligence obligations hereunder, including compliance with Section 2.5. Such reports shall also include the development funding expended by Processa. Processa shall present such report to Akashi in conjunction with a meeting (either in person or by teleconference, as the Parties may agree) with Processa's personnel responsible for the conduct of such development (and, if applicable, pre-commercial launch activities) which personnel shall include at least one Processa representative responsible for such development (and, if applicable, pre-commercial launch activities) at a level of vice president or higher, and shall provide such additional information to Akashi as Akashi may reasonably request. Such reports shall be made on a calendar quarter basis (within ninety (90) days following the end of each calendar quarter) until the Initiation of a clinical trial for a Licensed Product, and on a semi-annual basis thereafter (within ninety (90) days following January 1 and July 1 of each calendar year).

2.2 Data Sharing and Technology Transfer.

2.2.1 Akashi hereby agrees to provide to Processa, as soon as reasonably practicable following the Effective Date, access to all Product Records/Filings and any other technical data or Licensed Know-How Controlled by Akashi and its Affiliates in connection with and specifically relating to the development of HT-100, and to transfer and deliver to Processa copies of all documents (such as copies of the relevant patent filings, clinical studies, clinical protocols, all IND-related documents, all correspondence with the FDA) included therein that a reasonable person would expect to be material to the exercise of the licenses granted hereunder by Processa or otherwise requested by Processa (either specifically or by category). Processa and its Affiliates and Sublicensees shall have the right to use, without additional payment, any and all such Product Records/Filings and all other CMC, pre-clinical or clinical information and data and/or Licensed Know-How provided to it hereunder to support any regulatory filings for the Licensed Products and to otherwise exercise the license granted to it in accordance with Section 3.1 in accordance with the terms of this Agreement.

2.2.2 To the extent ownership is not otherwise transferred to Processa hereunder and to the extent access thereto is reasonably required in order to seek or obtain Regulatory Approval for the Licensed Products or otherwise in connection with the exercise of the licenses granted herein, Akashi hereby grants to Processa and its Affiliates a Right of Reference to any Product Records/Filing disclosed by Akashi or its Affiliate pursuant to Section 2.2.1 for use in regulatory filings for the Licensed Product by Processa and its Affiliates. Processa may sublicense the Right of Reference set forth in this Section 2.2.2 to its permitted Sublicensees of the Licensed Product as reasonably required. Prior to the Effective Date, Akashi has notified FDA of the withdrawal of the IND filed by Akashi with the FDA with respect to HT-100 (the "**Prior IND**"). The Prior IND will be transferred to Processa if allowed by the FDA and requested by Processa, and Processa is hereby given the Right of Reference and any other right to use such Prior IND for any purpose consistent with applicable laws and Processa's exercise of the licenses granted herein.

2.2.3 Akashi shall promptly, and in any event within sixty (60) days after the Effective Date, conduct a technology transfer of all Licensed Know-How in Akashi's possession and Control in accordance with Section 2.2.1. Akashi shall pay for all reasonable expenses and out-of-pocket costs incurred in connection with the technology transfer activities set forth in Section 2.2.1.

2.3 Regulatory Approvals and Regulatory Reporting. From and after the Effective Date, Processa will be responsible for the preparation and filing of all applications for Regulatory Approvals for the Licensed Products with the applicable Regulatory Authorities in the Territory, including the filing of an IND under which all relevant activities hereunder shall be conducted. Processa shall prepare and file the IND and any applications for Regulatory Approval for the Licensed Products with the Regulatory Authorities in its name and at its cost. Processa shall file, in its own name and at its own expense, all other applications for any approvals required for any clinical study or other study or action necessary or desirable to obtain such Regulatory Approval. Processa shall have the sole responsibility for communicating with any Regulatory Authority regarding any applications for Regulatory Approval or any Regulatory Approval for the Licensed Products once granted or any such other applications. Processa shall be responsible for filing, at its own expense, all reports required to be filed in order to maintain any Regulatory Approvals granted for the Licensed Products. The efforts of Processa's Affiliates and Sublicensees shall be treated as the efforts of Processa when evaluating Processa's compliance with this Section 2.3.

2.4 Licensed Product Labeling. Processa shall be solely responsible for the administrative aspects of preparing, updating and maintaining product labeling in connection with commercialization of the Licensed Products. Such labeling may include but is not limited to text and graphical contents of printed labels and labeling components, including but not necessarily limited to healthcare professional leaflets or inserts, patient leaflets or inserts, and cartons. The efforts of Processa's Affiliates and Sublicensees shall be treated as the efforts of Processa when evaluating Processa's compliance with this Section 2.4.

2.5 Specific Diligence Obligations. Without limiting the generality of Processa's obligations under this Section 2, including Section 2.1, Processa agrees to the following:

2.5.1 The Parties have agreed that the financial consideration to be paid to Akashi in exchange for the rights granted and materials transferred hereunder will be largely deferred until such time as Processa has substantially advanced the development of HT-100 and Licensed Products and commenced commercialization of Licensed Products, such that Akashi is reliant on Processa's diligent development of HT-100 and Licensed Products and commercialization of the Licensed Products to fully receive the benefit of its bargain. Further, Processa acknowledges that the diligent conduct of such development requires the commitment by Processa of an appropriate level of funding directed to such development. Accordingly, and without limiting the generality of Section 2.1.1:

| Diligence Milestones | Date (On or Before) |
|---|---|
| 1. FDA Meeting Request for 1st Indication | 18 Months after Effective Date |
| 2. IND submission for DMD or any Indication | 6/30/22 |
| 3. Initiation of Phase 1 or 2 Trial for DMD or any other Indication | 12/30/22 |
| | |

2.5.2 Processa shall promptly provide written notice to Akashi if at any time during the term of this Agreement: (i) Processa, its Affiliates, or Sublicensees are not actively pursuing development of the Licensed Products for a period of twelve (12) consecutive months at any time following the Effective Date and prior to the first NDA submission; or (ii) prior to such time as Regulatory Approval of a Licensed Product has been achieved Processa decides to suspend the further development of Licensed Products. Such notice shall be deemed a termination of this Agreement by Processa pursuant to Section 11.2.

2.6 Compliance. Processa, its Affiliates, and its Sublicensees shall comply with all applicable rules, laws and regulations in connection with their performance under this Agreement.

3. LICENSE GRANT

3.1 License. Subject to the terms and conditions of this Agreement, Akashi hereby grants and agrees to grant to Processa an exclusive license under the Licensed Products, Licensed IP, and Product Records/Filings, to research, develop, manufacture, make, have made, use, import, export, sell, offer to sell, have sold, commercialize, supply, and sublicense across multiple levels, the Licensed Products within the Field in the Territory.

3.2 Sublicenses.

3.2.1 Processa shall have the right to grant sublicenses under the licenses granted in Section 3.1 to its Affiliates, subject to Section 13.16, and provided that Processa provides Akashi with written notice of each such sublicense within sixty (60) days of granting such sublicense.

3.2.2 Processa may grant sublicenses under the license in Section 3.1 to Third Parties, subject to the remainder of this Section 3.2.2 and subject to Akashi's prior written consent to such sublicense, which consent shall not be unreasonably withheld or delayed by Akashi. Processa shall, within sixty (60) days after granting any sublicense to a Third Party, provide Akashi with a true, complete and legible copy of such sublicense agreement and each amendment thereto, provided that Processa may redact from such agreement or amendment any financial terms that are unrelated to this Agreement. Processa shall remain directly responsible for each of its Sublicensees' compliance with this Agreement.

## 4. ROYALTIES AND OTHER PAYMENTS

4.1 Upfront Payment. As partial consideration for the licenses granted to Processa under this Agreement, Processa shall pay an upfront payment of ten thousand U.S. dollars (US$10,000) to Akashi within five (5) business days of the full execution of this Agreement.

4.2 Development and Regulatory Milestone Payments.

4.2.1 As additional consideration for the licenses granted to Processa under this Agreement, Processa shall pay Akashi development and regulatory milestone payments as set forth below. Each milestone payment owed by Processa to Akashi pursuant to this Section 4.2.1 shall be payable by Processa within sixty (60) days following the first achievement of the corresponding milestone event by Processa or a Processa Affiliate. For clarity, in the event that any such milestone event is achieved by a Sublicensee, no payment under this Section 4.2.1 shall be due. For the avoidance of doubt, each milestone payment is only payable once, regardless of the number of times such milestone may be achieved by Processa, or its Affiliates, and shall be non-refundable and non-creditable. In addition, if a given clinical or Regulatory Approval milestone event is achieved by Processa or a Processa Affiliate for a Licensed Product in the second Indication without one or more preceding clinical milestone events for the relevant Indication having been achieved by Processa or its Affiliate with respect to such Licensed Product, then the milestone payments corresponding to such skipped clinical milestone events shall be made simultaneously upon achievement of such clinical or Regulatory Approval milestone event by such Licensed Product and for such Indication.

| **Milestone Event** | **Amount If Processa or a Processa Affiliate Achieves Event** |
|---|---|
| 1. Initiation of 1st Pivotal Trial for 1st Indication | US$200,000 |
| 2. 1st Indication approved by Regulatory Authority in the US | US$3 Million |
| 3. 1st Indication approved by Regulatory Authority outside US | US$3 Million |
| 4. Initiation of 1st Phase 1 or 2 Trial in Patients for 2nd Indication | US$50,000 |
| 5. Initiation of 1st Pivotal Trial for 2nd Indication | US$100,000 |
| 6. 2nd Indication approved by Regulatory Authority in the US | US$3 Million |
| 7. 2nd indication approved by Regulatory Authority outside US | US$3 Million |

4.2.2 As additional consideration for the licenses granted to Processa under this Agreement, in the event that Processa or its Affiliate grants sublicenses under the licenses granted in Section 3.1 and in the event that Processa or its Affiliate receives any milestone payment from any Sublicensee for any event relating to the clinical development, Regulatory Approval or First Commercial Sale of a Licensed Product for a first or second Indication that is achieved by or on behalf of such Sublicensee (and for clarity not by Processa or its Affiliate),

whether or not such event is listed in items 1-7 above, Processa shall pay Akashi fifty percent (50%) of any such milestone payment paid to Processa or its Affiliate by the relevant Sublicensee within sixty (60) days of receipt of the relevant amount by Processa or its Affiliate. For clarity, the milestone payments set forth in Section 4.2.1 shall not apply with respect to events achieved by Sublicensees.

4.3 Sales Milestone Payments.

4.3.1 As additional consideration for the licenses granted to Processa under this Agreement, Processa shall pay Akashi one-time, non-refundable, non-creditable annual net sales milestone payments based on the achievement during a calendar year of one or more thresholds for Annual Net Sales. The annual net sales milestone payments shall be paid within sixty (60) days after the end of the first calendar quarter within the relevant calendar year in which the Annual Net Sales of all Licensed Products in the Territory first reach the relevant threshold for Annual Net Sales. For clarity, an annual net sales milestone payment for a given threshold for Annual Net Sales listed in Section 4.3.2 (or a pro-rata portion thereof as determined in accordance with Section 4.3.4) will be due once and only once during the term of this Agreement, at the time the threshold is first achieved by Processa and/or its Affiliates, alone or in combination with Sublicensees. Thereafter, the threshold for Annual Net Sales and the corresponding annual net sales milestone payment in Section 4.3.2 will no longer apply. The determination of the amount of any annual net sales milestone payments will be based on whether sales of Licensed Products during the pertinent calendar year are made only by Processa and/or its Affiliates (Section 4.3.2), only by Sublicensees (Section 4.3.3), or by Processa and/or its Affiliates and by Sublicensees (Section 4.3.4).

4.3.2 In the event that Licensed Products are sold only by Processa and/or its Affiliates (i.e., no sales by Sublicensees) during a pertinent calendar year and Processa and/or its Affiliates are the first to achieve one or more of the Annual Net Sales thresholds set forth in the table below, the annual net sales milestone payment from Processa to Akashi shall be in the corresponding amount set forth in the table below.

| **Annual Net Sales Threshold** | **Annual Net Sales Milestone Payment** |
|---|---|
| US$50 Million | US$5 Million |
| US$250 Million | US$15 Million |
| US$500 Million | US$20 Million |
| US$750 Million | US$30 Million |
| US$1 Billion | US$40 Million |

4.3.3 In the event that Licensed Products are sold only by one or more Sublicensees (i.e., no sales by Processa and/or its Affiliates) during a pertinent calendar year and in the event that Processa or its Affiliate receives any milestone payment from any Sublicensee based on achievement of any Annual Net Sales (or substantially equivalent) threshold in such calendar year, Processa shall pay Akashi fifty percent (50%) of any such annual net sales milestone payments paid by Sublicensees to Processa or its Affiliate. For clarity, the annual net sales milestone payments set forth in Section 4.3.2 for any achieved Annual Net Sales (or

substantially equivalent) threshold shall not apply if Licensed Products are sold only by one or more Sublicensees (i.e., no sales by Processa and/or its Affiliates) during the pertinent calendar year.

4.3.4 In the event that Licensed Products are sold by Processa and/or its Affiliates and by one or more Sublicensees during a pertinent calendar year and they collectively are the first to achieve one or more of the Annual Net Sales thresholds set forth in the table in Section 4.3.2, the amount of the corresponding annual net sales milestone payments due to Akashi for such calendar year shall be determined on the following basis (and except to the extent specifically referenced below, the annual net sales milestone payments set forth in Section 4.3.2 for each such achieved Annual Net Sales threshold shall no longer apply):

1) The total Annual Net Sales (C) for determination of threshold achievement shall be determined by adding the Annual Net Sales as of the relevant date by Processa and/or its Affiliates (A) and the Annual Net Sales as of the relevant date by Sublicensee(s) (B) (i.e., C = A+B).

2) The total Annual Net Sales (C) as of the relevant time shall be used to determine whether or not the achievement of any relevant threshold for Annual Net Sales in the table in Section 4.3.2 has occurred.

3) The annual net sales milestone payment corresponding to the achieved Annual Net Sales threshold due based on Net Sales by Processa and its Affiliates shall be determined by determining the percentage of the total Annual Net Sales (C) attributable to Annual Net Sales by Processa and/or its Affiliates (A), and multiplying that percentage by the annual net sales milestone payment in the table in Section 4.3.2 corresponding to the achieved Annual Net Sales threshold.

4) In addition to any amount payable based on Annual Net Sales of Processa and its Affiliates in the pertinent calendar year as determined in 3) above, Processa shall pay to Akashi fifty percent of any amount that Processa or its Affiliate receives as milestone payments from Sublicensees based on achievement of any Annual Net Sales (or substantially equivalent) threshold during the pertinent calendar year.

4.4 Royalties.

4.4.1 As additional consideration for the licenses granted to Processa under this Agreement, during the Royalty Term for each Licensed Product and country, Processa shall pay royalties on Net Sales of Licensed Products to Akashi based on total Annual Net Sales by Processa, its Affiliates, and Sublicensees of Licensed Products in the Territory in accordance with this Section 4.4. The determination of the royalties to be paid by Processa to Akashi shall

be based on whether sales of Licensed Products during the pertinent year are made only by Processa and/or its Affiliates (Section 4.4.2), only by Sublicensees (Section 4.4.3), or by Processa and/or its Affiliates and by Sublicensees (Section 4.4.4). Royalties will be payable on a calendar quarter basis. Within sixty (60) days after the end of each calendar quarter following the First Commercial Sale of the first Licensed Product, Processa shall deliver to Akashi a report containing the following information for the prior calendar quarter on a Licensed Product-by-Licensed Product and country-by-country basis, and reported separately for Net Sales by Processa and its Affiliates and for Net Sales of its Sublicensees: (a) the gross sales associated with each Licensed Product sold by Processa and its Affiliates and, separately, Sublicensees; (b) a calculation of Net Sales of each Licensed Product that is sold by Processa, its Affiliates and, separately, its Sublicensees; and (c) a calculation of payments due to Akashi with respect to the foregoing. Concurrently with such report, Processa shall remit to Akashi any payment due for the applicable calendar quarter. At Akashi's request, Processa shall also provide to Akashi reasonable supporting documentation. If no royalties are due to Akashi for any such reporting period, the report shall so state. The method of payment shall be by check or wire transfer to an address or account specified in writing by Akashi.

4.4.2 In the event that Licensed Products are sold only by Processa and/or its Affiliates (i.e., no sales by Sublicensees) during the pertinent calendar quarter, the applicable royalty rate shall be determined as follows:

| **On that Portion of Annual Net Sales** | **Royalty Rate If Processa or its Affiliate Sells the Product** |
|---|---|
| ≤ US$250 Million | 8% |
| >US$250 Million | 12% |

4.4.3 In the event that Licensed Products are sold only by one or more Sublicensees (no sales by Processa and/or its Affiliates) during the pertinent calendar quarter, Processa shall pay Akashi fifty percent (50%) of any royalties paid by such Sublicensees to Processa for such calendar quarter, and the table set forth in Section 4.4.2 shall not apply to such calendar quarter.

4.4.4 In the event that Licensed Products are sold by Processa and/or its Affiliates and by one or more Sublicensees during the pertinent calendar quarter, the royalties to be paid by Processa to Akashi shall be determined on the following basis (and except to the extent specifically referenced below, the table set forth in Section 4.4.2 shall not apply to such calendar quarter):

1) The total Annual Net Sales (C) as of the end of the relevant calendar quarter shall be determined by adding the Annual Net Sales achieved by Processa and/or its Affiliates (A) and the Annual Net Sales by Sublicensee(s) (B), in each case as of the end of the relevant calendar quarter (i.e., C = A+B).

2) The total Annual Net Sales (C) as of the end of the relevant calendar quarter shall be used to determine the corresponding royalty rate in the table in Section 4.4.2.

3) The royalty to be paid by Processa to Akashi on Net Sales by Processa and its Affiliates shall be the royalty rate indicated in the table in Section 4.4.2 for that portion the Annual Net Sales (C), except as otherwise provide below. For clarity, if C as of the end of the relevant calendar quarter is less than or equal to US$250 Million, royalties payable on Net Sales by Processa and its Affiliates in the relevant calendar quarter shall be 8%, and if C as of the end of the prior calendar quarter is greater than US$250 Million, royalties payable on Net Sales by Processa and its Affiliates in the relevant calendar quarter shall be 12%. In the event that the US$250 Million threshold is reached during the relevant calendar quarter, royalties payable on Net Sales by Processa and its Affiliates in the relevant calendar quarter shall be 10%.

4) The royalty to be paid by Processa to Akashi on Net Sales by Sublicensees shall be fifty percent of any royalties that Processa receives from Sublicensees for Net Sales by or on behalf of Sublicensees in the relevant calendar quarter.

4.5 Upfront Sublicense Payments. As additional consideration for the licenses granted to Processa under this Agreement, (a) if Processa grants or agrees in writing to grant one or more sublicenses with respect to any Licensed Product prior to the first FDA meeting with respect to Licensed Product held with the FDA after the Effective Date, or prior to starting the first pre-clinical study with respect to Licensed Product after the Effective Date, whichever comes first (such earlier date, the "**Start Point**"), then Processa shall pay Akashi seventy-five percent (75%) of any upfront sublicense fee and/or upfront Sublicensee equity, and of any related option fee and/or option equity, received from such Sublicensee and not required to be used by Processa for the development of the Licensed Product, and (b) if Processa grants or agrees in writing to grant one or more sublicenses with respect to any Licensed Product after the Start Point, then Processa shall no longer pay Akashi seventy-five percent (75%) as provided above but instead shall pay Akashi forty percent (40%) of any upfront Sublicensee fee and/or upfront Sublicensee equity, and of any related option fee and/or option equity, received from such Sublicensee and not required to be used by Processa for the development of the Licensed Product. Any payment due to Akashi in accordance with this Section 4.5 shall be made within sixty (60) days of receipt of the relevant amount by Processa or its Affiliate. For clarity, all milestone payment obligations and royalty payment obligations from Processa to Akashi specified in other sections of this Section 4 are not affected by this Section 4.5.

4.6 Anti-Stacking. If Processa and/or its Affiliate is obligated to take a royalty-bearing license under intellectual property rights owned by a Third Party in order to research,

develop, manufacture, make, have made, use, import, export, sell, offer to sell, have sold, commercialize, supply, and sublicense across multiple levels the Licensed Products within the Field in the Territory for any Licensed Product, then Processa may deduct fifty percent (50%) of any royalties actually paid to such Third Party based on sales of the relevant Licensed Product from royalties owed to Akashi under this Agreement for such Licensed Product; provided, however, that in no event will the royalties owed to Akashi for the relevant Licensed Product in any royalty reporting period be reduced to less than twenty-five percent (25%) of the total royalties otherwise due on Net Sales.

5. ROYALTY REPORTS AND ACCOUNTING

5.1 Royalty Reports. During the term of this Agreement, Processa shall timely furnish to Akashi written royalty reports as specified in Section 4.4 for each royalty reporting period, as well as reports showing the calculation of any payments due to Akashi with respect to any milestones achieved by Processa, its Affiliates or Sublicensees and/or sublicenses granted by Processa.

5.2 Audits.

5.2.1 Upon the written request of Akashi and not more than once in each calendar year, Processa shall permit an independent certified public accounting firm selected by Akashi and reasonably acceptable to Processa, at Akashi's expense, to have access during normal business hours to such of the records of Processa as may be reasonably necessary to verify the accuracy of the amounts paid to Akashi and reports provided to Akashi hereunder. The accounting firm shall disclose to Akashi only whether or not the payments and reports are correct and the amount of any discrepancies. No other information shall be shared.

5.2.2 If such accounting firm concludes that additional payments were owed during the relevant period, Processa shall make such additional payments, along with any corresponding interest payments, within sixty (60) days of the date Akashi delivers to Processa such accounting firm's written report so concluding. The fees charged by such accounting firm shall be paid by Akashi; provided, if the audit correctly discloses that the amounts payable by Processa for the audited period are five percent (5%) or more than the amounts actually paid for such period, then Processa shall pay the reasonable fees and expenses charged by such accounting firm.

5.2.3 Akashi shall treat all financial information subject to review under this Section 5 as confidential, and shall cause its accounting firm to retain all such financial information in confidence under Section 9 below.

6. PAYMENTS

6.1 Payment Terms. Royalties, and any payments based on the achievement of milestones or sublicensing, shown to have accrued by each report provided for under Section 5.1 above, shall be due as specified in Section 4. Payment in whole or in part may be made in advance of the relevant due date.

6.2 Exchange Control. If at any time legal restrictions prevent the prompt remittance of part or all royalties with respect to any country in the Territory where the Licensed Product is sold, Processa shall have the right, in its sole discretion, to make such payments by depositing the amount thereof in local currency to Akashi's account in a bank or other depository institution in such country. If the royalty rate specified in this Agreement exceeds the permissible rate established in any country, the royalty rate for sales in such country shall be adjusted to the highest legally permissible or government-approved rate.

6.3 Withholding Taxes. Processa shall be entitled to deduct the amount of any withholding taxes, value-added taxes or other taxes, levies or charges with respect to such amounts, other than United States taxes, payable by Processa, its Affiliates or Sublicensees, or any taxes required to be withheld by Processa, its Affiliates or Sublicensees, to the extent Processa, its Affiliates or Sublicensees pay to the appropriate governmental authority on behalf of Akashi such taxes, levies or charges. Processa shall use reasonable efforts to minimize any such taxes, levies or charges required to be withheld on behalf of Akashi by Processa, its Affiliates or Sublicensees. Processa promptly shall deliver to Akashi proof of payment of all such taxes, levies and other charges, together with copies of all communications from or with such governmental authority with respect thereto.

6.4 Interest. Without limiting any other rights or remedies available to Akashi, Processa shall pay Akashi interest on any payments that are not paid on or before the date such payments are due under this Agreement at an annual rate of one percent (1%) above the prime rate as published by *The Wall Street Journal, Eastern Edition,* on the date such payments first became due, or the maximum applicable legal rate, if less, calculated based on the total number of days payment is delinquent.

7. Foreground IP Ownership

7.1 Foreground IP. Processa shall own all inventions (whether patentable or not), improvements, and Know-How that are conceived, discovered, developed, or otherwise made by or on behalf of Processa or its Affiliates, or their respective employees, agents or subcontractors in the course of performing activities under this Agreement that are reasonably necessary or useful for the Exploitation of HT-100 or Licensed Products in the Field, and whether or not patentable (collectively, "**Foreground IP**"), and any and all Patents claiming such Foreground IP ("**Foreground Patents**"). Processa shall own all Product Records/Filings with respect to the Licensed Products made by or on behalf of Processa or its Affiliates, or their respective employees, agents or subcontractors in the course of performing activities under this Agreement.

7.2 No Other Rights. Except as expressly set forth in this Agreement, neither Party grants to the other Party any right or license, express or implied, under any of such Party's Rights.

8. REPRESENTATIONS AND WARRANTIES

8.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party as follows as of the Effective Date:

8.1.1 Corporate Existence. Such Party is a corporation duly organized, validly existing and in good standing under the laws of the state in which it is incorporated or organized.

8.1.2 Authorization and Enforcement of Obligations. Such Party (a) has the organizational power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder, and (b) has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms.

8.1.3 No Consents. All necessary consents, approvals, and authorizations of all governmental authorities and other Persons required to be obtained by such Party in connection with this Agreement have been obtained.

8.1.4 No Conflict. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (a) do not conflict with or violate any requirement of applicable laws or regulations, and (b) do not conflict with, or constitute a default under, any contractual obligation of it.

8.2 Additional Akashi Representations and Warranties. In addition, Akashi hereby represents and warrants to Processa that, as of the Effective Date:

8.2.1 Each item of the Licensed Patents set forth in Exhibit B (a) Akashi has the right to license, (b) to Akashi's knowledge, if issued, is valid, subsisting and in full force and effect, (c) has not been abandoned or passed into the public domain, and (d) is free and clear of any liens or encumbrances.

8.2.2 Akashi has not transferred ownership of, or granted any license of or right to use, or authorized the retention of any rights to use or joint ownership of, any Licensed IP to any Person in any manner that would conflict with the license granted to Processa in Section 3.1.

8.2.3 To Akashi's knowledge, no claim or litigation has been brought or threatened by any Third Party alleging that (a) the Licensed Patents are invalid or unenforceable or (b) the Exploitation of HT-100 and/or any subject matter covered by the Licensed IP infringe or misappropriate or would infringe or misappropriate any right of any Third Party.

8.2.4 The Licensed IP and the Product Records/Filings and other Licensed Know-How to be provided to Processa in accordance with Section 2.2 include all of the Patents, Know-How, and Products Records/Filings that are Controlled by Akashi that are reasonably necessary for Processa to research, develop, manufacture, make, have made, use, import, export, sell, offer to sell, have sold, commercialize and supply the Licensed Products within the Field in the Territory.

## 9. CONFIDENTIALITY

9.1 Confidentiality Obligations. Confidential Information shall be governed by the terms of this Agreement, which supersedes the prior Confidentiality Agreement. Recipient shall keep and hold Confidential Information of Discloser in strictest confidence, and shall not use such Confidential Information for any purpose, other than as may be reasonably necessary for the performance of its duties or the exercise of its rights under this Agreement, without Discloser's prior written consent. Recipient shall not disclose any such Confidential Information to any person or entity without Discloser's prior written consent, except to its and its Affiliates' employees, consultants and agents, as necessary for purposes of performing Recipient's duties hereunder, under the terms and conditions no less protective of the Confidential Information than the terms and conditions of this Section 9. The obligations of confidentiality under this Section 9 shall last with respect to each item of Confidential Information until one of the exceptions in Section 1.4 applies to such Confidential Information.

9.2 Permitted Disclosures. Notwithstanding anything herein to the contrary, Recipient may disclose Confidential Information of Discloser to the extent necessary to: (a) comply with an applicable law, regulation of a governmental agency or order of a court of competent jurisdiction, (b) to disclose information to any governmental agency for purposes of obtaining approval to test or market a Licensed Product, or (c) prosecute or defend litigation; provided that if Recipient is required by law or regulation to make any such disclosure of Discloser's Confidential Information, it will give reasonable advance notice to Discloser of such disclosure requirement and will use commercially reasonable efforts to assist such Discloser to secure a protective order or confidential treatment of the Confidential Information required to be disclosed. In addition, notwithstanding anything herein to the contrary, Recipient may disclose Discloser's Confidential Information to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances: (i) in order for it to reasonably fulfill its obligations herein and to conduct its ordinary course of business, to its subcontractors, vendors, outside legal counsel, accountants and auditors under obligations of confidentiality substantially similar in scope to the confidentiality obligations herein; (ii) in connection with prosecuting and enforcing intellectual property rights in connection with Recipient's rights and obligations pursuant to this Agreement; and (iii) in connection with exercising its rights hereunder, to its Affiliates, potential and future bona fide collaborators (including Sublicensees, potential and permitted acquirers or assignees and potential investment bankers, investors and lenders);

9.3 Confidential Terms. Each of the Parties agrees not to disclose to any Third Party the terms and conditions of this Agreement without the prior approval of the other Party, except to advisors (including financial advisors, attorneys and accountants), potential and existing bona fide investors, financing sources, merger or other business partners and acquirers, and others on a need to know basis, in each case under circumstances that reasonably protect the confidentiality thereof, or to the extent required by applicable law.

9.4 SEC or Similar Filings. Either Party may disclose the terms of this Agreement and events related to the development or commercialization of Licensed Products (including the receipt of milestone payments) to the extent reasonably required to comply with applicable laws, rules and regulations, including, without limitation, the rules and regulations promulgated by the United States Securities and Exchange Commission comparable foreign

regulator and self-regulatory organizations (such as securities exchanges). Subject to the foregoing, before disclosing this Agreement or any of the terms hereof or other events pursuant to this Section 9.4, the Parties will reasonably consult with one another on the terms of this Agreement to be redacted in making any such disclosure and the scope of such disclosure. The disclosing Party agrees, at its own expense, to seek confidential treatment of portions of this Agreement, or such terms, as may be reasonably and timely requested by the other Party.

9.5 Injunctive Relief Authorized. Each Party as a Recipient acknowledges and agrees that (a) the Confidential Information of Discloser is of a special, unique, unusual, extraordinary and intellectual character; (b) the unauthorized use or disclosure of any Confidential Information of Discloser would constitute a material breach of this Agreement; (c) the interests of Discloser in and to the Confidential Information would be irreparably injured by the unauthorized use or disclosure of such information; and (d) money damages would not be sufficient to compensate Discloser for any such unauthorized use or disclosure. Accordingly, Recipient agrees that, in addition to any other remedies available to Discloser at law, in equity or under this Agreement, Discloser shall be entitled to seek specific performance, injunctive relief and other equitable relief to prevent any actual or threatened use or disclosure of the Confidential Information of Discloser without obligation to post any bond.

## 10. PATENTS

### 10.1 Prosecution and Maintenance.

10.1.1 Licensed Patents. From and after the Effective Date, Processa shall be responsible for and shall control, in its sole discretion, the filing, prosecution, and maintenance of the Licensed Patents. In connection with such activities, Processa shall have the right to transfer the responsibility for such filing, prosecution and maintenance of the Licensed Patents to patent counsel (outside or internal) selected by Processa and reasonably acceptable to Akashi, and Akashi shall cooperate with Processa as reasonably requested by Processa, and at Processa's expense, to facilitate control of such filing, prosecution and maintenance by Processa. In any event, Processa shall pay for all costs and expenses incurred during the term of this Agreement in preparing, filing, prosecuting, and maintaining the Licensed Patents as set forth herein. In the event that Processa decides not to continue the prosecution or maintenance of any Licensed Patent in any country, Processa shall provide Akashi with notice of this decision at least thirty (30) days prior to any pending lapse or abandonment thereof and will allow Akashi to assume responsibility therefor. In the event that Akashi elects to assume responsibility for such prosecution or maintenance, Akashi shall have the right to transfer the responsibility for such filing, prosecution and maintenance of such Licensed Patent(s) to patent counsel (outside or internal) selected by Akashi, and Processa shall cooperate with Akashi as reasonably requested by Akashi, and at Akashi's expense, to facilitate control of such prosecution and maintenance by Akashi. Akashi shall pay for all costs and expenses incurred by it in preparing, filing, prosecuting, and maintaining any patents and patent applications for which Akashi has elected to assume responsibility for prosecution or maintenance.

10.1.2 Foreground Patents. Processa shall be responsible for and shall control, in its sole discretion, the preparation, filing, prosecution, and maintenance of the

Foreground Patents. Processa shall pay for all costs and expenses incurred in preparing, filing, prosecuting, and maintaining the Foreground Patents.

10.2 Enforcement.

10.2.1 Generally. Each Party shall notify the other Party of any infringement known to such Party of any Licensed Patent or Foreground Patent by a Third Party that is manufacturing, using, offering for sale, selling or importing a product that is utilizing, comprises, contains or constitutes HT-100 or a Licensed Product (each, a "**Product Infringement**") and shall provide the other Party with the available evidence, if any, of such infringement.

10.2.2 Licensed Patents.

(a) With respect to any Product Infringement that occurs during the term of this Agreement, Processa shall have the sole right, but not the obligation, to enforce the Licensed Patents with respect to any such Product Infringement or otherwise abate such Product Infringement. In such event, Processa shall have the right to control any litigation or other enforcement action and to enter into, or permit, the settlement of any such litigation or other enforcement action with respect to the Licensed Patents and such Product Infringement, and shall consider, in good faith, the interests of Akashi in so doing. Akashi agrees to cooperate reasonably with Processa in any action to enforce the Licensed Patents with respect to Product Infringements under this Section 10.2.2, including by executing reasonably appropriate documents, cooperating in discovery and joining as a party in any such suit if deemed a necessary party, provided that Processa reimburses Akashi promptly for any costs and expenses incurred by Akashi in providing such assistance and cooperation. Processa shall pay for all other costs and expenses incurred in connection with such enforcement action.

(b) Notwithstanding Section 10.2.2(a), Processa shall not settle any enforcement action under this Section 10.2 or otherwise consent to an adverse judgment in such action that adversely affects the rights or interests of Akashi without the prior written consent of Akashi.

(c) All monies recovered upon the final judgment or settlement of any such suit to enforce the Licensed Patents with respect to a Product Infringement pursuant to this Section 10.2.2 shall be first used to reimburse each Party pro rata for the costs and expenses incurred in connection with such suit, and the remainder, if any, shall be retained by Processa in its entirety, and shall be deemed Net Sales of Licensed Products in the Territory made by Processa and subject to sales milestones payments pursuant to Section 4.3 and royalty payments pursuant to Section 4.4.

10.2.3 Foreground Patents.

(a) Processa, at its sole cost, shall have the sole right, but not the obligation, to enforce the Foreground Patents with respect to any Product Infringement or otherwise abate such Product Infringement. In such event, Processa shall have the right to control any litigation or other enforcement action and to enter into, or permit, the settlement of any such litigation or other enforcement action with respect to the Foreground Patent and such Product

Infringement, and shall consider, in good faith, the interests of Akashi in so doing. Akashi agrees to cooperate reasonably with Processa in any action to enforce the Foreground Patents with respect to Product Infringements under this Section 10.2.3, including by executing reasonably appropriate documents, cooperating in discovery and joining as a party in any such suit if deemed a necessary party, provided that Processa reimburses Akashi promptly for any costs and expenses incurred by Akashi in providing such assistance and cooperation.

(b) All monies recovered upon the final judgment or settlement of any such suit to enforce the Foreground Patents with respect to a Product Infringement pursuant to this Section 10.2.3 shall be first used to reimburse each Party for the costs and expenses incurred in connection with such suit, and the remainder, if any, shall be retained by Processa in its entirety.

## 11. TERMINATION

11.1 Expiration. Subject to early termination pursuant to the provisions of Sections 11.2, 11.3, and 11.4 below, this Agreement shall expire on the expiration of all of Processa's obligations to pay royalties to Akashi under Section 4.4 above. Upon expiration of the Royalty Term, on a Licensed-Product-by-Licensed Product and country-by-country basis, the licenses granted to Processa by Akashi under this Agreement with respect to the relevant Licensed Product and country shall be fully paid-up and irrevocable.

11.2 Termination by Processa. Processa may terminate this Agreement in its entirety, in its sole discretion, at any time upon ninety (90) days prior written notice to Akashi.

11.3 Termination for Cause. Either Party will have the right to terminate this Agreement in full upon delivery of written notice to the other Party in the event of any material breach by the other Party of any material terms and conditions of this Agreement (a "**Material Breach**"), provided, that such termination will not be effective if such breach has been cured within sixty (60) days (fifteen (15) days with respect to any payment breach) after written notice thereof is given by the non-breaching Party to the breaching Party specifying in reasonable detail the nature of the alleged breach; *provided that* if the allegedly breaching Party notifies the non-breaching Party in writing within thirty (30) days of its receipt of the relevant notice of breach provided pursuant to this Section 11.3 that it disputes in good faith that it has committed a Material Breach, or that it has not timely cured such breach, then such termination shall not be effective unless and until the dispute is resolved in the favor of the non-breaching Party pursuant to Section 13.4, and if Akashi is the allegedly breaching Party, the due date for all payments that become due to Akashi hereunder prior to resolution of the dispute shall be tolled unless and until (i) the dispute is resolved in favor of Akashi, or Processa does not effectuate termination of this Agreement upon resolution of the dispute, in which event they shall be payable in full to Akashi within ten (10) days of such event, or (ii) the dispute is resolved in favor of Processa and Processa terminates the Agreement, in which event fifty percent (50%) of the tolled payment shall be due within ten (10) days of any election by Processa to retain its license after termination as permitted in Section 11.5.1.

11.4 Termination for Patent Challenges. If, during the term of this Agreement, Processa or any of its Affiliates or Sublicensees (a) commences or participates in any action or proceeding (including any patent opposition or re-examination proceeding), or otherwise asserts

any claim, challenging or denying the validity or enforceability of any claim of Akashi's or its Affiliates' patents or patent applications that are licensed to Processa under this Agreement or (b) knowingly assists any other Person in bringing or prosecuting any action or proceeding (including any patent opposition or re-examination proceeding) challenging or denying the validity or enforceability of any claim of Akashi's or its Affiliates' patents or patent applications that are licensed to Processa under this Agreement (each of (a) and (b), a "**Patent Challenge**"), then, to the extent permitted by applicable laws, Akashi shall have the right, in its sole discretion, to give notice to Processa that Akashi intends to terminate the license(s) granted to Processa under such patents and applications pursuant to this Agreement sixty (60) days following such notice, and, unless Processa withdraws or causes to be withdrawn all such Patent Challenge(s) within such sixty (60) day period, Akashi shall have the right to terminate the licenses granted to Processa under such patents and applications pursuant to this Agreement by providing written notice thereof to Processa.

11.5 Effect of Expiration or Termination. Upon termination by Akashi under Sections 11.3 or 11.4 of this Agreement, or by Processa under Section 11.2 or Section 11.3 of this Agreement:

11.5.1 Termination of Licenses. All rights and licenses granted to Processa hereunder shall terminate; *provided*, *however*, that if this Agreement is terminated by Processa in accordance with Section 11.3 due to Material Breach by Akashi, Processa may elect in writing within thirty (30) days of the termination date to retain the rights granted to it pursuant to Article 3, in which event the licenses granted hereunder shall continue in accordance with the terms of this Agreement, and associated payments shall be made to Akashi in accordance with the terms of Article 4, but at a rate of 50% of the amounts otherwise due.

11.5.2 Transfer of Development Activities and Know-How. Upon any termination where Processa does not elect to retain rights as permitted in Section 11.5.1:

(a) If Processa is conducting any development activity with respect to HT-100 or any Licensed Product on the date of notice of termination, and then Akashi shall notify Processa within sixty (60) days after the notice of termination: (i) with regard to any clinical trial, whether Akashi elects to have Processa: (A) complete such clinical trial on behalf of Akashi (unless Processa has material safety concerns regarding continuation of such clinical trial of which it has notified Akashi in writing), (B) wind down such clinical trial as soon as practicable or (C) transfer such clinical trial to Akashi as soon as practicable, in each case, subject to compliance with ethical, legal and contractual requirements; and (ii) with regard to any other development activity, whether Akashi elects to have Processa wind down or transfer such activity to Akashi.

(b) If Akashi notifies Processa of its election to have Processa wind down such clinical trial or other development activity (or fails to provide notice within such sixty (60) day period), then Processa shall wind-down such clinical trial or development activity as soon as practicable, subject to compliance with ethical, legal and contractual requirements.

(c) If Akashi notifies Processa of its election to have Processa transfer such clinical trial or other development activity to Akashi, then Processa shall use

Commercially Reasonable Efforts to transfer, and Akashi shall use Commercially Reasonable Efforts to assume, such clinical trial or other development activity as promptly as practicable (and, in any event, within three (3) months) after the effective date of termination.

(d) To the extent any Know-How Controlled by Processa, its Affiliates or Sublicensees that specifically relates to HT-100 or any Licensed Products is not transferred to Akashi pursuant to subsections (a) through (c) above, Processa will transfer and assign such Know-How to Akashi or its designee within ninety (90) days of the effective date of termination.

(e) The activities set forth in this Section 11.5.2 shall be performed at Processa's expense, unless Processa terminates this Agreement pursuant to Section 11.3 for Akashi's material breach, in which case such activities shall be at Akashi's expense.

11.5.3 Confidential Information. Processa shall, within sixty (60) days after the effective date of termination and at Processa's expense, return or destroy, at Akashi's election, all Licensed Know-How and other Confidential Information of Akashi (provided that Processa may keep one copy of such Confidential Information for archival purposes only and such additional copies of or any computer records or files containing such Confidential Information that have been created solely by Processa's automatic or routine archiving and back-up procedures, to the extent created and retained in a manner consistent with Processa's standard archiving and back-up procedures, but not for any other use or purpose, subject to an ongoing obligation of confidentiality in accordance with Section 9). All Know-How assigned or transferred to Akashi pursuant to this Section 11.5 shall thereafter be deemed to be Confidential Information of Akashi for the purposes of Section 9. Accordingly, Akashi shall be deemed the Discloser and Processa shall be deemed the Recipient with respect to such information, and Section 1.4(d) shall not apply to such information.

11.5.4 Product Records/Filings. Processa shall, and hereby does, and shall cause its Affiliates and Sublicensees to, assign to Akashi, as of the effective date of termination, all its right, title and interest in, to and under all of Processa's and its Affiliates' and Sublicensees' ownership interest in any and all Product Records/Filings, including any Regulatory Approvals for the Products, and Processa shall transfer or cause to be transferred all such Product Records/Filings to Akashi promptly after the effective date of termination.

11.5.5 License. Processa shall, and hereby does, and shall cause its Affiliates and Sublicensees to, grant to Akashi, as of the effective date of termination, an exclusive, perpetual, irrevocable, royalty-free, sublicensable (through multiple tiers) license, under all Patents, Know-How and other intellectual property Controlled by Processa, its Affiliates or Sublicensees as of the effective date of termination (and not subject to assignment to Akashi hereunder) solely to the extent necessary or specifically useful to Exploit HT-100 and Licensed Products in the Territory.

11.5.6 Inventory. At Akashi's request, Processa shall assign and transfer to Akashi any inventory of HT-100 and Licensed Products then in Processa's or any of its Affiliates' possession or control subject to Akashi's reimbursement of Processa's reasonable,

documented, out-of-pocket costs incurred in acquiring such inventory and with respect to shipping thereof.

11.5.7 Sublicenses. All sublicenses that are granted by Processa pursuant to this Agreement and in accordance with Section 3.2 where the Sublicensee is in compliance with its sublicense agreement and this Agreement as of the date of such termination will remain in effect and will be assigned to Akashi, provided that such Sublicensee agrees in writing to assume and perform all obligations of Processa hereunder, and provided further that Akashi will not be bound to perform any duties or obligations, or to grant any rights, set forth in any sublicense agreements that extend beyond the duties and obligations of Akashi, or grant of rights by Akashi, set forth in this Agreement.

11.5.8 Further Actions. Processa shall, and shall cause its Affiliates and Sublicensees to, take such other actions, and execute any instruments, assignments, and documents, as reasonably requested by Akashi as may be necessary to effect the foregoing provisions of this Section 11.5.

11.5.9 Termination Not Sole Remedy. For clarity, termination is not the sole remedy under this Agreement for any Material Breach and, whether or not termination is effected and notwithstanding anything contained in this Agreement to the contrary, all other remedies will remain available except as otherwise expressly set forth herein.

11.6 Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination, and the provisions of Sections 5.2, 6, 7, 9, 10, 11.5, 12 and 13 shall survive the expiration or termination of this Agreement.

## 12. INDEMNIFICATION

12.1 Indemnification by Processa. Processa shall defend, indemnify and hold Akashi and its Affiliates and their respective directors, officers, employees and agents harmless from all losses, liabilities, damages and expenses (including reasonable attorneys' fees and costs) (collectively, "**Losses**") resulting from any claims, demands, actions and other proceedings by any Third Party to the extent resulting from (a) Processa's or its Affiliates' or Sublicensees' use of the Licensed IP or Foreground IP or research, development, registration, use, manufacturing, commercialization, promotion, sale, storage, transportation or other disposition or Exploitation of HT-100 or any Licensed Product under this Agreement or (b) Processa's breach of this Agreement except to the extent such Losses are subject to Akashi's indemnification obligations under Section 12.2 below.

12.2 Indemnification by Akashi. Akashi shall defend, indemnify and hold Processa and its Affiliates and their respective directors, officers, employees and agents harmless from all Losses resulting from any claims, demands, actions and other proceedings by any Third Party to the extent resulting from the material breach of the representations and warranties made by Akashi or its Affiliates in this Agreement.

12.3 Procedure. The Party seeking indemnification (the "**Indemnified Party**") promptly shall notify the other Party (the "**Indemnifying Party**") of any claim, demand, action,

or other proceeding for which the Indemnified Party intends to claim indemnification. The Indemnifying Party shall have the right to participate in, and to the extent the Indemnifying Party so desires jointly with any other indemnitor similarly noticed, to assume the defense thereof with counsel selected by the Indemnifying Party; provided, however, that the Indemnified Party shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnified Party, if representation of the Indemnified Party by the counsel retained by the Indemnifying Party would be inappropriate due to actual or potential differing interests between the Indemnified Party and any other party represented by such counsel in such proceedings. The indemnity obligations under this Section 12 shall not apply to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the prior express written consent of the Indemnifying Party, which consent shall not be unreasonably withheld, conditioned, or delayed. The failure to deliver notice to the Indemnifying Party within a reasonable time after notice of any such claim or demand, or the commencement of any such action or other proceeding, if prejudicial to its ability to defend such claim, demand, action or other proceeding, shall relieve such Indemnifying Party of any liability to the Indemnified Party under this Section 12 with respect thereto, but the omission so to deliver notice to the Indemnifying Party shall not relieve it of any liability that it may have to the Indemnified Party other than under this Section 12. The Indemnifying Party may not settle or otherwise consent to an adverse judgment in any such claim, demand, action, or other proceeding, that diminishes the rights or interests of, or places any obligations upon, the Indemnified Party without the prior express written consent of the Indemnified Party, which consent shall not be unreasonably withheld, conditioned, or delayed. The Indemnified Party, its employees and agents, shall reasonably cooperate with the Indemnifying Party and its legal representatives in the investigation of any claim, demand, action, or other proceeding covered by this Section 12.

12.4 LIMITATION OF DAMAGES. IN NO EVENT SHALL EITHER PARTY BE LIABLE HEREUNDER TO THE OTHER PARTY FOR ANY PUNITIVE, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING LOST REVENUE, LOST PROFITS OR LOST SAVINGS, EXCEPT TO THE EXTENT CONSTITUTING DIRECT DAMAGES) HOWEVER CAUSED AND UNDER ANY THEORY, EVEN IF IT HAS NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. THE LIMITATIONS SET FORTH IN THIS SECTION 12.4 SHALL NOT APPLY WITH RESPECT TO (I) ANY BREACH OF SECTION 9 OR (II) THE INTENTIONAL MISCONDUCT OR GROSS NEGLIGENCE OF A PARTY. NOTHING IN THIS SECTION 12.4 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF A PARTY UNDER THIS SECTION 12 WITH RESPECT TO ANY DAMAGES OWED OR PAID TO A THIRD PARTY IN CONNECTION WITH A THIRD PARTY CLAIM.

12.5 Insurance.

12.5.1 Processa shall maintain at its own cost and at all times during the term of this Agreement policies of insurance consistent with normal business practices of prudent pharmaceutical companies similarly situated. Such insurance policies shall include, without limitation, commercial general liability insurance, including, without limitation, product liability, covering claims for damages because of bodily injury (including, without limitation, death), personal injury, and property damage arising out of Processa's acts or omissions and including coverage for contractual liabilities. Without limiting the foregoing, no later than Processa's

commencement of clinical trials in respect of any Licensed Product, Processa shall obtain, and maintain in full force and effect, adequate clinical trials insurance, for claims arising out of or in connection with such clinical trials. In addition, no later than the commencement of commercial distribution of any Licensed Product by or on behalf of Processa, Processa shall obtain, and maintain in full force and effect, adequate general and product liability insurance for bodily injury and property damage claims.

12.5.2 The policies described in Section 12.5.1 above will be in such amounts and cover such risks as are reasonable and prudent for those types of policies, but shall in no event be less than, in the aggregate: (a) one million U.S. dollars (US$1,000,000) as of the Effective Date, (b) ten million U.S. dollars (US$10,000,000) as of the commencement of any clinical trial of Licensed Product and for so long as such clinical trials are continuing, and (c) twenty million U.S. dollars (US$20,000,000) as of the commercial launch of any Licensed Product and for so long as sales of Licensed Products are continuing. Such policies will be written by insurance companies with an A.M. Best's rating of A:VIII or higher (or if such policies are not subject to the Best rating, then by carriers who are reasonably acceptable to Akashi). The foregoing policies will: (i) cover claims arising out of the performance of this Agreement that are made within a period of not less than six (6) years after the expiration or earlier termination of this Agreement; and (ii) be primary and non-contributory to any liability insurance carried by Akashi, which insurance will be excess for claims and losses arising out of the performance of this Agreement. The policies described above will be specifically endorsed to list Akashi as an additional insured, and Processa will notify Akashi at least sixty (60) days in advance of any cancellation or non-renewal of or material changes in of such insurance coverage. Processa shall provide Akashi with a valid, current certificate of insurance as evidence of the insurance required herein upon request. Maintenance of such insurance coverage will not relieve Processa of any responsibility under this Agreement for damages in excess of insurance limits or otherwise.

## 13. MISCELLANEOUS

13.1 Notices. Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties to the other shall be in writing and addressed to such other Party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor for purposes of this Section 13.1, and shall be effective upon receipt by the addressee.

If to Akashi:

Akashi Therapeutics, Inc.
635 Main Street, Suite 3
Great Barrington, MA 01230

Attention: Tom Wicka

If to Processa:

Processa Pharmaceuticals, Inc.
7380 Coca Cola Drive, Suite 106
Hanover, MD 21076
Attn: Wendy Guy

13.2 Assignment. Except as otherwise expressly provided under this Agreement, neither this Agreement nor any of Processa's rights or obligations hereunder may be assigned or otherwise transferred (whether voluntarily, by operation of law or otherwise) by Processa without the prior express written consent of Akashi, which will not be unreasonably withheld, conditioned, or delayed; provided, however, that such consent shall not be required in connection with the sale of substantially all of the assets of Processa to which this Agreement relates, or in the case of a merger, consolidation or other reorganization of Processa, subject in each case to the assignee agreeing in writing to be bound by the terms of this Agreement and with notice thereof to be provided to Akashi. Akashi may assign this Agreement or any of its rights or obligations under this Agreement to any Third Party without Processa's consent. In the case of any permitted assignment or transfer of or under this Agreement, this Agreement shall be binding upon, and inure to the benefit of, the successors, executors, heirs, representatives, administrators and assignees of the Parties hereto. Any permitted assignee shall assume in writing all obligations of its assignor under this Agreement. Any purported assignment or transfer in violation of this Section 13.2 shall be void.

13.3 Governing Law; Costs. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without regard to the conflicts of law principles thereof.

13.4 Dispute Resolution.

13.4.1 Resolution by Senior Executives. The Parties shall seek to settle amicably any and all disputes or differences arising out of or in connection with this Agreement ("**Dispute**"). Any Dispute between the Parties shall be promptly presented to the Chief Executive Officer of Processa and the Chief Executive Office of Akashi, or their respective designees, for resolution. Such officers, or their designees, shall attempt in good faith to promptly resolve such Dispute.

13.4.2 Arbitration. If a dispute between the Parties arising out of or relating to the validity or interpretation of, compliance with, breach or alleged breach of or termination of this Agreement cannot be resolved within thirty (30) days of presentation to the Chief Executive Officers, or their respective designees, for resolution, either Party may refer such dispute to binding arbitration to be conducted as set forth below in this Section 13.4.2.

(a) A Party may submit such dispute to arbitration by notifying the other Party, in writing, of such dispute. The number of arbitrators shall be one. Within thirty (30) days after receipt of such notice, the Parties shall designate in writing a single arbitrator to resolve the dispute; provided, however, that if the Parties cannot agree on an arbitrator within such thirty (30) day period, the arbitrator shall be selected by the New York, NY, office of the American Arbitration Association (the "AAA") or, if such office does not exist or is unable to make a selection, by the office of the AAA nearest to New York, NY. The arbitrator shall have scientific and legal experience relevant to the subject matter of the dispute. In any case the arbitrator shall not be an Affiliate, employee, consultant, officer, director or stockholder of either Party, or otherwise have any current or previous relationship with either Party or their respective Affiliates. The governing law in Section 13.3 shall govern any such proceedings. The language of the arbitration shall be English.

(b) Within sixty (60) days after the designation of the arbitrator, the arbitrator and the Parties shall meet, and each Party shall provide to the arbitrator a written summary of all disputed issues, such Party's position on such disputed issues and such Party's proposed ruling on the merits of each such issue.

(c) The arbitrator shall set a date for a hearing, which shall be no later than thirty (30) days after the submission of written proposals pursuant to Section 13.4.2(b), for the presentation of evidence and legal argument concerning each of the issues identified by the Parties. The Parties shall have the right to be represented by counsel. Except as provided herein, the arbitration shall be governed by the Commercial Arbitration Rules of the AAA applicable at the time of the notice of arbitration pursuant to Section 13.4.2(a); provided, however, that the Federal Rules of Evidence shall apply with regard to the admissibility of evidence in such hearing. In any such arbitration proceeding, the Parties shall be entitled to all remedies to which they would be entitled in a United States District Court and to full discovery to the same degree permitted under the Federal Rules of Civil Procedure.

(d) The arbitrator shall use his or her best efforts to rule on each disputed issue within thirty (30) days after completion of the hearing described in Section 13.4.2(c). The determination of the arbitrator as to the resolution of any dispute shall be binding and conclusive upon all Parties. All rulings of the arbitrator shall be in writing and shall be delivered to the Parties except to the extent that the Commercial Arbitration Rules of the AAA provide otherwise. Nothing contained herein shall be construed to permit the arbitrator to award punitive, exemplary or any similar damages. The arbitrator shall render a "reasoned decision" within the meaning of the Commercial Arbitration Rules, which shall include findings of fact and conclusions of law.

(e) The (i) attorneys' fees of the Parties in any arbitration, (ii) fees of the arbitrator and (iii) costs and expenses of the arbitration shall be borne by the Parties in a proportion determined by the arbitrator.

(f) Any arbitration pursuant to this Section 13.4.2 shall be conducted in a place to be mutually agreed, provided that if the Parties cannot agree on such place, the arbitration shall be conducted in New York, NY. Any arbitration award may be entered in and enforced by a court in accordance with Section 13.3.

(g) Notwithstanding anything in this Section 13.4, each Party shall have the right to seek injunctive or other equitable relief from a court of competent jurisdiction that may be necessary to avoid irreparable harm, maintain the status quo or preserve the subject matter of the arbitration.

13.5 Entire Agreement. This Agreement contains the entire understanding of the Parties with respect to the subject matter hereof. There are no agreements, representations, warranties, covenants, or undertakings with respect to the subject matter hereof other than those expressly set forth herein. All express or implied representations, agreements and understandings relating to such subject matter, either oral or written, heretofore made are expressly superseded by this Agreement, including, without limitation the Confidentiality Agreement.

13.6 Modifications. The terms and conditions of this Agreement may not be amended or modified, except in a writing signed by both Parties.

13.7 Independent Contractors. Each Party hereby acknowledges that the Parties shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture, or agency. Neither Party shall have the authority to make any statements, representations, or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior consent of the other Party to do so.

13.8 Remedies. All remedies, either under this Agreement, by law, or otherwise afforded to any Party, shall be cumulative and not alternative.

13.9 Force Majeure. Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement solely to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including but not limited to fire, floods, embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority or the other Party. If any such event continues for more than ninety (90) days, then such other Party shall have the right to terminate this Agreement upon sixty (60) days prior written notice to the affected Party.

13.10 Fees and Expenses. Each Party shall pay its own costs and expenses in connection with this Agreement and the transactions contemplated hereby (including the fees and expenses of its advisers, accountants, and legal counsel).

13.11 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the U.S. Bankruptcy Code to the extent permitted thereunder. The Parties shall retain and may fully exercise all of their respective rights and elections under the U.S. Bankruptcy Code. Upon the bankruptcy of any Party, the non-bankrupt Party shall further be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property (solely to the extent that such license in effect at such time), and such, if not already in its possession, shall be promptly delivered to the non-bankrupt Party, unless the bankrupt Party elects to continue, and continues, to perform all of its obligations under this Agreement.

13.12 Further Assurances. At any time or from time to time after the date hereof, the Parties agree to cooperate with each other, and at the request of the other Party, to execute and deliver any further instruments or documents and to take all such further action as the other Party may reasonably request in order to evidence or effectuate the consummation of the transactions contemplated hereby and to otherwise carry out the intent of the Parties hereunder.

13.13 Interpretation. The captions to the Sections of this Agreement are not a part of this Agreement, however, are included for convenience of reference and shall not affect its

meaning or interpretation. In this Agreement: (i) the word "including," "includes," "included," and "include" shall be deemed to be followed by the phrase "without limitation" or like expression; (ii) the singular shall include the plural and *vice versa*; (iii) masculine, feminine, and neuter pronouns and expressions shall be interchangeable; (iv) the words "hereof," "herein," "hereto," "hereby," "hereunder," and derivative or similar words refer to this Agreement as an entirety and not solely to any particular provision of this Agreement; (v) each reference in this Agreement to a particular Section, appendix, schedule, or exhibit means a Section, appendix, schedule, or exhibit of or to this Agreement, as amended in accordance with Section 13.5, unless another agreement is specified; (vi) "the word "will" shall be construed to have the same meaning and effect as the word "shall"; (vii) "or" is not disjunctive (i.e., it means "and/or") unless the context clearly requires otherwise; (viii) references to any Party or Person shall include its permitted successors or assigns; and (ix) whenever this Agreement refers to a number of days, such number shall refer to calendar days unless business days are specified; and business days means any day, except Saturday and Sunday, on which commercial banking institutions in New York, New York are open for business. This Agreement has been prepared jointly and shall not be strictly construed against either Party.

13.14 Waivers. It is agreed that no delay or omission to exercise any right, power or remedy accruing to any Party, upon any breach, default or noncompliance by the other Party under this Agreement, shall impair any such right, power or remedy, nor shall it be construed to be a waiver of any such breach, default or noncompliance, or any acquiescence therein, or of or in any similar breach, default or noncompliance thereafter occurring. It is further agreed that any waiver, permit, consent or approval of any kind or character on the part of any Party hereto of any breach, default or noncompliance under this Agreement or any waiver on such Party's part of any provisions or conditions of this Agreement, must be in writing and shall be effective only to the extent specifically set forth in such writing. The waiver by a Party of any right hereunder, or of any failure to perform or breach by the other Party hereunder, shall not be deemed a waiver of any other right hereunder or of any other breach or failure by the other Party hereunder whether of a similar nature or otherwise.

13.15 Severability. Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, all other provisions shall continue in full force and effect, and the Parties shall substitute for the invalid, illegal or unenforceable provision a valid, legal and enforceable provision which conforms as nearly as possible with the original intent of the Parties.

13.16 Enforcement. Each Party hereto acknowledges that money damages would not be an adequate remedy in the event that any of the covenants or agreements in this Agreement are not performed by the Parties in accordance with its terms, and it is therefore agreed that in addition to and without limiting any other remedy or right each Party may have, each Party will have the right to seek an injunction, temporary restraining order or other equitable relief in any court of competent jurisdiction enjoining any such breach and enforcing specifically the terms and provisions hereof.

13.17 Extension to Affiliates. Processa shall have the right to extend the rights and obligations granted in this Agreement to one or more of its Affiliates, subject to any relevant requirements of Section 3.2.1. All applicable terms and provisions of this Agreement shall apply

to any such Affiliate to which this Agreement has been extended to the same extent as such terms and provisions apply to Processa. Processa shall remain directly liable for any acts or omissions of its Affiliates, and Processa hereby expressly waives any requirement that Akashi exhaust any right, power or remedy, or proceed directly against such Affiliate, for any obligation or performance hereunder prior to proceeding directly against Processa.

13.18 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

*[Signature Page Follows.]*

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

AKASHI THERAPEUTICS, INC.

By DocuSigned by: Thomas Wicka 05DEEEC1037F480...

Name Thomas Wicka

Title CEO

PROCESSA PHARMACEUTICALS, INC.

By DocuSigned by: Wendy Guy 3E95D4CBD5424AF...

Name Wendy Guy

Title Chief Administrative Officer

*[Signature Page to License Agreement]*

**Exhibit 10.9**

# LICENSE AGREEMENT

**BY AND BETWEEN**

**PROCESSA PHARMACEUTICALS, INC.**

**AND**

**APOSENSE LTD**

**DATED AS OF MAY 24, 2020**

**TABLE OF CONTENTS [TO BE UPDATED PRIOR TO EXECUTION]**

**LICENSE AGREEMENT**

**THIS LICENSE AGREEMENT** is entered into this 24th day of May 2020 (the "Effective Date"), by and between Processa Pharmaceuticals, Inc. a company organized under the laws of Delaware, having a business address at 7380 Coca Cola Drive, Suite 106, Hanover, MD 21076 ("Processa"), and Aposense LTD, a company in Israel whose principal place of business is at 5-7 Ha'Odem St., Petach Tikva, Isreal ("Aposense").

WHEREAS, Aposense has developed or obtained rights to Aposense Know-How, Aposense Patent Rights and the Aposense Compound (each as defined below); and

WHEREAS, Processa desires to obtain a license the Aposense Patent Rights and the Aposense Know-How to Develop and Commercialize Compounds and Products (each as defined below), under the terms and conditions set forth herein, and Aposense desires to grant such a license;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, the Parties agree as follows:

## ARTICLE I
## DEFINITIONS

The following terms, whether used in the singular or plural, shall have the following meanings:

1.1 "Affiliate". Affiliate means any Person directly or indirectly controlled by, controlling or under common control with, a Party, but only for so long as such control shall continue. For purposes of this definition, "control" (including, with correlative meanings, "controlled by", "controlling" and "under common control with") means, with respect to a Person, possession, direct or indirect, of (a) the power to direct or cause direction of the management and policies of such Person (whether through ownership of securities or partnership or other ownership interests, by contract or otherwise), or (b) at least 50% of the voting securities (whether directly or pursuant to any vested and exercisable option, warrant or other similar arrangement) or other comparable equity interests. For clarity, neither of the Parties shall be deemed to be an "Affiliate" of the other.

1.2 "Bankruptcy Code". Bankruptcy Code means Title 11 of the U.S. Code, as amended from time to time.

1.3 "Business Day". Business Day means a day that is not a Saturday, Sunday or a day on which banking institutions in Baltimore, Maryland or Petach Tikva, Isreal are authorized by Law to remain closed.

1.4 "Calendar Quarter". Calendar Quarter means each of the periods ending on March 31, June 30, September 30, and December 31 of any Calendar Year.

1.5 "Calendar Year". Calendar Year means each calendar year during the Term.

1.6 "Combination Product". Combination Product means (a) any pharmaceutical product that is a single formulation consisting of a Compound and one or more other active compounds or active ingredients, which other active compounds or active ingredients are not Compounds ("Other API") or (b) any combination of a Compound sold together with any separately formulated Other API for a single invoiced price.

1.7 "Commercialization" or "Commercialize". Commercialization or Commercialize means activities directed to obtaining pricing and reimbursement approvals, marketing, promoting, Manufacturing commercial supplies of, distributing, importing, offering for sale, or selling a product.

1.8 "Commercially Reasonable Efforts". Commercially Reasonable Efforts means, with respect to an objective, the reasonable, diligent, good faith efforts of a Party (including the efforts of its Affiliates and Sublicensees) to accomplish such objective that a biopharmaceutical company of comparable size and resources would normally use to accomplish a similar objective under similar circumstances, and, specifically with respect to obligations hereunder relating to a Compound or Product, the carrying out of such obligations with those efforts and resources that a biopharmaceutical company of comparable size and resources would use were it Developing, Manufacturing or Commercializing its own pharmaceutical products that are at a similar stage of development or product life cycle and of similar market potential as the Compound or Product, taking into account actual and potential issues of safety, efficacy or stability, product profile (including product modality, category and mechanism of action), stage of development or life cycle status, product labeling or anticipated labeling, the present and future market potential, past performance of the Compound or Product, actual and projected Development, Regulatory Approval, pricing and reimbursement approval, Manufacturing and Commercialization costs, existing or projected pricing, sales, reimbursement and financial return, medical and clinical considerations, present and future regulatory environment, any issues regarding the ability to Manufacture the Compound or Product, the likelihood and timing of obtaining Regulatory Approvals and pricing and reimbursement approvals, proprietary position, strength and duration of patent protection and anticipated exclusivity, competitive Third Party products at the time and the likely competitive environment at the time of projected entry into the market and thereafter, and any other relevant scientific, technical, operational and commercial factors, all as measured by the facts and circumstances at the time such efforts are due. Commercially Reasonable Efforts will be determined on a country-by-country and indication-by-indication basis for the Compound or Product, and the level of effort is expected to change over time, reflecting changes in the status and value of the Compound or Product and the market conditions and country(ies) involved.

1.9 "Compound". Compound means ATT-11T together with together with all analogs, derivatives, metabolites, stereoisomers, polymorphs, formulations, mixtures or compositions thereof, and any existing or future improved or modified versions of the foregoing developed by or on behalf of Processa, its Affiliates or Sublicensees.

1.10 "Aposense Intellectual Property". Aposense Intellectual Property means the Aposense Know-How and the Aposense Patent Rights.

1.11 "Aposense Know-How". Aposense Know-How means all Know-How that is Controlled by Aposense or any of its Affiliates as of the Effective Date or thereafter during the Term (other than any Know-How included in Joint Intellectual Property) that is necessary or useful to Develop, Manufacture or Commercialize any Compound or Product; provided, however, that, if Aposense is acquired by a Third Party, "Aposense Know-How" shall exclude any Know-How that (a) is Controlled by such Third Party or the Affiliates of such Third Party (other than Aposense and the Persons that were Aposense's Affiliates immediately prior to the closing of such acquisition transaction (such Affiliates, "Aposense Pre-Existing Affiliates")) ("Aposense Excluded Affiliates") and (b) was not Controlled by Aposense or any of the Aposense Pre-Existing Affiliates immediately prior to the closing of such acquisition transaction; provided further that, if, after the closing of such acquisition, any such Aposense Excluded Affiliate Develops or Commercializes any Compound or Product or otherwise performs any activities or obtains any rights with respect to any Compound or Product, such Affiliate will cease to be a Aposense Excluded Affiliate and applicable Know-How that is Controlled by such Affiliate shall be included in Aposense Know-How.

1.12 "Aposense Patent Rights". Aposense Patent Rights means all Patent Rights in the Territory that are Controlled by Aposense or any of its Affiliates as of the Effective Date or thereafter during the Term (other than Joint Patent Rights) that Cover any Compound or Product. The Aposense Patent Rights existing as of the Effective Date are set forth on Schedule 1.12; provided, however, that, if Aposense is acquired by a Third Party, "Aposense Patent Rights" shall exclude any Patent Rights that (a) are Controlled by such Third Party or the Affiliates of such Third Party (other than Aposense and Aposense Pre-Existing Affiliates) and (b) were not Controlled by Aposense or any of the Aposense Pre-Existing Affiliates immediately prior to the closing of such acquisition transaction; provided further that, if, after the closing of such acquisition, any such Aposense Excluded Affiliate Develops or Commercializes any Compound or Product or otherwise performs any activities or obtains any rights with respect to any Compound or Product, such Affiliate will cease to be a Aposense Excluded Affiliate and applicable Patent Rights that are Controlled by such Affiliate shall be included in Aposense Patent Rights.

1.13 "Clinical Trial" shall mean any study in which human subjects are dosed with a drug, whether approved or investigational, including any Phase I, II, III or IV clinical study.

1.14 "Control" or "Controlled". Control or Controlled means, with respect to any tangible property or intellectual property right or other intangible property, the possession (whether by ownership or license (other than by grant of a license to one Party by the other Party pursuant to this Agreement or by grant of a license or sublicense to a Sublicensee by Processa pursuant to a license or sublicense agreement)) by a Person of the ability to grant to another Person access to such tangible property or access to or a license or sublicense to such intellectual property right or other intangible property, as provided herein without violating the terms of any agreement with any other Person.

1.15 "Cover", "Covering" or "Covered". Cover, Covering or Covered means, with respect to a compound, product, technology, process or method that, in the absence of ownership of or a license granted under a Patent Right, the manufacture, use, offer for sale, sale or importation of such compound or product or the practice of such technology, process or method

would infringe such Patent Right (or, in the case of a Patent Right that has not yet issued, would infringe such Patent Right if it were to issue).

1.16 "Development" or "Develop". Development or Develop means pre-clinical, non-clinical and clinical drug research, discovery and development activities, including IND-enabling toxicology and other IND-enabling pre-clinical development efforts, stability testing, process development, compound property optimization, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, clinical pharmacology, Manufacturing supplies of compounds and products for pre-clinical, non-clinical and clinical use, clinical studies (including pre- and post-approval studies and investigator sponsored clinical studies), regulatory affairs, and Regulatory Approval and clinical study regulatory activities (excluding regulatory activities directed to obtaining pricing and reimbursement approvals).

1.17 "EMA". EMA means the European Medicines Agency and any successor agency.

1.18 "FDA". FDA means the U.S. Food and Drug Administration and any successor agency.

1.19 "Field". Field means all medical uses.

1.20 "First Commercial Sale". First Commercial Sale means, with respect to a Product in a country, the first sale of such Product in such country by Processa, any of its Affiliates or any Sublicensee to the first unrelated Third Party (excluding any Sublicensee) in such country for use or consumption of such Product in such country after receipt of the first Regulatory Approval for such Product in such country. Sales for purposes of testing the Product and sample purposes shall not be deemed a First Commercial Sale. For clarity, First Commercial Sale will be determined on a Product-by-Product and country-by-country basis, as applicable.

1.21 "Governmental Authority". Governmental Authority means any national, federal, state or local government, or political subdivision thereof, or any multinational organization or authority or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body.

1.22 "IND". IND means an investigational new drug application filed with the FDA with respect to a Compound or Product, or an equivalent application filed with the Regulatory Authority of a country or regulatory jurisdiction in the Territory other than the U.S., and all amendments and supplements thereto.

1.23 "Joint Intellectual Property". Joint Intellectual Property means the Joint Inventions and Joint Patent Rights.

1.24 "Know-How". Know-How means all unpatented technical information, trade secrets, formulae, standards, knowledge, directions, instructions, test protocols, procedures and

results, studies, analyses, raw material sources, data, manufacturing data, and any other confidential or proprietary interest in information.

1.25 "Law" or "Laws". Law or Laws means all laws, statutes, rules, regulations, orders, judgments, or ordinances of any Governmental Authority.

1.26 "Losses". Losses means any and all (a) claims, losses, liabilities, damages, fines, royalties, governmental penalties or punitive damages, deficiencies, interest, awards, judgments, and settlement amounts (including special, indirect, incidental, and consequential damages, lost profits, and Third Party punitive and multiple damages), and (b) in connection with all of the items referred to in clause (a) above, any and all costs and expenses (including reasonable counsel fees and all other expenses reasonably incurred in investigating, preparing or defending any litigation or proceeding, commenced or threatened).

1.27 "Major European Country". Major European Country means France, Germany, or the United Kingdom.

1.28 "Major Markets". Major Markets means, collectively, the U.S., each of the Major European Countries and Japan, and Major Market means any one of the foregoing.

1.29 "Manufacture" or "Manufacturing". Manufacture or Manufacturing means activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and storage of a product.

1.30 "MHLW". MHLW means the Japanese Ministry of Health, Labour and Welfare, and any successor agency.

1.31 "NDA". NDA means a New Drug Application, as defined in the Act, filed with the FDA with respect to a Compound or Product, or an equivalent application filed with the Regulatory Authority of a country in the Territory other than the U.S., and all amendments and supplements thereto.

1.32 "Net Sales". Net Sales means the gross amounts billed or invoiced by Processa, or any of its Affiliates or Sublicensees, to any Third Party that is not a Sublicensee with respect to sales of Products in the Territory, calculated in the same manner as reported in such Person's audited financial statements, less the following:

(a) Volume, cash or trade discounts, credits or allowances, including discounts in the form of inventory management fees paid to wholesalers and distributors all to the extent such discounts are included in the invoices and actually granted;

(b) Credits, refunds or allowances granted upon returns, rejections or recalls and for retroactive price reductions or billing errors;

(c) Freight, postage, shipping and insurance costs incurred in transporting the applicable Products to the extent that such items are applicable to such sale and are separately itemized and invoiced and actually paid as evidenced by invoices, receipts or other appropriate documents;

(d) Amounts paid (including rebates and chargeback payments or credits or other equivalents thereof) to formularies, government or government agency programs, trade customers, managed health care organizations and pharmacy benefit managers (or equivalents thereof) to obtain listing or purchase of the applicable Products not to exceed [__%] of the billed or invoiced amount;

(e) Bad debts, uncollectible amounts, and collection costs relating to the sale of Products that are actually written off; and

(f) To the extent not reimbursed by a third party, taxes, tariffs, duties or other governmental charges (other than income taxes) levied on, absorbed, or otherwise imposed on the sales, transportation, delivery, use, exportation, or importation of the applicable Products.

Sales of Products between Processa and its Affiliates or Sublicensees for resale shall be excluded from the computation of Net Sales, provided that the subsequent resale of such Products to a Third Party are included in the computation of Net Sales. Disposal or use of Products at or below cost for regulatory, development or charitable purposes, such as clinical trials, compassionate use, named patient use, or indigent patient programs, shall not be deemed a sale hereunder.

With respect to any sale of any Product in a given country for any substantive consideration other than monetary consideration on arm's length terms (which has the effect of reducing the invoiced amount below what it would have been in the absence of such non-monetary consideration), for purposes of calculating the Net Sales under this Agreement, such Product shall be deemed to be sold exclusively for cash at the average Net Sales price charged to Third Parties for cash sales in such country during the applicable reporting period (or if there were only *de minimis* cash sales in such country, at the fair market value as determined in good faith based on pricing in comparable markets).

If a Product is sold as part of a Combination Product, Net Sales will be the product of (x) Net Sales of the Combination Product calculated as above (*i.e.*, calculated as for a non-Combination Product) and (y) the fraction (A/(A+B)), where:

(i) A is the average selling price of the Product comprising a Compound as the sole therapeutically active ingredient during the most recently completed Calendar Quarter during which such non-Combination Product was sold in such country; and

(ii) B is the average selling price in such country of products containing the Other API contained in the Combination Product as the sole therapeutically active ingredient when sold separately during the most recently completed Calendar Quarter during which such products were sold in such country.

If both A and B cannot be determined by reference to non-Combination Product sales as described above, then Net Sales for purposes of determining royalty payments will be calculated as above, but the average selling price in the above equation shall be determined by mutual agreement reached in good faith by the Parties prior to the end of the accounting period in question based on an equitable method of determining same that takes into account, in the

applicable country, variations in dosage units and the relative fair market value of each therapeutically active ingredient in the Combination Product. If the Parties are unable to reach such an agreement prior to the end of the applicable accounting period, then the Parties will refer such matter to a jointly selected Third Party with expertise in the pricing of pharmaceutical products that is not an employee, consultant, legal advisor, officer, director or stockholder of, and does not have any conflict of interest with respect to, either Party for resolution, which will be final and binding on the Parties.

1.33 "Condition Precedent Period". Condition Precedent Period means the period of time beginning on the Effective Date and ending on the date nine (9) months after the Effective Date.

1.34 "Party". Party means either Aposense or Processa; "Parties" means both Aposense and Processa.

1.35 "Patent Rights". Patent Rights means all patent applications, patents, certificates of invention, applications for certificates of invention and priority patent filings, including any continuations, continuations-in-part, renewals, requests for continued examination and divisions of any such patents and patent applications, any patents or certificates of invention issuing from any of the foregoing, any extensions, reissues, reexaminations, substitutions, confirmations, registrations, revalidations, revisions, additions or supplementary patent certificates thereto, and all foreign counterparts thereof.

1.36 "Payments". Payments means royalties and other amounts payable by Processa to Aposense pursuant to this Agreement.

1.37 "Person". Person means any natural person or any corporation, company, partnership, joint venture, firm, Governmental Authority, or other entity, including a Party.

1.38 "Pivotal Clinical Trial" shall mean (a) a Phase III Clinical Trial that is intended by Company or its Affiliates or Sublicensees to be submitted (together with any other registration trials that are prospectively planned when such Phase III Clinical Trial is Initiated) for Regulatory Approval in the U.S. or the EU, or (b) any other Clinical Trial that is intended by Company or its Affiliates or Sublicensees to establish that a Product is safe and efficacious for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with such pharmaceutical product in the dosage range to be prescribed, which Clinical Trial is a registration trial intended by Company or its Affiliates or Sublicensees to be sufficient for filing an application for a Regulatory Approval for such product in the U.S. or another country or some or all of an extra-national territory, solely as evidenced by the acceptance for filing for a Regulatory Approval for such Product after completion of such Clinical Trial.

1.39 "Processa Intellectual Property" means, collectively, Processa Know-How and Processa Patent Rights.

1.40 "Processa Know-How". Processa Know-How means all Know-How Controlled as of the Effective Date or thereafter during the Term by Processa or any of its Affiliates (other than any Know-How included in Joint Intellectual Property) that is used by Processa or any of its

Affiliates in the Development, Manufacture or Commercialization of any Compound or Product; provided, however, that, if Processa is acquired by a Third Party, "Processa Know-How" shall exclude any Know-How that (a) is Controlled by such Third Party or the Affiliates of such Third Party (other than Processa and the Persons that were Processa's Affiliates immediately prior to the closing of such acquisition transaction (such Affiliates, "Processa Pre-Existing Affiliates")) ("Processa Excluded Affiliates") and (b) was not Controlled by Processa or any of the Processa Pre-Existing Affiliates immediately prior to the closing of such acquisition transaction; provided further that, if, after the closing of such acquisition, any such Processa Excluded Affiliate Develops or Commercializes any Compound or Product or otherwise performs any activities or obtains any rights with respect to any Compound or Product, such Affiliate will cease to be a Processa Excluded Affiliate and applicable Know-How that is Controlled by such Affiliate shall be included in Processa Know-How.

1.41 "Processa Patent Rights". Processa Patent Rights means all Patent Rights in the Territory Controlled as of the Effective Date or thereafter during the Term by Processa or any of its Affiliates (other than Joint Patent Rights) that Cover any Compound or Product and are used by Processa or any of its Affiliates in the Development, Manufacture or Commercialization of any Compound or Product; provided, however, that, if Processa is acquired by a Third Party, "Processa Patent Rights" shall exclude any Patent Rights that (a) are Controlled by such Third Party or the Affiliates of such Third Party (other than Processa and Processa Pre-Existing Affiliates) and (b) were not Controlled by Processa or any of the Processa Pre-Existing Affiliates immediately prior to the closing of such acquisition transaction; provided further that, if, after the closing of such acquisition, any such Processa Excluded Affiliate Develops or Commercializes any Compound or Product or otherwise performs any activities or obtains any rights with respect to any Compound or Product, such Affiliate will cease to be a Processa Excluded Affiliate and applicable Patent Rights that are Controlled by such Affiliate shall be included in Processa Patent Rights.

1.42 "Product". Product means any pharmaceutical preparation containing one or more Compounds as its only active ingredient(s) or any Combination Product. For the avoidance of doubt, nothing in this Agreement grants to Processa any right or license under any Patent Rights or Know-How Controlled by Aposense with respect to any Other API or with respect to any product, Compound, metabolite or derivative thereof which does not comprise of an active SN-38 molecule, irinotecan or analogue of SN-38 or irinotecan.

1.43 "Regulatory Approval". Regulatory Approval means an approval by the applicable Regulatory Authority of an NDA and any other approval, license, registration, permit, notification or authorizations (or waiver) of the applicable Regulatory Authority, which is necessary for the manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale, or other commercialization of pharmaceutical products in a given country or regulatory jurisdiction, other than any pricing or reimbursement approval.

1.44 "Regulatory Authority". Regulatory Authority means any Governmental Authority with responsibility for granting licenses or approvals necessary for the development, manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale or other commercialization of pharmaceutical products in a country or regulatory jurisdiction, including but limited to the FDA, EMA or MHLW.

1.45 "Regulatory Exclusivity". Regulatory Exclusivity means exclusive marketing rights or data protection or other exclusivity rights conferred by any Regulatory Authority with respect to a Product in a country or regulatory jurisdiction within the Territory, other than a Patent Right, including orphan drug exclusivity, pediatric exclusivity and rights conferred in the U.S. under the Hatch-Waxman Act.

1.46 "Satisfactory Financing Round". Satisfactory Financing Round means the first financing round that enables Processa to satisfy all of the conditions in Sections 2.1 and to define the class and series of capital stock of Processa to be issued to Aposense and the price per class of stock to be used in the Equity Investment calculation described in Section 6.1.

1.47 "Satisfactory Financing Round Securities". Satisfactory Financing Round Securities means shares of the same class and series of capital stock of Processa issued to other investors in the Satisfactory Financing Round.

1.48 "Senior Executive". Senior Executive means, with respect to Aposense, the CEO of Aposense, or his or her designee, and, with respect to Processa, the CEO of Processa, or his or her designee. "Senior Executives" means the applicable officers of Aposense and Processa.

1.49 "Sublicensee". Sublicensee means a Third Party that has been granted a sublicense under the rights granted to Processa pursuant to Section 2.2 of this Agreement), beyond the mere right to purchase Compound or Product from Processa or its Affiliates.

1.50 "Territory". Territory means all countries of the world excluding the People's Republic of China.

1.51 "Third Party". Third Party means any Person other than Aposense or Processa or any of their respective Affiliates.

1.52 "U.S.". U.S. means the United States of America, including its territories and possessions.

1.53 "Valid Claim". Valid Claim means any claim of (a) an issued and unexpired patent within the Aposense Patent Rights that has not been revoked or held unenforceable or invalid by a final decision of a court or other Governmental Authority of competent jurisdiction, or that has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise; or (b) a patent application within the Aposense Patent Rights; provided that such a claim within a patent application has not been canceled, withdrawn, or abandoned or been pending for more than seven (7) years from the date of its first priority filing in the applicable country. For clarity, a claim of a patent that, pursuant to clause (b), had ceased to be a Valid Claim before it issued but that subsequently issues and is otherwise described by clause (a), shall again be considered to be a Valid Claim once it issues until it is no longer considered a Valid Claim in accordance with clause (a).

1.54 Additional Definitions. Each of the following definitions is set forth in the Section of this Agreement indicated below:

| Definition: | Section: |
|---|---|
| Abandoned Patents | Section 7.2(a) |
| Agents | Section 8.1 |
| Commercialization Plan | Section 4.2 |
| Aposense | Preamble |
| Aposense Excluded Affiliates | Section 1.11 |
| Aposense Parties | Section 10.1 |
| Aposense Pre-Existing Affiliates | Section 1.11 |
| Aposense Sole Inventions | Section 7.1(a) |
| Confidential Information | Section 8.2 |
| Confidentiality Agreement | Section 8.2 |
| Courts | Section 12.1 |
| Effective Date | Preamble |
| Indemnified Party | Section 10.3(a) |
| Indemnifying Party | Section 10.3(a) |
| Infringement Claim | Section 7.3(a) |
| Joint Inventions | Section 7.1(b) |
| Joint Patent Rights | Section 7.2(b) |
| Late Payment Notice | Section 6.14 |
| Other API | Section 1.6 |
| Paragraph IV Claim | Section 7.8(a) |
| Product Liability Claim | Section 10.1(b) |
| Processa | Preamble |
| Processa Excluded Affiliates | Section 1.40 |
| Processa Parties | Section 10.2 |
| Processa Pre-Existing Affiliates | Section 1.40 |
| Processa Sole Inventions | Section 7.1(a) |
| Royalty Term | Section 6.6(a) |
| Sole Inventions | Section 7.1(a) |
| Sublicensee Intellectual Property | Section 2.2(b) |
| Taxes | Section 6.11 |
| Term | Section 11.1 |
| Third Party Claims | Section 10.1 |
| Third Party Patent Licenses | Section 6.6(c) |

1.55 Captions; Certain Conventions; Construction. All headings and captions herein are for convenience only and shall not be interpreted as having any substantive meaning. The Schedules to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. Unless otherwise expressly provided herein or the context of this Agreement otherwise requires:

(a) words of any gender include each other gender;

(b) words such as "herein", "hereof" and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear;

(c) words using the singular shall include the plural, and vice versa;

(d) the words "include," "includes" and "including" shall be deemed to be followed by the phrase "but not limited to", "without limitation", "inter alia" or words of similar import;

(e) the word "or" shall be deemed to include the word "and" (*i.e.*, shall mean "and/or")

(f) references to "Article," "Section," "subsection", "paragraph", "clause" or other subdivision, or to a Schedule, without reference to a document, are to the specified provision or Schedule of this Agreement; and

(g) references to "$" or "dollars" shall be references to U.S. Dollars.

This Agreement shall be construed as if the Parties drafted it jointly.

## ARTICLE II
## GRANTS OF RIGHTS

2.1 Condition Precedent.

(a) The grant of license rights is conditioned upon: (i) the Company's closing of the Satisfactory Financing Round and the up-listing of the Company's shares to the NASDAQ or NYSE, and (ii) Aposense obtaining the approval of the Israel Innovation Authority for the consummation of the transactions set forth under conditions acceptable to Aposense (collectively, the "Condition Precedent") during the Condition Precedent Period. The date on which Processa and Aposense satisfy the Condition Precedent, if any, shall be the "Condition Precedent Satisfaction Date."

(b) Expiration of the Agreement. If, for any reason (including a failure to meet the conditions in Sections 2.1 prior to the end of the Condition Precedent Period), Processa and Aposense do not satisfy the Condition Precedent within the Condition Precedent Period, then this Agreement shall terminate in accordance with Section 11.2.

2.2 Licenses.

(a) License. Subject to the terms of this Agreement, upon Processa's satisfaction of the Condition Precedent pursuant to Section 2.1, Aposense shall, and hereby does, grant to Processa an exclusive (even as to Aposense and its Affiliates), royalty-bearing right and license, including the right to sublicense in accordance with Section 2.2(b), under the Aposense Intellectual Property and Aposense's interest in the Joint Intellectual Property, to Develop, Manufacture, use and Commercialize, including filing for, obtaining and maintaining Regulatory Approval for, Products in the Field in the Territory.

(b) Sublicenses. From and after the Condition Precedent Satisfaction Date, Processa shall have the right to grant sublicenses under the licenses to Aposense Intellectual Property and Aposense's interest in the Joint Intellectual Property granted to Processa under Section 2.2(a) to its Affiliates and to Third Parties subject to Aposense's prior written approval; provided, however, that any such sublicense shall be subject to all applicable terms and

conditions of this Agreement. Each agreement with each Sublicensee must include grants of rights sufficient to enable Processa to grant substantially the rights set forth in Sections 11.8(b) through 11.8(f) with respect to (i) all Know-How and Patent Rights (including all applicable pre-clinical and clinical data, including pharmacology and biology data; Manufacturing documents and materials; and Manufacturing technologies) Controlled by such Sublicensee during the Term and used by such Sublicensee in the Development, Manufacture or Commercialization of any Compound or Product (collectively, "Sublicensee Intellectual Property"); (ii) all filings with Regulatory Authorities in the Territory relating to Compounds and Products and Regulatory Approvals relating to Compounds and Products held by such Sublicensee, including related correspondence with Regulatory Authorities; (iii) all Manufacturing agreements to which such Sublicensee is a party that are related to Compounds or Products; (iv) all of such Sublicensee's inventory of Compounds and Products existing as of the applicable date; and (v) all trademarks owned by such Sublicensee and used solely in connection with the Products, along with all associated goodwill ((i) – (v), collectively, "Sublicense Materials").

2.3 Rights Retained by the Parties. Any rights of Aposense or Processa, as the case may be, not expressly granted to the other Party under the provisions of this Agreement shall be retained by such Party.

2.4 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement, including the licenses granted under Section 2.1, 2.2 or 11.8(e) to Patent Rights and Know-How (including any data included in the Know-How), are and will otherwise be deemed to be for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined in Section 101(35A) of the Bankruptcy Code. Each Party will retain and may fully exercise all of its respective rights and elections under the Bankruptcy Code. The Parties agree that each Party, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code or any other provisions of applicable Law outside the United States that provide similar protection for "intellectual property."

2.5 Transfer of Aposense Know-How. During the period beginning on the Condition Precedent Satisfaction Date and ending on the date that is ninety (90) days after the Condition Precedent Satisfaction Date, Aposense shall transition Aposense Know-How to Processa and provide Processa with reasonable amounts of consultation regarding the transferred Aposense Know-How.

## ARTICLE III
## DEVELOPMENT

3.1 General. From and after the Condition Precedent Satisfaction Date, and subject to the terms of this Agreement, including the requirements of ARTICLE V, Processa (or its Affiliates or Sublicensees) shall control and be solely responsible for the Development of and regulatory activities with respect to Compounds and Products in the Field in the Territory, including all costs and expenses relating thereto; provided, however, that, prior to the Condition Precedent Satisfaction Date, Aposense will reasonably cooperate with Processa, as Processa may reasonably request and at Processa's expense, to enable Processa to interact with FDA in order to discuss the Development of and regulatory activities with respect to Compounds and Products

for the indications Processa desires to pursue with respect to such Compounds and Products. If Processa requests Aposense's cooperation as described above, the Parties shall mutually agree in advance on a budget therefor, and Processa shall reimburse Aposense for any expenses incurred by Aposense under this Section 3.1 within thirty (30) days after receiving an invoice therefor.

3.2 Exchange of Information Regarding Development. At least once each Calendar Year, beginning on the Effective Date and ending on the date on which Processa obtains the first Regulatory Approval for a Product in a Major Market, Processa shall provide Aposense with a reasonably detailed report describing Processa's Development activities and the summary results thereof with respect to all Compounds and Products.

## ARTICLE IV
## COMMERCIALIZATION

4.1 General. From and after the Condition Precedent Satisfaction Date, and subject to the terms of this Agreement, including the requirements of ARTICLE V, Processa (or its Affiliates or Sublicensees) shall control and be solely responsible for the Commercialization of Products in the Field in the Territory, including all costs and expenses relating thereto.

4.2 Commercialization Plans. During the Royalty Term with respect to each Product, at least thirty (30) days prior to the commencement of each Calendar Year, Processa shall provide Aposense, for information purposes only, a summary of the planned Commercialization activities to be conducted by or on behalf of Processa and its Affiliates and Sublicensees with respect to such Product in each country in the Territory during such Calendar Year (each such plan, a "Commercialization Plan").

## ARTICLE V
## DILIGENCE

5.1 Commercially Reasonable Efforts. During the Term, Processa shall, directly or through its Affiliates or Sublicensees, use Commercially Reasonable Efforts, from and after the Option Exercise Date, to Develop and obtain Regulatory Approval for one (1) Product in the Field in the U.S. or at least one (1) other Major Market and (b) subject to obtaining Regulatory Approval in the applicable Major Market if required, Commercialize one (1) Product in the Field in the U.S. or at least one (1) other Major Market. Without limiting or derogating from the foregoing, Processa, by itself or through its Affiliates or Sublicensees, shall meet each of the following milestones within the respective time periods set forth herein:

(a) Submission of IND within 30 months from the Condition Precedent Satisfaction Date;

(b) Dosing of a first patient with a Product within 42 months from the Condition Precedent Satisfaction Date;

(c) Dosing of a first patient with a Product in a Pivotal Clinical Trial within 72 months from the Condition Precedent Satisfaction Date; and

(d) NDA submission within 120 months from the Condition Precedent Satisfaction Date.

5.2 Termination for Failure to Meet Diligence Obligation. If, at any time during the Term, Processa fails to timely achieve any of the foregoing milestones, or if Aposense reasonably believes that Processa (itself and through its Affiliates and Sublicensees) has not complied with its obligations under Section 5.1 to Develop one (1) Compound or Product in the Field in the U.S. or at least one (1) other Major Market for any consecutive nine (9) month period following the Condition Precedent Satisfaction Date, Aposense shall provide written notice to Processa specifying the nature of such reasonable belief, and Aposense may terminate this Agreement pursuant to Section 11.5.

## ARTICLE VI
## FINANCIAL PROVISIONS

6.1 Equity Investment. In partial consideration for the rights granted to Processa hereunder, if Processa satisfies the Condition Precedent pursuant to Section 2.1, within five (5) Business Days following the Condition Precedent Satisfaction Date, Processa shall issue to Aposense, for no additional consideration, shares of common stock representing the number of shares determined by dividing Two Million and Five Hundred Thousand Dollars ($2,500,000) by the lowest price per share paid by investors in the Satisfactory Financing Round. The shares of common stock received by Aposense will contain a restrictive legend that restricts the sale, transfer, or disposition of these shares ("**Lock-up**") for an initial period of six months following their issuance. After the passage of the six month period, 40% of the shares will be released and the Lock-Up restrictive legend removed, with an additional 30% of the shares being released and the Lock-Up restrictive legend removed upon the end of each of the next two subsequent quarters. In addition, the shares of common stock received by Aposense shall contain a customary restrictive legend that specifies that such shares of common stock have not been registered with the Securities and Exchange Commission ("**SEC**") until such time as Processa shall receive a satisfactory opinion of legal counsel that specifies that such restrictive legend is no longer required by law. Notwithstanding the foregoing, unless a resale exemption from registration is available to Aposense, at any time following the date that is one hundred and eighty (180) days following the date that Processa's Form S-1 Registration Statement (File No. 333-235511) is declared effective, Aposense may request that the shares of common stock issued to it be registered for resale with the SEC from time to time by Processa (without an underwriter or placement agent) (the "**Demand Registration**"). Upon receipt of a Demand Registration, Processa shall use commercially reasonable efforts to register such shares for resale by Aposense, provided that the registration statement will be filed within 30 days, and shall use its commercially reasonable efforts to and keep such registration statement effective for at least 12 months (or such shorter period as will terminate when all the shares covered by the registration statement have been sold or withdrawn). This Demand Registration right shall cease and no longer be applicable once the shares issued to Aposense issued hereunder are sold or may be sold without volume limitation restrictions under Rule 144 of the Securities Act of 1933, as amended. Processa shall have the option, but not the requirement to purchase from Aposense any and all of the issued shares at a price per share equal to the highest price per share paid by investors in the Satisfactory Financing Round for three months following their issuance date. Following such three months period, the Parties may discuss in good faith the purchase of shares by Processa it

being clarified that Aposense shall have full discretion and shall not be obligated to sell the shares.

6.2 Leak-Out Provision: During the 12 months following the issuance of the shares, Aposense can resell shares released to Aposense as stated in Section 6.1 if the transaction price of all shares sold is greater than both the volume weighted average closing price of shares on the last 14 days in which shares were traded and the closing share price of the preceding trading day of the transaction, provided however that in the event that the volume weighted average closing price of shares on any 5 days period is lower than the volume weighted average closing price of shares on any 5 day period preceding such 5 day period, then Aposense may sell up to 20% of the shares released to Aposense from Lock-up if the transaction price of all shares sold is greater than the closing share price of the preceding trading day of the transaction (i.e. regardless of the 14 days average price). In addition, no more than 20% of the shares released from lock-up to Aposense can be resold within a 7 day period if shares are resold based on the 5 day period volume weighted average price of shares. Following the first anniversary of the issuance of the shares, Aposense may resell the shares without any price limitation.

6.3 Development and Commercialization Costs. For clarity, following the Effective Date, Processa shall be solely responsible for all costs it incurs in Developing and Commercializing Compounds and Products, including all Manufacturing costs.

6.4 Development and Regulatory Milestone Payments. Each milestone payment owed by Processa to Aposense pursuant to this Section 6.3 shall be payable by Processa within thirty (30) days following the first achievement of the corresponding milestone event. For the avoidance of doubt, except for milestone events 7 and 8 which shall be payable for each additional approved indication, each milestone payment is only payable once, regardless of the number of times such milestone may be achieved by Processa, its Affiliates, and Sublicensees. For purposes of this Section 6.3, if the Initiation of a clinical trial of a Licensed Product satisfies more than one of the clinical milestone events below (*e.g.*, if the first clinical trial of a Licensed Product is a Pivotal Trial), then the milestone payments corresponding to both of such clinical milestone events shall be made simultaneously upon the Initiation of such clinical trial. In addition, if a given milestone event is achieved by a Licensed Product without one or more preceding milestone events having been achieved by such Licensed Product, then the milestone payments corresponding to such skipped milestone events shall be made simultaneously upon achievement of such milestone event by such Licensed Product.

| Milestone Event | Milestone Payment |
|---|---|
| 1. IND Clearance 1st Indication | $100,000 |
| 2. 1st Patient Dosed in 1st Pivotal Trial, 1st indication | $300,000 |
| 3. 1st Indication Approved in the US | $3,000,000 |
| 4. 1st Indication Approved ex-US | $1,500,000 |
| 5. 2nd Indication Approved in the US | $3,000,000 |
| 6. 2nd Indication Approved ex-US | $1,500,000 |
| 7. Any Additional Approved Indication in US | $1,000,000 |
| 8. Any Additional Approved Indication Ex-US | $1,000,000 |

6.5 Sales Milestone Payments. Processa shall pay Aposense the one-time, non-refundable, non-creditable sales milestone payments set forth in the table below within thirty (30) days after the end of the first Calendar Quarter during which the Worldwide Annual Net Sales first reach the values indicated below. For clarity, the milestone payment reached will apply once and only once when the milestone is first achieved. Thereafter, the milestone will no longer apply. In addition, if more than one Sales Milestone is achieved in a year, only the first Sales Milestone achieved in the year will be paid, provided that any additional Sales Milestones achieved during the same year will remain payable upon achievement of the applicable milestone in any of the following years. For illustration purposes, if at a given year Worldwide Annual Net Sales first reach $160,000,000 (without having reached $50,000,000 prior to such year); the Sales Milestone Payment for such year will be $3,000,000. If in any subsequent year, Worldwide Annual Net Sales reach $100,000,000, the Sales Milestone Payment for such year will be $6,000,000 (on account of the $100M milestone), and so on.

| Worldwide Annual Net Sales | Amount |
|---|---|
| $50M | $3,000,000 |
| $100M | $6,000,000 |
| $250M | $15,000,000 |
| $500M | $30,000,000 |
| $1 Billion | $60,000,000 |

6.6 Product Royalties.

(a) Royalty Rate. Processa shall pay to Aposense royalties, on a Product-by-Product basis, on worldwide Net Sales of Products in the Territory during each Calendar Year during the applicable Royalty Term for the aggregate Worldwide Annual Net Sales in the Territory, 7% of Net Sales. Notwithstanding the foregoing, with respect to Net Sales by Sublicensees, the royalties shall equal the lower of (i) 7% or (ii) 50% of the royalty percentage due to Processa from such Sublicensee, provided that the royalty percentage due to Aposense hereunder shall not be less than 4%. During any period within the Royalty Term applicable to a Licensed Product in a country when there is no Regulatory Exclusivity and no Valid Claim of a Licensed Patent in such country, the royalty rate(s) applicable to net sales of such Licensed

Product in such country shall be reduced to fifty percent (50%) of the otherwise applicable royalty rate(s) described in Section 6.5(a). Upon the expiration of the Royalty Term with respect to each Licensed Product in each country, Processa shall have a fully-paid up irrevocable license with respect to such Product in such country.

(b) Royalty Term and Adjustments. Processa's royalty obligations to Aposense under this Section 6.5 shall commence on a country-by-country and Product-by-Product basis on the Effective Date and shall expire on a country-by-country basis and Product-by-Product basis on the later of (i) expiration or invalidation of the last Valid Claim Covering such Product in such country or (ii) the tenth ($10^{th}$) anniversary of the date of the First Commercial Sale by Processa or any of its Affiliates or Sublicensees to a non-Sublicensee Third Party of such Product in such country (the "Royalty Term"); provided that, during any period within the Royalty Term remaining after the expiration of all Valid Claims Covering such Product in such country and all Regulatory Exclusivity as to such Product in such country, the royalties payable as to such Product in such country under this Section 6.5 shall be reduced to fifty percent (50%) of the royalties otherwise payable as to such Product in such country pursuant to Section 6.5. Such royalty reduction will be calculated by determining the portion of total Net Sales of the relevant Product in a Calendar Quarter that is attributable to the applicable country in which such reduction applies, and by determining the total royalties without reduction, and then reducing by fifty percent (50%) the applicable portion (based on Net Sales) of total royalties attributable to the country in which such reduction applies.

(c) Third Party Payments. If, in the opinion of patent counsel mutually acceptable to both Processa and Aposense, in order to Develop, Manufacture, use or Commercialize a Product in the Field in a country of the Territory without infringing any third party intellectual property rights relating to the Aposense Intellectual Property, Processa or its Affiliate or Sublicensee is obligated to obtain a license or comparable grant of rights (*e.g.*, a covenant not to sue) under any Patent Rights from a Third Party ("Third Party Patent Licenses") and pay a royalty under such Third Party Patent License with respect to such Product in such country, then, subject to Section 6.6(d), fifty percent (50%) of such royalties actually paid by Processa, its Affiliates or Sublicensees shall be creditable against royalties payable to Aposense hereunder with respect to such Product in such country; provided that, if Processa is obligated to enter into any Third Party Patent License, Processa shall use Commercially Reasonable Efforts to minimize the royalties owed by Processa under such Third Party Patent License.

(d) Limitation on Royalty Reductions. Notwithstanding anything to the contrary in this Section 6.5, in no event shall the royalties payable under this Section 6.5 with respect to Net Sales of any Product in any country in any Calendar Quarter be reduced to less than fifty percent (50%) of the royalties payable under Section 6.6(a) with respect to Net Sales of such Product in such country in such Calendar Quarter; provided, however, that any amount which is entitled to be credited under Section 6.6(c) but is not credited as a result of the foregoing limitation in this Section 6.6(d) shall be carried over and applied against royalties payable to Aposense in respect of such Product in such country in subsequent periods of the Royalty Term until the full deduction is taken.

6.7 Sublicense. If Processa sub-licenses the Product prior to the first patient dosed within the first Clinical Trial, Aposense shall receive 50% of any Sublicense Consideration. If Processa sublicenses the Product after the first patient dosed within the first Clinical Trial, Aposense shall receive 40% of any Sublicense Consideration. All royalty payment obligations from Processa to Aposense remain unchanged from Section 6.5. Notwithstanding the foregoing, in the event that Processa receives Sublicense Consideration on account of a specific Product, then in such case Processa shall be required to pay Aposense the applicable percentage of the Sublicense Consideration, but shall not be required to pay Development and Regulatory Milestone Payment or Net Sales Milestone Payment on account of such specific Product in addition to the Sublicense Payments. "Sublicense Considerations" shall mean any payments or other consideration that Processa or its Affiliates receive as a direct result of the grant of a sublicense or an option to obtain such sublicense, including without limitation license fees, license option fees, milestone payments, license maintenance fees and equity, provided that in the event that Processa or its Affiliates receive non-monetary consideration in connection with a sublicense, Sublicense Considerations shall be calculated based on the fair market value of such consideration or transaction, assuming an arm's length transaction made in the ordinary course of business. Notwithstanding the foregoing, "Sublicense Considerations" shall not include: (a) Net Sales or (b) amounts expressly dedicated to, and actually expended upon to reimburse Processa and its Affiliates for, the Development of Products after such grant of rights, up to the actual costs incurred by Processa and its Affiliates for such activities. Processa shall pay Aposense the sublicense fee within thirty (30) days after the receipt of the Sublicense Consideration.

6.8 License Back.

(a) In order to facilitate Aposense's right to commercialize Products in the People's Republic of China, Processa shall provide Aposense access to the data generated in the development of Products, including all data included in any regulatory submission, and Aposense shall be entitled to use such data and shall have all rights to use the Aposense Intellectual Property and any modifications or improvements developed by Processa in the development of Products, for the sole purpose of Development, Manufacturing, Commercializing, supplying (with the rights to all of the foregoing), and sub-license the Products in the People's Republic of China. In consideration for such license back, Processa will be entitled to receive 20% of all net proceeds Aposense obtains from Commercialization, licensing, or sublicensing the Products in the People's Republic of China. Since selling the Product outside of the People's Republic of China could have a major impact on the commercialization efforts of Processa or Processa's Sublicensee, any sale of the Product outside of the People's Republic of China by the licensee for the People's Republic of China will result in Processa receiving 50% of all net proceeds Aposense receives from the commercialization, licensing, or sublicensing of the Products in the People's Republic of China instead of 20% from the time the sale occurs and for as long as such breach continues .

(b) Aposense shall provide Processa access to the data generated in the development of Products for the People's Republic of China, including all data included in any regulatory submission, and Processa shall be entitled to use such data and shall have all rights to use the Aposense Intellectual Property and any modifications or improvements developed by Aposense's licensee for the People's Republic of China in the Development of Products, for the sole purpose of Development, Manufacturing, Commercializing, supplying (with the rights to all

of the foregoing), and sub-license the Products outside the People's Republic of China, all in accordance with the terms and conditions hereof.

6.9 Reports; Payments. Within thirty (30) days after the end of each Calendar Quarter commencing from the earlier of (a) the First Commercial Sale of a Product; or (b) the grant of a sublicense or receipt of Sublicense Consideration, Processa shall furnish Aposense with a quarterly report ("Periodic Report") detailing, at a minimum, the following information for the applicable Calendar Quarter, each listed by Product and by country of sale: (i) the total number of units of Product sold by Company, its Affiliates and Sublicensees for which royalties are owned to Aposense hereunder, including a breakdown of the number and type of Products sold, (ii) gross amounts received for all such sales, (iii) deductions by type taken from Net Sales as specified herein, (iv) Net Sales, (v) Royalties and milestone payments owed to Aposense, listed by category, (vi) Sublicense Consideration received during the preceding Calendar Quarter and sublicense fees due to Aposense, (vii) the currency in which the sales were made, including the computations for any applicable currency conversions, (viii) invoice dates and all other data enabling the royalties and sublicense fees payable to be calculated accurately and (ix) a detailed summary of progress against each development and commercial milestone, and an estimate of the timing of the achievement of the next development and commercial milestone. Once the events set forth in sub-section (a) or (b), above, have occurred, Periodic Reports shall be provided to Aposense whether or not royalties, milestone payments or sublicense fees are payable for a particular Calendar Quarter. In addition to the foregoing, upon Aposense's reasonable request, Processa will provide to Aposense such other information as may be reasonably requested by Aposense, and will otherwise cooperate with Aposense as reasonably necessary, to enable Aposense to verify Processa's compliance with the payment and related obligations under this Agreement, including verification of the calculation of amounts due to Aposense under this Agreement and of all financial information provided or required to be provided in the Periodic Reports. Concurrently with each such report, Processa shall pay to Aposense all amounts payable by it under Section 6.5.

6.10 Books and Records; Audit Rights. Processa shall keep complete and accurate records of the underlying revenue and expense data relating to the calculations of Net Sales and payments required by Section 6.3, 6.4, 6.5 and 6.6. Aposense shall have the right, once annually at its own expense, to have an independent, certified public accounting firm, selected by Aposense and reasonably acceptable to Processa, review any such records of Processa in the location(s) where such records are maintained by Processa upon reasonable notice (which shall be no less than fourteen (14) days prior notice) and during regular business hours and under obligations of strict confidence, for the sole purpose of verifying the basis and accuracy of payments made under Section 6.3, 6.4, 6.5 and 6.6within the thirty-six (36) month period preceding the date of the request for review. The report of such accounting firm shall be limited to a certificate stating whether any report made or payment submitted by Processa during such period is accurate or inaccurate and the actual amounts of Net Sales, and royalties due, for such period. Processa shall receive a copy of each such report concurrently with receipt by Aposense. Should such inspection lead to the discovery of a discrepancy to Aposense's detriment, Processa shall pay within five (5) Business Days after its receipt from the accounting firm of the certificate the amount of the discrepancy plus interest calculated in accordance with Section 6.14. Aposense shall pay the full cost of the review unless the underpayment of royalties is greater than five percent (5%) of the amount due for any applicable Calendar Year, in which case

Processa shall pay the reasonable cost charged by such accounting firm for such review. Any overpayment by Processa revealed by an examination shall be fully creditable against future Payments.

6.11 Tax Matters. Except as expressly provided below, no payments to be made to Aposense by Processa hereunder shall be reduced by or on account of any taxes, levies, imposts, duties, charges, assessments or fees (collectively, "Taxes"). Notwithstanding the immediately preceding sentence, if any applicable Law requires (with due regard to any relief to which Aposense may be entitled) that Taxes be deducted and withheld from any payment made to Aposense by Processa under this Agreement, Processa shall (a) deduct those Taxes, together with any interest and penalties properly assessed thereon, from such payment or from any other payment owed by Processa hereunder; (b) transmit the amounts so deducted to the proper Governmental Authority; (c) send evidence of the requirement together with proof of due transmission of the amounts described in clause (b) to Aposense promptly following such payment; and (d) remit to Aposense the net amount of such payment after taking account of such deduction. In determining whether to deduct any amount hereunder and prior to making such deduction, Processa shall contact Aposense and take due account of all documentation supplied by Aposense, and of other facts known to Processa, supporting a reduction in any Tax otherwise required to be deducted, or a credit therefor or refund thereof. Processa will reasonably cooperate with Aposense in respect of Tax matters relating to payments made by Processa to Aposense under this Agreement and any disputes with a Governmental Authority regarding such matters, including without limitation: (y) complying with reasonable requests from Aposense to change the form, place or other circumstances of payments to be made to Aposense by Processa under this Agreement so as to reduce the incidence of Taxes on such payments or recover any Taxes imposed on such payments (any such recovery to be for the benefit of Aposense); and (z) in connection with any official or unofficial audit or contest relating to such payments.

6.12 Payment Method and Currency Conversion. All Payments shall be made in U.S. dollars in immediately available funds via either a bank wire transfer, an ACH (automated clearing house) mechanism, or any other means of electronic funds transfer, at Processa's election, to Aposense's bank account, or to such other bank account as Aposense shall designate in a notice at least ten (10) days before the payment is due. Aposense's wiring instructions are set forth on Schedule 6.12. For the purposes of determining the amount of any royalties due for the relevant Calendar Quarter under Section 6.5, the amount of Net Sales in any foreign currency shall be converted into U.S. dollars in accordance with the prevailing rates of exchange for the relevant month for converting such first currency into such other currency used by Processa's (or its Sublicensee's) internal accounting systems, which are independently audited on an annual basis. Upon request by Aposense, Processa shall disclose the bases for the rates of exchange used for purposes of assuring that such rates reflect prevailing rates of exchange.

6.13 Blocked Payments. If by reason of applicable Laws in any country in the Territory, it becomes impossible or illegal for Processa or its Affiliates or Sublicensees to transfer, or have transferred on its behalf royalties or other payments to Aposense or to Processa or its Affiliates or Sublicensees, Processa shall promptly notify Aposense of the conditions preventing such transfer. To the extent any payments to Aposense cannot be transferred pursuant to the preceding sentence, such amounts shall be deposited in local currency in the relevant country to the credit of Aposense in a recognized banking institution designated by

Aposense or, if none is designated by Aposense within a period of thirty (30) days, in a recognized banking institution selected by Processa or its Affiliate or Sublicensee, as the case may be, and identified in a notice given to Aposense. If so deposited in a foreign country, Processa shall provide, or cause its Affiliate or Sublicensee to provide, reasonable cooperation to Aposense so as to allow Aposense to assume control over such deposit as promptly as practicable.

6.14 Late Payments. If a Party shall fail to make a timely payment pursuant to the terms of this Agreement, the other Party shall provide written notice of such failure to the non-paying Party (a "Late Payment Notice"), and interest shall accrue on the past due amount starting on the date of the Late Payment Notice at the thirty (30) day U.S. dollar London Interbank Offered Rate effective for the date that payment was due (as published in the Wall Street Journal) plus five percent (5%) per annum, computed for the actual number of days after the date of the Late Payment Notice that the payment was past due.

## ARTICLE VII
## INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION AND RELATED MATTERS

7.1 Ownership of Inventions.

(a) Sole Inventions. Each Party shall exclusively own all inventions relating to any Compound or Product or its manufacture or use made solely by such Party, its employees, agents, and consultants ("Sole Inventions"). Sole Inventions made solely by Processa, its employees, agents and consultants are referred to herein as "Processa Sole Inventions". Sole Inventions made solely by Aposense, its employees, agents and consultants are referred to herein as "Aposense Sole Inventions". For clarity, products Covered by Processa Sole Inventions shall be deemed Products for the purpose of this Agreement.

(b) Joint Inventions. The Parties shall jointly own all inventions relating to any Compound or Product or its manufacture or use made jointly by employees, agents and consultants of Processa, on the one hand, and employees, agents and consultants of Aposense, on the other hand, on the basis of each Party having an undivided interest in the whole ("Joint Inventions"). Joint Inventions may only be used in accordance with and subject to the terms and conditions of this Agreement.

(c) Inventorship. For purposes of determining whether an invention is a Processa Sole Invention, an Aposense Sole Invention or a Joint Invention, questions of inventorship shall be resolved in accordance with United States patent Laws.

7.2 Prosecution and Maintenance of Patent Rights.

(a) Prosecution of Aposense Patent Rights. With respect to Aposense Patent Rights, Aposense and Processa shall cooperate in good faith in connection with the continued prosecution and maintenance by Aposense of such Aposense Patent Rights. If Processa satisfies the Condition Precedent pursuant to Section 2.1, the out-of-pocket costs and expenses incurred by Aposense after the Condition Precedent Satisfaction Date to obtain, prosecute and maintain Aposense Patent Rights shall be borne one hundred percent (100%) by Processa. Aposense shall

notify Processa at least ninety (90) days prior to the deadline for entering into national phase with respect to any PCT application included in Aposense Patent Rights. No later than sixty (60) days prior to entry into national phase, Processa shall provide Aposense with a list of any countries in which Processa would like Aposense to file. Aposense shall file international patent applications, or designate for national filing and file, in all countries requested by Processa. Aposense shall promptly deliver to Processa copies of all official correspondence with the applicable patent and trademark offices in the Territory relating to the Aposense Patent Rights and, after the Condition Precedent Satisfaction Date shall promptly provide Processa drafts of all proposed material filings and correspondence to any patent authority with respect to the Aposense Patent Rights for Processa's review and comment prior to the submission of such proposed filings and correspondences. Aposense shall keep Processa informed of the status of all pending patent applications that pertain to any Compound or Product. Aposense, its agents and attorneys shall not unreasonably decline to implement or incorporate any comments of Processa regarding any aspect of such patent prosecutions. Aposense shall not abandon any Aposense Patent Rights (the "Abandoned Patents") without at least ninety (90) days' prior notice to Processa. If Aposense decides to abandon any Aposense Patent Rights, Processa shall have the option to continue to prosecute and maintain the Abandoned Patents in Aposense's name.

(b) Prosecution of Joint Patent Rights. Processa shall be responsible for obtaining, prosecuting, and/or maintaining patents and patent applications, in any countries in the Territory, Covering Joint Inventions ("Joint Patent Rights"). The out-of-pocket costs and expenses incurred to obtain, prosecute and maintain Joint Patent Rights shall be borne one-hundred percent (100%) by Processa. Processa shall keep Aposense informed of the status of all pending Joint Patent Rights. Processa, its agents and attorneys shall not unreasonably decline to implement or incorporate any comments of Aposense regarding any aspect of such patent prosecutions. Processa shall not abandon any Joint Patent Right without at least ninety (90) days' prior notice to Aposense. If Processa decides to abandon any Joint Patent Right, Aposense shall have the option to continue to prosecute and maintain such Joint Patent Right jointly in both Parties' names, at Aposense's sole expense.

(c) Prosecution of Processa Patent Rights. Processa has the sole right, but not the responsibility, to obtain, prosecute, and/or maintain the Processa Patent Rights. Processa shall keep Aposense informed of the status of all pending Processa Patent Rights. Processa, its agents and attorneys shall not unreasonably decline to implement or incorporate any comments of Aposense regarding any aspect of such patent prosecutions. Processa shall not abandon any Processa Patent Right without at least ninety (90) days' prior notice to Aposense. If Processa decides to abandon any Processa Patent Right, Aposense shall have the option to continue to prosecute and maintain such Processa Patent Right jointly in both Parties' names, at Aposense's sole expense.

(d) Cooperation. Each Party agrees to cooperate fully in the preparation, filing, prosecution, and maintenance of Aposense Patent Rights, Joint Patent Rights, and Processa Patent Rights, pursuant to this Section 7.2 and in the obtaining and maintenance of any patent term extensions, supplementary protection certificates, pediatric extensions, and their equivalent with respect thereto. Such cooperation includes: (i) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, so as enable the other Party to apply for and to prosecute patent applications in any country as

permitted by this Section 7.2; and (ii) promptly informing the other Party of any matters coming to such Party's attention that may affect the preparation, filing, prosecution, or maintenance of any such patent applications.

7.3 Third Party Infringement.

(a) Notice. Each Party shall promptly report in writing to the other Party during the Term any known or suspected (i) infringement of any of the Aposense Patent Rights, Processa Patent Rights or Joint Patent Rights, or (ii) unauthorized use or misappropriation of any of the Aposense Know-How, Processa Sole Invention or Joint Inventions, in the case of either clause (i) or clause (ii), that could reasonably be expected to impact the (A) Development, Manufacture, use or Commercialization of a Compound or Product in the Field in the Territory, or (B) scope of the rights licensed to Processa under ARTICLE II (an "Infringement Claim"), of which such Party becomes aware, and shall provide the other Party with all available evidence supporting such Infringement Claim.

(b) Initial Right to Enforce. Subject to Section 7.3(c), Processa (itself or through its Affiliate or Sublicensee) shall have the first right, but not the obligation, to initiate a suit, or take other appropriate action that it believes is reasonably required to protect (*i.e.*, prevent or abate actual or threatened infringement or misappropriation of) or otherwise enforce the Processa Intellectual Property, Aposense Intellectual Property and Joint Intellectual Property with respect to an Infringement Claim; provided, however, that Processa shall (i) consult with Aposense in good faith with respect to any claim that any Aposense Patent Right, Processa Patent Right or Joint Patent Right is invalid or unenforceable and (ii) implement any reasonable comment from Aposense regarding any aspect of defending against any such claim described in clause (i). Any such suit by Processa shall be brought either in the name of Aposense or its Affiliate, the name of Processa or its Affiliate, or the names of Processa, Aposense and their respective Affiliates, as may be required by the Law of the forum. For this purpose, Aposense shall execute such legal papers and cooperate in the prosecution of such suit, including providing full access to documents, information and witnesses as reasonably requested by Processa in connection with such suit, as may be reasonably requested by Processa; provided that Processa shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by Aposense in connection with such cooperation. For clarity, as between Aposense and Processa, (A) Aposense shall have the sole right, but not the obligation, to protect Aposense Intellectual Property against any suspected misappropriation or infringement that does not constitute an Infringement Claim and (B) the Parties shall jointly determine by mutual agreement whether and how to protect Joint Intellectual Property against any suspected misappropriation or infringement that does not constitute an Infringement Claim, and the provisions of this ARTICLE VII shall not apply with respect thereto.

(c) Step-In Right. If Processa does not initiate a suit or take other appropriate action that it has the initial right to initiate or take with respect to an Infringement Claim pursuant to Section 7.3(b), then Aposense may, in its discretion, provide Processa with notice of Aposense's intent to initiate a suit or take other appropriate action. If Aposense provides such notice and Processa does not initiate a suit or take such other appropriate action within thirty (30) days after receipt of such notice from Aposense, then Aposense shall have the right to initiate a suit or take other appropriate action that it believes is reasonably required to protect the Processa

Intellectual Property, Aposense Intellectual Property and Joint Intellectual Property. Any suit by Aposense shall be either in the name of Aposense or its Affiliate, the name of Processa or its Affiliate, or the names of Processa, Aposense, and their respective Affiliates, as may be required by the Law of the forum. For this purpose, Processa shall execute such legal papers and cooperate in the prosecution of such suit, including providing full access to documents, information and witnesses as reasonably requested by Aposense in connection with such suit, as may be reasonably requested by Aposense; provided that Aposense shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by Processa in connection with such cooperation.

(d) Conduct of Certain Actions; Costs. The Party initiating suit or taking other action with respect to an Infringement Claim shall have the sole and exclusive right to select counsel for, and otherwise control, any suit or action initiated by it pursuant to Section 7.3(b) or 7.3(c). The initiating Party shall assume and pay all of its own out-of-pocket costs incurred in connection with any litigation or proceedings initiated by it pursuant to Sections 7.3(b) and 7.3(c), including the fees and expenses of the counsel selected by it. The other Party shall have the right to participate, but not control, and be represented in, any such suit by its own counsel at its own expense.

(e) Recoveries. Except as otherwise agreed by the Parties as part of a cost-sharing arrangement, any damages, settlements, accounts of profits, or other financial compensation recovered from a Third Party by the Party that assumes control over enforcing any Infringement Claim shall be allocated between the Parties as follows:

(i) first, to reimburse the Parties' actual out-of-pocket expenses (including reasonable counsel fees and expenses) incurred in pursuing such Infringement Claim; and

(ii) second, if Processa controlled the defense of the Infringement Claim any remaining amount that represents compensatory damages relating to any Compound or Product (including lost sales or lost profits) shall be deemed Net Sales and paid to Processa, less an amount equal to royalty payments to Aposense on such deemed Net Sales in accordance with the royalty provisions of Section 6.5, which amount shall be paid to Aposense, and any remaining amount that represents punitive damages shall be shared equally by the Parties. If Aposense controlled the defense of the Infringement Claim any remaining amount following reimbursement of expenses under clause (i) shall be retained by Aposense.

7.4 Patent Invalidity Claim. Each of the Parties shall promptly notify the other in the event of any legal or administrative action by any Third Party against a Aposense Patent Right, Processa Patent Right or Joint Patent Right of which it becomes aware, including any nullity, revocation, reexamination or compulsory license proceeding. Aposense shall have the first right, but not the obligation, to defend against any such action involving a Aposense Patent Right, and the costs of any such defense shall be at Aposense's expense; provided, however, that, in the case of any *inter partes* review or similar post-grant matter before the Patent Trial and Appeal Board or similar administrative body that is based on the same subject matter as any claim or counterclaim in any Infringement Claim or Paragraph IV Claim, Processa shall have the first right, but not the obligation, to defend against any such action involving a Aposense Patent

Right, and the costs of any such defense shall be at Processa's expense. Processa shall have the first right, but not the obligation, to defend against any such action involving a Processa Patent Right or Joint Patent Right, and the costs of any such defense shall be at Processa's expense. If the Party that has the first right to defend against any such action involving such Aposense Patent Right, Processa Patent Right or Joint Patent Right does not do so, then the other Party shall have the right, but not the obligation, to defend such action and any such defense shall be at such other Party's expense. Upon request of the Party that defends against any such action involving a Aposense Patent Rights, Processa Patent Right or Joint Patent Right, the other Party agrees to join in any such action and to cooperate reasonably with the defending Party, including providing full access to documents, information and witnesses as reasonably requested by the defending Party in connection with such action, provided that the defending Party shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by the other Party in connection with such cooperation.

7.5 Claimed Infringement. Each of the Parties shall promptly notify the other in the event a Party becomes aware that the practice by either Party of the Aposense Patent Rights infringes, or is suspected or alleged to infringe, the intellectual property rights of any Third Party in the Territory, and shall promptly provide the other Party with any notice it receives or has received from a Third Party related to such suspected, alleged or actual infringement.

7.6 Patent Term Extensions. Processa shall have the exclusive right and obligation to seek patent term extensions or supplemental patent protection, including supplementary protection certificates, in each country in the Territory in relation to the Products at Processa's expense. Aposense and Processa shall cooperate in connection with all such activities, and Processa, its agents and attorneys will give due consideration to all timely suggestions and comments of Aposense regarding any such activities; provided that all final decisions shall be made by Processa.

7.7 Patent Marking. Processa shall comply with the patent marking statutes in each country in the Territory in which any Product is sold by Processa, its Affiliates, or its Sublicensees.

7.8 Certification under Drug Price Competition and Patent Restoration Act.

(a) Notice. If a Party becomes aware of any certification filed pursuant to 21 U.S.C. § 355(b)(2)(A) or 355(j)(2)(A)(vii)(IV) or its successor provisions, or any similar provision in any country in the Territory other than the U.S., claiming that any Aposense Patent Rights, Processa Patent Rights or Joint Patent Rights are invalid or otherwise unenforceable, or that infringement will not arise from the manufacture, use, import or sale of a product by a Third Party (a "Paragraph IV Claim"), such Party shall promptly notify the other Party in writing within five (5) Business Days after its receipt thereof.

(b) Control of Response; Recoveries. Processa shall have the first right, but not the obligation, to initiate and control patent infringement litigation for any Paragraph IV Claim; provided, however, that Processa shall (i) consult with Aposense in good faith with respect to any claim that any Aposense Patent Right, Processa Patent Right or Joint Patent Right is invalid or unenforceable and (ii) implement any comment from Aposense regarding any aspect

of defending against any such claim. Any suit by Processa shall be brought either in the name of Aposense or its Affiliate, the name of Processa or its Affiliate, or the names of Processa, Aposense, and their respective Affiliates, as may be required by the Law of the forum. For this purpose, Aposense shall execute such legal papers and cooperate in the prosecution of such suit, including providing full access to documents, information and witnesses, as may be reasonably requested by Processa; provided that Processa shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by Aposense in connection with such cooperation. If Processa elects not to assume control over litigating any Paragraph IV Claim, Processa shall notify Aposense as soon as practicable but in any event not later than ten (10) days before the first action required to litigate such Paragraph IV Claim so that Aposense may, but shall not be required to, assume sole control over litigating such Paragraph IV Claim using counsel of its own choice. Any suit by Aposense shall be either in the name of Aposense or its Affiliate, the name of Processa or its Affiliate, or the names of Processa, Aposense, and their respective Affiliates, as may be required by the Law of the forum. For this purpose, Processa shall execute such legal papers and cooperate in the prosecution of such suit, including providing full access to documents, information and witnesses, as may be reasonably requested by Aposense; provided that Aposense shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by Processa in connection with such cooperation. Any compensation recovered as a result of such litigation shall be allocated as set forth in Section 7.3(e) above.

7.9 Privileged Communications. In furtherance of this Agreement, it is expected that Processa and Aposense will, from time to time, disclose to one another privileged communications with counsel, including opinions, memoranda, letters, and other written, electronic and verbal communications. Such disclosures are made with the understanding that they shall remain confidential, that they will not be deemed to waive any applicable attorney-client or attorney work product or other privilege and that they are made in connection with the shared community of legal interests existing between Aposense and Processa, including the community of legal interests in avoiding infringement of any valid, enforceable patents of Third Parties and maintaining the validity of Aposense Patent Rights, Processa Patent Rights and Joint Patent Rights.

7.10 Settlement. Neither Party shall unilaterally enter into any settlement or compromise of any suit, action or proceeding under this ARTICLE VII that would in any manner alter, diminish, or be in derogation of the other Party's rights under this Agreement without the prior written consent of such other Party, which shall not be unreasonably withheld.

## ARTICLE VIII
## CONFIDENTIAL INFORMATION

8.1 Treatment of Confidential Information. During the Term and for five (5) years thereafter, each Party shall maintain Confidential Information (as defined in Section 8.2) of the other Party in confidence, and shall not disclose, divulge or otherwise communicate such Confidential Information to others (except for agents, directors, officers, employees, consultants, subcontractors, licensees, sublicensees, partners, Affiliates and advisors who have a need to know such information to perform obligations or exercise rights on behalf of such Party (collectively, "Agents") under obligations of confidentiality no less stringent than those set forth

in this ARTICLE VIII) or use it for any purpose other than in connection with the Development, Manufacture, use or Commercialization of Compounds or Products pursuant to this Agreement or otherwise to accomplish the purposes of this Agreement, including exercising its rights or performing its obligations hereunder, and each Party shall exercise Commercially Reasonable Efforts to prevent and restrain the unauthorized disclosure of such Confidential Information by any of its Agents, which efforts shall be at least as diligent as those generally used by such Party in protecting its own confidential and proprietary information, and in any event no less than reasonable efforts. Each Party will be responsible for any breach of this ARTICLE VIII by its Agents. Either receiving Party may disclose Confidential Information of the disclosing Party (a) to Governmental Authorities in order to comply with applicable Laws, respond to inquiries, requests or investigations by Governmental Authorities, including filing, prosecuting or maintaining Patent Rights as permitted by this Agreement; (b) to comply with the regulations or requirements of any stock exchange; (c) to the extent useful to Develop, Manufacture, use or Commercialize any Compound or Product, including making regulatory filings for any Compound or Product, in accordance with this Agreement; (d) to the extent necessary or useful in order to defend or prosecute litigation; and (e) to potential and actual *bona fide* investors, acquirors and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition or collaboration; provided that (x) with respect to any disclosure in accordance with Section 8.1(a), (b) or (d), the receiving Party shall promptly provide prior notice of such disclosure to the disclosing Party and use Commercially Reasonable Efforts to avoid or minimize the degree of such disclosure, (y) with respect to any disclosure in accordance with Section 8.1(a) or (d), the receiving Party will use efforts to secure confidential treatment of such Confidential Information at least as diligent as such Party would use to protect its own confidential information, but in no event less than reasonable efforts, and (z) with respect to any disclosure in accordance with Section 8.1(e),the receiving Party shall obtain the same confidentiality obligations from any Third Parties to which it discloses the Confidential Information of the disclosing Party as it obtains with respect to its own similar types of confidential information, and in any event such obligations shall be no less stringent than those set forth in this ARTICLE VIII.

8.2 Confidential Information. "Confidential Information" means all trade secrets or other proprietary information, including any proprietary data and materials (whether or not patentable or protectable as a trade secret), that is disclosed by a Party to the other Party. All information disclosed prior to the Effective Date by Aposense to Processa pursuant to the Amended and Restated Nondisclosure Agreement by and between the Parties, dated as of February 2, 2017, as amended through the Effective Date (the "Confidentiality Agreement"), shall be deemed "Confidential Information" of Aposense. Notwithstanding the foregoing, there shall be excluded from the foregoing definition of Confidential Information any of the foregoing that:

(a) either before or after the date of the disclosure to the receiving Party is lawfully disclosed to the receiving Party by a Third Party without any violation of any obligation to the other Party; or

(b) either before or after the date of the disclosure to the receiving Party, becomes published or generally known to the public through no fault or omission on the part of the receiving Party or its Agents; or

(c) is independently developed by or for the receiving Party without reference to or reliance upon the disclosing Party's Confidential Information as demonstrated by contemporaneous written records of the receiving Party.

8.3 Publications. The Parties recognize the desirability of publishing and publicly disclosing the results of clinical trials of pharmaceutical products. Accordingly, subject to coordination through designated representatives of each Party, Processa shall be free to publicly disclose the results of clinical trials involving Compounds or Products, subject to prior review by Aposense for issues of patentability and protection of its Confidential Information, in a manner consistent with all Laws applicable to Processa and best industry practices. In addition, if Processa intends to publish articles in scientific or medical journals or to make presentations of the results of clinical trials involving Compounds or Products, Processa shall provide Aposense through the designated representatives of each Party at its earliest opportunity with any proposed abstracts, manuscripts or summaries of presentations that cover the results of Development of any Compound or Product. Aposense shall respond promptly through its designated representative, and in any event no later than thirty (30) days after receipt of such proposed publication or presentation, or such shorter period as may be required by the publication. If timely requested by Aposense, Processa agrees to allow a reasonable period (not to exceed sixty (60) days) to permit filings for patent protection and to otherwise address issues of Confidential Information or related competitive harm to the reasonable satisfaction of Aposense. In addition, Processa will consider in good faith any comments furnished by Aposense to Processa during such period. Processa shall be responsible to assure that its Affiliates and licensees agree to, and comply with, equivalent undertakings in favor of Aposense. Aposense and its Affiliates may make any publication or public disclosure of any data concerning the Compounds or Products that existed as of the Effective Date, provided that Aposense provides Processa at least thirty (30) days (or such shorter period as may be required by the publication) to review such publication or public disclosure, allows a reasonable period (not to exceed sixty (60) days) to permit filings for patent protection and to otherwise address issues of Confidential Information or related competitive harm to the reasonable satisfaction of Processa, and reasonably considers any timely comments provided by Processa with respect to such publication or public disclosure. Aposense shall not, and shall cause each of its Affiliates, licensees, and sublicensees not to, make any other publications or public disclosures regarding the Compounds or Products without Processa's prior written consent. If Processa consents to Aposense making such publications, Aposense shall provide Processa a reasonable opportunity to comment on any such publications and such comments shall not be unreasonably rejected. All publications involving Compounds or Products shall include appropriate acknowledgement consistent with standard scientific practice of any contributions of each Party to the results being publicly disclosed.

8.4 Press Releases and Other Disclosures. The Parties recognize that each Party may from time to time desire to issue press releases and make other public statements or disclosures regarding the subject matter of this Agreement. In such event, the Party desiring to issue a press release or make a public statement or disclosure shall provide the other Party with a copy of the proposed press release, statement or disclosure for review and approval in advance (except that neither Party shall have any obligation to disclose or approve the disclosure of Confidential Information except to the extent required or permitted pursuant to this ARTICLE VIII). No other public statement or disclosure concerning the existence or terms of this Agreement shall be made, either directly or indirectly, by either Party, without first obtaining the written approval of

the other Party. Once any public statement or disclosure has been approved in accordance with this Section 8.4, then either Party may appropriately communicate information contained in such permitted statement or disclosure. Notwithstanding the foregoing provisions of this Section 8.4 this ARTICLE VIII, a Party may (a) disclose the existence and terms of this Agreement where required, as reasonably determined by the disclosing Party, by applicable Law, by applicable stock exchange regulation or by order or other ruling of a competent court and (b) disclose the existence and terms of this Agreement under obligations of confidentiality no less stringent than those set forth in this ARTICLE VIII to agents, advisors, contractors, licensees, sublicensees, and *bona fide* investors, acquirors and other financial or commercial partners, and to potential agents, advisors, contractors, licensees, sublicensees, and *bona fide* investors, acquirors and other financial or commercial partners. To the extent a Party determines in good faith that it is required by applicable Law to publicly file, register or notify this Agreement with a Governmental Authority, including public filings pursuant to securities Laws, it shall provide a proposed redacted form of the Agreement to the other Party a reasonable amount of time prior to filing for the other Party to review such draft and propose changes to such proposed redactions. The Party making such filing, registration or notification shall incorporate any proposed changes timely requested by the other Party, absent a reasonable basis for not making such changes, and shall use Commercially Reasonable Efforts to seek confidential treatment for any terms that the other Party timely requests be kept confidential, to the extent such confidential treatment is reasonably available consistent with applicable Law. Each Party shall be responsible for its own legal and other external costs in connection with any such filing, registration, or notification.

8.5 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that a Party would suffer upon unauthorized disclosure, use, or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages would not be a sufficient remedy for any breach of this ARTICLE VIII. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this ARTICLE VIII.

## ARTICLE IX
## REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 Aposense's Representations. Aposense hereby represents and warrants as of the Effective Date as follows:

(a) Aposense has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder. The execution, delivery, and performance of this Agreement has been duly and validly authorized and approved by all necessary corporate action on the part of Aposense. Aposense has taken all other action required by Law, its certificate of incorporation or by-laws, or any agreement to which it is a party or by which it or its assets are bound, to authorize such execution, delivery, and performance. Assuming due authorization, execution, and delivery on the part of Processa, this Agreement constitutes a legal, valid, and binding obligation of Aposense, enforceable against Aposense in accordance with its terms.

(b) The execution and delivery of this Agreement by Aposense will not violate any Israeli Law or, to Aposense's knowledge, any Law of any Governmental Authority outside Israel.

(c) The execution and delivery of this Agreement by Aposense do not require Aposense to obtain any permit, authorization or consent from any Governmental Authority or from any other Person which has not been obtained prior to the Effective Date, and such execution and delivery by Aposense will not result in the breach of or give rise to any termination of, rescission, renegotiation or acceleration under or trigger any other rights under any agreement or contract to which Aposense may be a party that relates to the Aposense Patent Rights or the Aposense Know-How.

(d) Schedule 1.12 is a complete and correct list of all Patent Rights owned by Aposense as of the Effective Date that Cover any Compound or Product. No Patent Right that covers any Compound or Product has been licensed to Aposense.

(e) Aposense is the legal and beneficial owner of all the Patent Rights identified on Schedule 1.12, free and clear of any liens, mortgages, security interests or other similar encumbrances. All assignments to Aposense of ownership rights relating to such Patent Rights are valid and enforceable. All of the Patent Rights listed identified on Schedule 1.12 that are issued patents are in full force and effect, and all applicable filing, maintenance and other fees required to be paid to a patent office with respect to the Patent Rights listed identified on Schedule 1.12 have been timely paid. Aposense has the right to grant the licenses granted by it in this Agreement and has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the Aposense Intellectual Property in a manner that conflicts with any rights granted to Processa hereunder.

(f) There is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to Aposense's knowledge, threatened against Aposense in connection with the Compounds or Products or any Aposense Patent Rights, Aposense Know-How or against or relating to the transactions contemplated by this Agreement. Aposense has not received any written notice from a Third Party that the Development of any Compound or Product conducted by Aposense has infringed, or that any Development or Commercialization of any Compound or Product will infringe, any Patent Rights of any Third Party.

(g) No claim or action has been brought or, to Aposense's knowledge, threatened by any Third Party alleging that the Aposense Patent Rights are invalid or unenforceable, and no Aposense Patent Rights are the subject of any litigation, interference, post-grant review, opposition, cancellation or other proceeding challenging the validity or enforceability of the Aposense Patent Rights.

(h) Neither Aposense nor, to the knowledge of Aposense, any of its directors, officers, employees, agents or subcontractors has been convicted of any crime or engaged in any conduct that has resulted in, or would reasonably be expected to result, in debarment by the FDA under 21 U.S.C. § 335a or any similar state or foreign Law.

9.2 Processa's Representations. Processa hereby represents and warrants as of the Effective Date as follows:

(a) Processa has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder. The execution, delivery, and performance of this Agreement has been duly and validly authorized and approved by all necessary corporate action on the part of Processa. Processa has taken all other action required by Law, its certificate of incorporation or by-laws or any agreement to which it is a party or by which it or its assets are bound to authorize such execution, delivery and (subject to obtaining all necessary governmental approvals with respect to the Development, Manufacture, use and Commercialization of Compounds and Products) performance. Assuming due authorization, execution, and delivery on the part of Aposense, this Agreement constitutes a legal, valid, and binding obligation of Processa, enforceable against Processa in accordance with its terms.

(b) The execution and delivery of this Agreement by Processa will not violate any U.S. Law or, to Processa's knowledge, any Law of any Governmental Authority outside the U.S.

(c) There is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to the knowledge of Processa, threatened against Processa in connection with or relating to the transactions contemplated by this Agreement.

(d) The execution and delivery of this Agreement do not require Processa to obtain any permit, authorization or consent from any Governmental Authority or from any other Person, and such execution and delivery by Processa will not result in the breach of or give rise to any termination of, rescission, renegotiation or acceleration under or trigger any other rights under any agreement or contract to which Processa may be a party that relates to the Products, Processa Patent Rights or Processa Know-How.

(e) Neither Processa nor, to the knowledge of Processa, any of its directors, officers, employees, agents or subcontractors has been convicted of any crime or engaged in any conduct that has resulted in, or would reasonably be expected to result, in debarment by the FDA under 21 U.S.C. § 335a or any similar state or foreign Law.

9.3 Aposense Covenants. Aposense covenants and agrees during the Term that, subject to Processa's, its Affiliates' and Sublicensees' performance of their obligations under this Agreement:

(a) Aposense shall not grant to any Third Party any rights that would be inconsistent or conflict with Processa's rights hereunder.

(b) Subject to Section 12.7, Aposense shall not assign, transfer, convey, or otherwise encumber its right, title, and interest in the Aposense Intellectual Property in a manner that conflicts with any rights granted to Processa hereunder.

9.4 Processa Covenant.

(a) Processa shall conduct, and shall use Commercially Reasonable Efforts to cause its contractors and consultants to conduct, all of their activities contemplated under this Agreement in accordance with all applicable Laws of the country in which such activities are conducted, including applicable requirements of "good laboratory practices", "good clinical practices" and "good manufacturing practices", as applicable, as defined by the FDA.

(b) Subject to Section 12.7, Processa shall not assign, transfer, convey, or otherwise encumber its right, title, and interest in the Processa Intellectual Property in a manner that conflicts with any rights granted hereunder to Aposense upon termination.

9.5 No Warranty. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED. IN PARTICULAR, BUT WITHOUT LIMITATION, EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY CONCERNING WHETHER ANY OF THE COMPOUNDS OR PRODUCTS ARE FIT FOR ANY PARTICULAR PURPOSE OR SAFE FOR HUMAN CONSUMPTION.

## ARTICLE X
## INDEMNIFICATION

10.1 Indemnification in Favor of Aposense. Processa shall indemnify, defend and hold harmless the Aposense Parties from and against any and all Losses incurred, suffered or sustained by any of the Aposense Parties or to which any of the Aposense Parties becomes subject as a result of any Third Party claim, action, suit, proceeding, liability or obligation (which in no event includes any claim by any Processa Party or any Aposense Party) (collectively, "Third Party Claims") arising out of, relating to or resulting from:

(a) any misrepresentation or breach of any representation, warranty, covenant or agreement made by Processa in this Agreement; or

(b) the Development Manufacture or Commercialization of Compounds or Products by Processa, its Affiliates or Sublicensees, including all Third Party Claims involving death or bodily injury caused or allegedly caused by the use of such a Compound or Product, and even if such a Compound or Product is altered for use for a purpose not intended (any and all such Third Party Claims "Product Liability Claims"); or

(c) any actual or alleged infringement of any trademark, Patent Right or other intellectual property right, or misappropriation of any trade secret, of any Third Party as a result of the Development, Manufacture or Commercialization of Compounds or Products by Processa, its Affiliates or Sublicensees; or

(d) the gross negligence or willful misconduct of any of the Processa Parties (as hereinafter defined) in connection with Processa's performance of this Agreement.

For purposes of this ARTICLE X, "Aposense Parties" means Aposense, its Affiliates and their respective agents, directors, officers, licensees, sublicensees and employees.

The indemnification obligations set forth in this Section 10.1 shall not apply to the extent that any Loss is the result of (i) a breach of any representation, warranty, covenant, or agreement made by Aposense in this Agreement or (ii) the gross negligence or willful misconduct of any applicable Aposense Party.

10.2 Indemnification in Favor of Processa. Aposense shall indemnify, defend and hold harmless the Processa Parties from and against any and all Losses incurred, suffered or sustained by any of the Processa Parties or to which any of the Processa Parties becomes subject as a result of any Third Party Claim arising out of, relating to or resulting from:

(a) any misrepresentation or breach of any representation, warranty, covenant or agreement made by Aposense in this Agreement; or

(b) the Development, Manufacture or Commercialization of Compounds or Products by Aposense, its Affiliates, licensees (excluding Processa) or sublicensees prior to the execution of this Agreement and after any termination of this Agreement, including all Product Liability Claims arising out of any such pre-Agreement, post-termination Development, Manufacture or Commercialization by Aposense, its Affiliates, licensees (excluding Processa) or sublicensees; or

(c) any actual or alleged infringement of any trademark, Patent Right or other intellectual property right, or misappropriation of any trade secret, of any Third Party as a result of the Development, Manufacture or Commercialization of Compounds or Products by Aposense, its Affiliates, licensees (excluding Processa) or sublicensees prior to the execution of this Agreement and after any termination of this Agreement; or

(d) the gross negligence or willful misconduct of any of the Aposense Parties in connection with Aposense's performance of this Agreement.

For purposes of this ARTICLE X, "Processa Parties" means Processa, its Affiliates and their respective agents, directors, officers, licensees, sublicensees and employees.

The indemnification obligations set forth in this Section 10.2 shall not apply to the extent that any Loss is the result of (i) a breach of any representation, warranty, covenant, or agreement made by Processa in this Agreement, or (ii) the gross negligence or willful misconduct of any applicable Processa Party.

10.3 General Indemnification Procedures.

(a) A Aposense Party or Processa Party seeking indemnification pursuant to this ARTICLE X (an "Indemnified Party") shall give prompt notice to the Party from whom such indemnification is sought (the "Indemnifying Party") of the commencement or assertion of any Third Party Claim in respect of which indemnity may be sought hereunder, shall give the Indemnifying Party such information with respect to any indemnified matter as the Indemnifying Party may reasonably request, and shall not make any admission concerning any Third Party Claim, unless such admission is required by applicable Law or legal process, including in response to questions presented in depositions or interrogatories. Any admission made by the Indemnified Party or the failure to give such notice shall relieve the Indemnifying Party of any

liability hereunder only to the extent that the ability of the Indemnifying Party to defend such Third Party Claim is prejudiced thereby (and no admission required by applicable Law or legal process shall be deemed to result in prejudice). The Indemnifying Party shall assume and conduct the defense of such Third Party Claim, with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party. Subject to the initial and continuing satisfaction of the terms and conditions of this ARTICLE X by the Indemnifying Party, the Indemnifying Party shall have full control of such Third Party Claim, including settlement negotiations and any legal proceedings. If the Indemnifying Party does not assume the defense of such Third Party Claim in accordance with this Section 10.3, the Indemnified Party may defend the Third Party Claim. If both Parties are Indemnifying Parties with respect to the same Third Party Claim, the Parties shall determine by mutual agreement, within twenty (20) days following their receipt of notice of commencement or assertion of such Third Party Claim (or such lesser period of time as may be required to respond properly to such claim), which Party shall assume the lead role in the defense thereof. Should the Indemnifying Parties be unable to mutually agree on which of them shall assume the lead role in the defense of such Third Party Claim, both Indemnifying Parties shall be entitled to participate in such defense through counsel of their respective choosing.

(b) Any Indemnified Party or Indemnifying Party not managing the defense of a Third Party Claim shall have the right to participate in (but not control), at its own expense (subject to the immediately succeeding sentence), the defense. The Indemnifying Party managing the defense shall not be liable for any litigation cost or expense incurred, without its consent, by the Indemnified Party where the action or proceeding is under the control of such Indemnifying Party; provided, however, that, if the Indemnifying Party managing the defense fails to take reasonable steps necessary to defend such Third Party Claim, the Indemnified Party may assume its own defense, and the Indemnifying Party managing the defense will be liable for all reasonable costs or expenses paid or incurred in connection therewith.

(c) The Indemnifying Party shall not, except with the consent of the Indemnified Party, consent to a settlement of, or the entry of any judgment against, an Indemnified Party arising from any Third Party Claim to the extent such settlement or judgment involves equitable or other non-monetary relief from the Indemnified Party. No Party shall, without the prior written consent of the other Party or the Indemnified Party, enter into any compromise or settlement that commits the other Party or the Indemnified Party to take, or to forbear to take, any action.

(d) The Parties shall cooperate in the defense or prosecution of any Third Party Claim and shall furnish such records, information and testimony, and attend such conferences, discovery proceedings, hearings, trials and appeals, as may be reasonably requested in connection therewith; provided, however, that the Indemnifying Party shall reimburse the Indemnified Party for any out-of-pocket expenses actually and reasonably incurred in connection with any such cooperation.

(e) Any indemnification hereunder shall be made net of any insurance proceeds actually recovered by the Indemnified Party from unaffiliated Third Parties; provided, however, that if, following the payment to the Indemnified Party of any amount under this ARTICLE X, such Indemnified Party recovers any such insurance proceeds in respect of the

claim for which such indemnification payment was made, the Indemnified Party shall promptly pay an amount equal to the amount of such proceeds (but not exceeding the amount of such net indemnification payment) to the Indemnifying Party.

(f) The Parties agree and acknowledge that the provisions of this ARTICLE X represent the Indemnified Party's exclusive recourse with respect to any Losses for Third Party Claims for which indemnification is provided to the Indemnified Party under this ARTICLE X.

10.4 Insurance. During the Term, if the Condition Precedent is satisfied, and thereafter for so long as a Third Party Claim may be brought for which Processa must indemnify Aposense pursuant to Section 10.1, Processa shall obtain and maintain, at its sole cost and expense, product liability insurance in amounts that are reasonable and customary in the pharmaceutical industry, but in no event less than $5 million per occurrence or claim, and $10 million in the aggregate, or a comparable program of self-insurance. Such product liability insurance shall insure against all liability, including product liability and property damage arising out of the Development, use or Commercialization of Compounds and Products by Processa, its Affiliates, or Sublicensees in the Territory. Without limiting the generality of the foregoing, Processa shall maintain comprehensive general liability insurance, including product liability insurance, to cover its activities and, unless its Affiliates and Sublicensees maintain comparable coverage, the activities of its Affiliates and Sublicensees, with respect to Compounds and Products. Processa shall provide satisfactory evidence of adequate insurance coverage to Aposense upon the request of Aposense prior to the Condition Precedent Satisfaction Date and, upon the written request of Aposense, concurrent with any renewal or replacement of such coverage.

## ARTICLE XI
## TERM AND TERMINATION

11.1 Term. The term of this Agreement (the "Term") shall commence on the Effective Date and, unless earlier terminated as provided in this ARTICLE XI, shall continue in full force and effect until the expiration of the last Royalty Term. On a country-by-country and Product-by-Product basis, upon the expiration of the Royalty Term in such country with respect to such Product, Processa shall have a fully paid-up, perpetual, irrevocable license under the Aposense Intellectual Property and Aposense's interest in the Joint Intellectual Property with respect to such Product in such country.

11.2 Termination for Failure to Satisfy Condition Precedent. If, for any reason (including a failure to meet the conditions in Section 2.1 prior to end of the Condition Precedent Period), Processa or Aposense does not satisfy the Condition Precedent within the Condition Precedent Period, then this Agreement shall automatically terminate in its entirety on the day after the last day of the Condition Precedent Period.

11.3 Termination for Convenience. Processa shall have the right upon sixty (60) days prior written notice to Aposense to terminate this Agreement in its entirety for any reason.

11.4 Termination for Cause. In the event of a material breach of this Agreement by a Party, the other Party may give the Party in default notice requiring it to cure such default, which

notice shall specify the nature of the breach. If such material breach is not cured within ninety (90) days after receipt of such notice (or within fifteen (15) days in the case of a payment breach), the notifying Party shall be entitled (without prejudice to any other rights conferred on it by this Agreement or under applicable Law) to terminate this Agreement by giving written notice to the defaulting Party. The right of either Party to terminate this Agreement as set forth in this Section 11.4 shall not be affected in any way by its waiver of, or failure to take action with respect to, any previous default.

11.5 Additional Termination by Aposense. In the event that Aposense has provided written notice to Processa pursuant to Section 5.2, if Processa does not respond to Aposense in writing within sixty (60) days of receipt of such notice from Aposense and reasonably demonstrate in such response compliance with Processa's obligations under Section 5.1, Aposense shall be entitled (without prejudice to any other rights conferred on it by this Agreement or under applicable Law) to terminate this Agreement by giving written notice to Processa.

11.6 Termination for Insolvency. This Agreement may be terminated by a Party upon written notice to the other Party if (a) the other Party shall make an assignment for the benefit of its creditors, file a petition in bankruptcy, petition or apply to any tribunal for the appointment of a custodian, receiver or trustee for it or a substantial part of its assets, or shall commence any proceeding under any bankruptcy, reorganization, readjustment of debt, dissolution or liquidation law or statute of any jurisdiction, whether now or hereafter in effect; or (b) if there shall have been filed against the other Party any such *bona fide* petition or application, or any such proceeding shall have been commenced against it, in which an order for relief is entered or that remains undismissed or unstayed for a period of ninety (90) days or more; or (c) if the other Party by any act or omission shall consent to, approve of or acquiesce in any such petition, application or proceeding or order for relief or the appointment of a custodian, receiver or trustee for it or any substantial part of its assets, or shall suffer any such custodianship, receivership or trusteeship to continue undischarged or unstayed for a period of ninety (90) days or more. Termination shall be effective upon the date specified in such notice.

11.7 Termination for Challenge of Aposense Patent Rights. If Processa or any of Processa's Affiliates or Sublicensees commences an action in any court or tribunal of competent jurisdiction that challenges, opposes or disputes the validity, enforceability or patentability of any Aposense Patent Rights, or any of the claims thereof, or supports or assists any Third Party that commences such an action in any such court or tribunal, Aposense shall have the right to terminate this Agreement upon notice to Processa; provided, however, that Aposense shall not have a right to terminate if the challenge is brought by a Sublicensee, either directly or indirectly through any Third Party, and Processa or the Affiliate, as the case may be, terminates such Sublicensee's sublicense rights hereunder within thirty (30) days after becoming aware of such challenge.

11.8 Consequences of Termination. If this Agreement (w) terminates automatically pursuant to Section 11.2, (x) is terminated by Aposense under Section 11.4, 11.5, 11.6 or 11.7, (y) is terminated by Processa under Section 11.3, or (z) is terminated by Processa under Section 11.4 or 11.6, then the licenses granted to Processa in Section 2.2 and, except as provided in this Section 11.8 and Sections 11.9 and 11.10 (and any Articles and Sections referenced therein), all

other rights and obligations of the Parties under this Agreement shall terminate. Upon a termination described in clause (x) (but not clause (w), (y) or (z)) of this Section 11.8, clause (a) shall apply, and, upon a termination described in clause (w), (x) or (y) (but not clause (z)), Processa shall grant, and shall cause any applicable Affiliate to grant, Aposense any combination of the following clauses (b) through (f) elected by Aposense, provided that (i) upon a termination described in clause (w), only clause (c) and, to the extent that any Processa Intellectual Property, Sublicensee Intellectual Property or Joint Intellectual Property exists as of such termination, clause (e) shall apply, and (ii) Processa shall only be required to grant Aposense rights to Sublicensee Materials under the applicable sublicense agreement(s) with Sublicensee(s) to whom Aposense has not granted a direct license pursuant to Section 11.8(a):

(a) Sublicenses. Aposense hereby grants, effective automatically upon any termination of this Agreement by Aposense pursuant to Section 11.4, 11.5, 11.6 or 11.7, a direct license to each then-existing Sublicensee, provided that (i) such Sublicensee is not in breach under the applicable sublicense, (ii) such Sublicensee's failure to comply with the terms of its sublicense or other actions or omissions were not a basis for such termination, and (iii) such Sublicensee continues to satisfy all obligations under this Agreement applicable to such sublicense, including the diligence obligations set forth in ARTICLE V and all payments to Aposense required under Section 6, from and after the date that such direct license becomes effective.

(b) Regulatory Matters. Ownership of all filings with Regulatory Authorities in the Territory relating to Compounds and Products and Regulatory Approvals relating to Compounds and Products held Processa or its Affiliates or applicable Sublicensees, including related correspondence with Regulatory Authorities, and Processa shall provide copies thereof to Aposense;

(c) Pre-clinical and Clinical Matters. Possession of all pre-clinical and clinical data, including pharmacology and biology data, within the Processa Know-How and applicable Sublicensee Intellectual Property;

(d) Manufacturing Matters. At Aposense's option, to be exercised no later than the later of (x) thirty (30) days after the effective date of termination or (y) thirty (30) days after Aposense's receipt of the applicable Manufacturing agreements,

(i) use of Commercially Reasonable Efforts by Processa and its Affiliates and applicable Sublicensees to effect the assignment of each Manufacturing agreement specific and exclusive to Compounds or Products to Aposense, if such agreement is then in effect and such assignment is permitted under such agreement or by the applicable Third Party; provided that Processa and its applicable Affiliates and applicable Sublicensees shall be released to the extent the applicable Third Party will permit from any obligation arising out of such agreement following such assignment and Aposense shall execute such documentation reasonably satisfactory to Processa to effectuate such agreement; provided further that if any such agreement is specific but not exclusive to Compounds or Products, or is not assigned to Aposense for any reason, Processa will discuss in good faith with Aposense terms upon which Processa and its Affiliates and applicable Sublicensees shall use Commercially Reasonable Efforts to provide Aposense with the benefits of such agreement to the extent it relates to

Compounds or Products for a limited period of time (not to exceed six (6) months) and upon payment of a reasonably acceptable fee to Processa;

(ii) for a period of up to six (6) months following the effective date of termination, (A) cooperation with Aposense in reasonable respects to transfer Manufacturing documents and materials within the Processa Know-How and applicable Sublicensee Intellectual Property that are used (at the time of the termination) by Processa or its Affiliates or applicable Sublicensees exclusively in the Manufacture of Compounds and Products to the extent such Manufacturing documents and materials are not obtained by Aposense pursuant to the assignment of agreements pursuant to paragraph (i) above, and (B) cooperation with Aposense to provide Aposense with reasonable access to and right to use such Manufacturing documents and materials in Processa's or its Affiliates' or applicable Sublicensees' possession or Control to the extent they relate to, but are not used exclusively in, the Manufacture of Compounds and Products, subject to appropriate confidentiality and limitation on use protections applicable to for Manufacturing documents and materials;

(iii) for a period of up to six (6) months following the effective date of termination, (A) cooperation with Aposense in reasonable respects to transfer Manufacturing technologies within the Processa Intellectual Property and applicable Sublicensee Intellectual Property that are used (at the time of the termination) by Processa or its Affiliates or applicable Sublicensees exclusively in the Manufacture of Compounds and Products, and (B) cooperation with Aposense to provide Aposense with reasonable access to and right to use such Manufacturing technologies Controlled by Processa or its Affiliates (other than Processa Excluded Affiliates) or applicable Sublicensees to the extent they relate to, but are not used exclusively in, the Manufacture of Compounds and Products and that Processa or such Affiliates or Sublicensees are permitted to provide such access to Aposense; provided that Aposense shall reimburse Processa for Processa's reasonable out-of-pocket expenses to provide such requested assistance, to the extent such Manufacturing technologies are not obtained by Aposense pursuant to the assignment of agreements pursuant to paragraph (i) above; and

(iv) sale of Processa's or its Affiliates' or applicable Sublicensees' then-existing inventory of Compounds and Products to Aposense, at Processa's or its applicable Affiliates' or applicable Sublicensees' cost of Manufacture, but only if the following conditions have been met: (A) such Compounds and Products meet the applicable release specifications; and (B) Processa does not reasonably believe the continued use of such Compounds and Products causes safety concerns;

(e) License Grant. At Aposense's option, to be exercised by written notice to Processa no later than thirty (30) days after the effective date of termination, a worldwide license, with the right to sublicense, under the Processa Patent Rights, Processa Know-How, Processa's interest in the Joint Intellectual Property, and applicable Sublicensee Intellectual Property, solely to make, have made, use, sell, offer for sale and import Compounds and Products in the Field that were Developed or Commercialized prior to the effective date of termination, which license would be, at Aposense's election, either (i) non-exclusive, fully paid-up, non-royalty-bearing, irrevocable and perpetual or (ii) exclusive and royalty-bearing subject to mutual agreement by Aposense and Processa on commercially reasonable terms; provided that, notwithstanding the foregoing, with respect to any Processa Patent Rights or Processa Know-

How that Processa acquired from a Third Party (by license or otherwise), or any applicable Sublicensee Intellectual Property that the applicable Sublicensee(s) acquired from a Third Party (by license or otherwise), Processa or the applicable Sublicensee(s) shall only be required to grant to Aposense a license to such Processa Patent Rights, Processa Know-How or Sublicensee Intellectual Property to the extent permitted under the applicable agreement with such Third Party, and Aposense shall pay Processa or such Sublicensee or such Third Party, as determined by Processa, any payment due to such Third Party relating to the Compounds and Products; provided further that Aposense shall execute such documentation reasonably satisfactory to Processa to effectuate such agreement; and if the license granted to Aposense is exclusive, Aposense shall have the same enforcement rights with respect to any Processa Patent Rights and Patent Rights within the Sublicensee Intellectual Property that exclusively Cover Products that are licensed to Aposense pursuant to this Section 11.8(e) as Processa has with respect to Infringement Claims pursuant to Section 7.3 (to the extent that Processa or the applicable Sublicensee(s) have such rights with respect to such Processa Patent Rights or Patent Rights within the Sublicensee Intellectual Property, as applicable), provided that any enforcement of Processa Patent Rights, Joint Patent Rights or Patent Rights within the Sublicensee Intellectual Property that Cover subject matter other than such Products shall be performed by Aposense only with the consultation and prior agreement of Processa or the applicable Sublicensee, which such agreement shall not unreasonably withheld, delayed or conditioned.

(f) Assignment of Trademarks. Assign to Aposense all of Processa's or its applicable Sublicensees' right, title and interest in any trademark owned by Processa or its Affiliates or applicable Sublicensees and used solely in connection with the Products, along with all associated goodwill.

11.9 Effect of Termination or Expiration; Accrued Rights and Obligations. Termination or expiration of this Agreement for any reason shall not release either Party from any liability that, at the time of such termination or expiration, has already accrued or that is attributable to a period prior to such termination (including payment obligations accrued prior to the effective date of termination or expiration pursuant to ARTICLE VI) nor preclude either Party from pursuing any right or remedy it may have hereunder or at Law or in equity with respect to any breach of this Agreement.

11.10 Survival. The rights and obligations set forth in this Agreement shall extend beyond the Term or termination or expiration of this Agreement only to the extent expressly provided for in this Agreement or to the extent required to give effect to a termination or expiration of this Agreement or the consequences of a termination or expiration of this Agreement as expressly provided for in this Agreement. Without limiting the generality of the foregoing, it is agreed that the provisions of ARTICLE I, Sections 2.3, 2.4, 6.10 (only for thirty-six (36) months after expiration or termination), 6.11, 6.12, 6.13, 6.14, 7.1, 7.9, 8.1, 8.2, 8.5, 9.5, ARTICLE X, and Sections 11.1 (last sentence as to any such license that became perpetual and irrevocable prior to expiration or termination), 11.8, 11.9, 11.10 and ARTICLE XII shall survive expiration or termination of this Agreement for any reason.

## ARTICLE XII
## MISCELLANEOUS

12.1 Governing Law; Jurisdiction. This Agreement shall be governed by and interpreted in accordance with the internal laws of England and Wales, without regard to its conflicts of laws rules. Each Party (a) irrevocably submits to the exclusive jurisdiction in the state court sitting in London, England (collectively, the "Courts"), for purposes of any action, suit or other proceeding arising out of this Agreement, and (b) agrees not to raise any objection at any time to the laying or maintaining of the venue of any such action, suit or proceeding in any of the Courts, irrevocably waives any claim that such action, suit or other proceeding has been brought in an inconvenient forum and further irrevocably waives the right to object, with respect to such action, suit or other proceeding, that such Court does not have any jurisdiction over such Party. Either Party may serve any process required by such Courts by way of notice under this Agreement. Notwithstanding anything to the contrary in this Section 12.1, each Party shall have the right to institute judicial proceedings against the other Party or anyone acting by, through, or under such other Party, in any court of competent jurisdiction, in order to enforce the instituting Party's rights hereunder through reformation of contract, specific performance, injunction, or similar equitable relief.

12.2 Dispute Resolution. In the event of a dispute arising out of or relating to this Agreement, either Party shall provide written notice of the dispute to the other, in which event the dispute shall be referred to the Senior Executives of each Party, for attempted resolution by good faith negotiations within twenty (20) days after such notice is received. In the event the Senior Executives do not resolve such dispute within the allotted twenty (20) days, either Party may, after the expiration of the twenty (20) day period, seek to resolve the dispute in accordance with Section 12.1.

12.3 Waiver. Waiver by a Party of a breach hereunder by the other Party shall not be construed as a waiver of any succeeding breach of the same or any other provision. No delay or omission by a Party to exercise or avail itself of any right, power, or privilege that it has or may have hereunder shall operate as a waiver of any right, power, or privilege by such Party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.

12.4 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address specified in this Section 12.4 and shall be: (a) delivered personally; (b) sent by registered or certified mail, return receipt requested, postage prepaid; (c) sent via a reputable nationwide overnight courier service; or (d) sent by facsimile or other electronic transmission. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service, or when transmitted with confirmation of receipt, if transmitted by facsimile or other electronic transmission (if such transmission is on a Business Day; otherwise, on the next Business Day following such transmission).

Notices to Processa shall be addressed to:

Processa Pharmaceuticals, Inc.
7380 Coca Cola Drive, Suite 106
Hanover, MD 21076
Attn: Wendy Guy, Chief Administrative Officer
Email: wguy@processapharmaceuticals.com

Notices to Aposense shall be addressed to:

Aposense LTD.
5-7 Ha'Odem St.
Petach Tikva, Isreal
Attn: Chief Financial Officer
Email: Yuvalg@aposense.com

Either Party may change its address by giving notice to the other Party in the manner provided above.

12.5 Entire Agreement. This Agreement (including Schedules) contains the complete understanding of the Parties with respect to the subject matter of this Agreement and supersedes all prior understandings and writings between the Parties relating to such subject matter.

12.6 Severability. If any provision of this Agreement is held unenforceable by a court or tribunal of competent jurisdiction because it is invalid or conflicts with any Law of any relevant jurisdiction, the validity of the remaining provisions shall not be affected. In such event, the Parties shall negotiate a substitute provision that, to the extent possible, accomplishes the original business purpose.

12.7 Assignment. Neither this Agreement nor any right or obligation hereunder may be assigned or otherwise transferred by any Party without the consent of the other Party; provided, however, that any Party may, without such consent, assign this Agreement, in whole or in part: (a) to any of its respective Affiliates, provided that such Affiliate has acknowledged and confirmed in writing that effective as of such assignment, such Affiliate shall be bound by this Agreement to the identical extent applicable to the assigning Party; or (b) to any successor in interest by way of merger, acquisition or sale of all or substantially all of its business or assets relating to the subject matter of this Agreement, provided that such successor (if the applicable Party is not the surviving entity in such transaction) agrees in writing to be bound by the terms of this Agreement to the identical extent applicable to the assigning Party. Any purported assignment in violation of this Section 12.7 shall be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement.

12.8 Counterparts; Exchange by Facsimile. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and that together shall constitute one and the same instrument. Such counterparts may be exchanged by facsimile or PDF (provided that each executed counterpart is transmitted in one complete transmission or

electronic mail message). Where there is an exchange of executed counterparts by facsimile or PDF, each Party shall be bound by the Agreement notwithstanding that original copies of the Agreement may not be exchanged immediately. The Parties shall cooperate after execution of the Agreement and exchange by facsimile or PDF to ensure that each Party obtains an original executed copy of this Agreement with reasonable promptness.

12.9 Force Majeure. No Party shall be liable for failure of or delay in performing obligations set forth in this Agreement, and no Party shall be deemed in breach of its obligations, if such failure or delay is due to a natural disaster, explosion, fire, flood, tornadoes, thunderstorms, earthquake, war, terrorism, riots, embargo, losses or shortages of power, labor stoppage, substance or material shortages, damage to or loss of product in transit not due to a failure by such Party or its Affiliates to exercise reasonable care, events caused by reason of Laws of any Governmental Authority, events caused by acts or omissions of a Third Party not induced or solicited by such Party or its Affiliates, or any other cause reasonably beyond the control of such Party or its Affiliates; provided that such Party uses Commercially Reasonable Efforts to overcome the difficulties created by such force majeure event and to resume performance of its obligations as soon as practicable.

12.10 Third-Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party other than a Aposense Party or a Processa Party, as applicable, that is an Indemnified Party under ARTICLE X, and no Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against either Party.

12.11 Relationship of the Parties. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other, except as expressly provided in this Agreement. Neither Party shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said other Party's approval. For all purposes and notwithstanding any other provision of this Agreement to the contrary, the legal relationship under this Agreement of each Party to the other Party shall be that of independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint venturers between the Parties.

12.12 Performance by Affiliates. To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations.

12.13 No Consequential or Punitive Damages. NEITHER PARTY WILL BE LIABLE FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, OR PUNITIVE DAMAGES, INCLUDING LOST PROFITS, ARISING FROM OR RELATING TO THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTHING IN THIS SECTION 12.13 IS INTENDED TO LIMIT OR RESTRICT (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY UNDER THIS AGREEMENT WITH RESPECT TO THIRD PARTY CLAIMS, OR (B) DAMAGES TO WHICH A PARTY MAY BE ENTITLED FOR BREACH OF CONFIDENTIALITY AND

LIMITATION ON USE OBLIGATIONS SET FORTH IN THIS AGREEMENT, OR (C) DAMAGES TO WHICH A PARTY MAY BE ENTITLED FOR THE WILLFUL MISCONDUCT, INTENTIONAL BREACH OR FRAUD OF THE OTHER PARTY.

*[Signature page follows]*

IN WITNESS WHEREOF, the Parties have signed this Agreement as of the Effective Date.

**PROCESSA PHARMACEUTICALS, INC.**

By: _____

Name: David Young

Title: CEO

**APOSENSE LTD**

By: _____

Name: Yuval Gottenstein

Title: CFO

**Schedule 1.12** Current as of _____, 2020

**Schedule 6.12**

**Aposense Wiring Instructions**

Company Name: Aposense Ltd.
Bank Name: Union bank of Israel Ltd.
Bank Branch Number- 062
IBAN: IL15 0130 6200 0006 2460 022
Swift code: UNBKILITDMD

**Exhibit 10.11**

***Execution Copy***

**LICENSE AGREEMENT**

**BY AND BETWEEN**

**PROCESSA PHARMACEUTICALS, INC.**

**AND**

**YUHAN CORPORATION**

**DATED AS OF AUGUST 19, 2020**

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**LICENSE AGREEMENT**

**THIS LICENSE AGREEMENT** is entered into this 19th day of August 2020 (the "Effective Date"), by and between Processa Pharmaceuticals, Inc. a company organized under the laws of Delaware, having a business address at 7380 Coca Cola Drive, Suite 106, Hanover, MD 21076 ("Processa"), and Yuhan Corporation a company in Seoul, Korea, whose principal place of business is at 74, Noryangjin-ro, Dongjak-gu, Seoul, Korea ("Yuhan").

WHEREAS, Yuhan has developed or obtained rights to Yuhan Know-How, Yuhan Patent Rights and the Compound (each as defined below); and

WHEREAS, Processa desires to obtain a license of the Yuhan Patent Rights and the Yuhan Know-How to Develop and Commercialize Compounds and Products (each as defined below), under the terms and conditions set forth herein, and Yuhan desires to grant such a license;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, the Parties agree as follows:

## ARTICLE I
## DEFINITIONS

The following terms, whether used in the singular or plural, shall have the following meanings:

1.1 "Affiliate." Affiliate means any Person directly or indirectly controlled by, controlling or under common control with, a Party, but only for so long as such control shall continue. For purposes of this definition, "control" (including, with correlative meanings, "controlled by," "controlling," and "under common control with") means, with respect to a Person, possession, direct or indirect, of (a) the power to direct or cause direction of the management and policies of such Person (whether through ownership of securities or partnership or other ownership interests, by contract or otherwise), or (b) at least 50% of the voting securities (whether directly or pursuant to any vested and exercisable option, warrant or other similar arrangement) or other comparable equity interests. For clarity, neither of the Parties shall be deemed to be an "Affiliate" of the other.

1.2 "Bankruptcy Code." Bankruptcy Code means Title 11 of the U.S. Code, as amended from time to time.

1.3 "Business Day." Business Day means a day that is not a Saturday, Sunday, or a day on which banking institutions in Baltimore, Maryland or in South Korea are authorized by Law to remain closed.

1.4 "Calendar Quarter." Calendar Quarter means each of the periods ending on March 31, June 30, September 30, and December 31 of any Calendar Year.

1.5 "Calendar Year." Calendar Year means each calendar year during the Term.

1.6 "Combination Product." Combination Product means (a) any pharmaceutical product that is a single formulation consisting of a Compound and one or more other active compounds or active ingredients, which other active compounds or active ingredients are not Compounds ("Other API") or (b) any combination of a Compound sold together with any separately formulated Other API for a single invoiced price.

1.7 "Commercialization" or "Commercialize." Commercialization or Commercialize means activities directed to obtaining pricing and reimbursement approvals, marketing, promoting, Manufacturing commercial supplies of, distributing, importing, offering for sale, or selling a product.

1.8 "Commercially Reasonable Efforts." Commercially Reasonable Efforts means, with respect to an objective, the reasonable, diligent, good faith efforts of a Party (including the efforts of its Affiliates and Sublicensees) to accomplish such objective that a biopharmaceutical company of comparable size and resources would normally use to accomplish a similar objective under similar circumstances, and, specifically with respect to obligations hereunder relating to a Compound or Product, the carrying out of such obligations with those efforts and resources that a biopharmaceutical company of comparable size and resources would use were it Developing, Manufacturing or Commercializing its own pharmaceutical products that are at a similar stage of development or product life cycle and of similar market potential as the Compound or Product, taking into account actual and potential issues of safety, efficacy or stability, product profile (including product modality, category and mechanism of action), stage of development or life cycle status, product labeling or anticipated labeling, the present and future market potential, past performance of the Compound or Product, actual and projected Development, Regulatory Approval, pricing and reimbursement approval, Manufacturing and Commercialization costs, existing or projected pricing, sales, reimbursement and financial return, medical and clinical considerations, present and future regulatory environment, any issues regarding the ability to Manufacture the Compound or Product, the likelihood and timing of obtaining Regulatory Approvals and pricing and reimbursement approvals, proprietary position, strength and duration of patent protection and anticipated exclusivity, competitive Third Party products at the time and the likely competitive environment at the time of projected entry into the market and thereafter, and any other relevant scientific, technical, operational and commercial factors, all as measured by the facts and circumstances at the time such efforts are due. Commercially Reasonable Efforts will be determined on a country-by-country and indication-by-indication basis for the Compound or Product, and the level of effort is expected to change over time, reflecting changes in the status and value of the Compound or Product and the market conditions and country(ies) involved.

1.9 "Clinical Trial." Clinical Trial shall mean any study in which human subjects are dosed with a drug, whether approved or investigational, including any Phase 1 Clinical Trial, Phase 2 Clinical Trial, Phase 3 Clinical Trial, or any Pivotal Clinical Trial.

1.10 "Compound." Compound means YH12852, which has the chemical structure set forth on Schedule 1.10, together with all analogs, derivatives, metabolites, stereoisomers, polymorphs, formulations, mixtures or compositions thereof, and any existing or future improved or modified versions of the foregoing developed by or on behalf of Processa, its Affiliates or Sublicensees.

1.11 "Control" or "Controlled." Control or Controlled means, with respect to any tangible property or intellectual property right or other intangible property, the possession (whether by ownership or license (other than by grant of a license to one Party by the other Party pursuant to this Agreement or by grant of a license or sublicense to a Sublicensee by Processa pursuant to a license or sublicense agreement)) by a Person of the ability to grant to another Person access to such tangible property or access to or a license or sublicense to such intellectual property right or other intangible property, as provided herein without violating the terms of any agreement with any other Person.

1.12 "Cover," "Covering" or "Covered." Cover, Covering or Covered means, with respect to a compound, product, technology, process or method that, in the absence of ownership of or a license granted under a Patent Right, the manufacture, use, offer for sale, sale or importation of such compound or product or the practice of such technology, process or method would infringe such Patent Right (or, in the case of a Patent Right that has not yet issued, would infringe such Patent Right if it were to issue).

1.13 "CTA." CTA means (a) a clinical trial authorization application filed with a Regulatory Authority in any regulatory jurisdiction outside the United States, the filing of which is necessary to commence or conduct clinical testing of a drug or biologic product in humans in such jurisdiction; or (b) documentation issued by a Regulatory Authority that permits the conduct of clinical testing of a product in humans in a regulatory jurisdiction.

1.14 "Development" or "Develop." Development or Develop means pre-clinical, non-clinical and clinical drug research, discovery and development activities, including IND-enabling toxicology and other IND-enabling pre-clinical development efforts, stability testing, process development, compound property optimization, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, clinical pharmacology, Manufacturing supplies of compounds and products for pre-clinical, non-clinical and clinical use, clinical studies (including pre- and post-approval studies and investigator sponsored clinical studies), regulatory affairs, and Regulatory Approval and clinical study regulatory activities (excluding regulatory activities directed to obtaining pricing and reimbursement approvals).

1.15 "EMA." EMA means the European Medicines Agency and any successor agency.

1.16 "FDA." FDA means the U.S. Food and Drug Administration and any successor agency.

1.17 "Field." Field means for use in the treatment, prevention, palliation, and/or diagnosis of any and all human and/or animal diseases, disorder, or conditions.

1.18 "First Commercial Sale." First Commercial Sale means, with respect to a Product in a country, the first sale of such Product in such country by Processa, any of its Affiliates or any Sublicensee to the first unrelated Third Party (excluding any Sublicensee) in such country for use or consumption of such Product in such country after receipt of the first Regulatory Approval for such Product in such country. Sales for purposes of testing the Product and sample purposes shall not be deemed a First Commercial Sale. For clarity, First Commercial Sale will be determined on a Product-by-Product and country-by-country basis, as applicable.

1.19 "FPFV." FPFV means the first patient's first screening visit in a Clinical Trial at or prior to which such subject signs an informed consent to participate in such Clinical Trial.

1.20 "Governmental Authority." Governmental Authority means any national, federal, state or local government, or political subdivision thereof, or any multinational organization or authority or any authority, agency, or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body.

1.21 "IND." IND means an investigational new drug application filed with the FDA with respect to a Compound or Product, or an equivalent application filed with the Regulatory Authority of a country or regulatory jurisdiction in the Territory other than the United States, and all amendments and supplements thereto.

1.22 "Joint Intellectual Property." Joint Intellectual Property means the Joint Inventions and Joint Patent Rights.

1.23 "Know-How." Know-How means all unpatented technical information, trade secrets, formulae, standards, knowledge, directions, instructions, test protocols, procedures and results, studies, analyses, raw material sources, data, Manufacturing data, and any other confidential or proprietary interest in information.

1.24 "Law" or "Laws." Law or Laws means all laws, statutes, rules, regulations, orders, judgments, or ordinances of any Governmental Authority.

1.25 "Losses." Losses means any and all (a) claims, losses, liabilities, damages, fines, royalties, governmental penalties or punitive damages, deficiencies, interest, awards, judgments, and settlement amounts (including special, indirect, incidental, and consequential damages, lost profits, and Third Party punitive and multiple damages) payable to a Third Party, and (b) in connection with all of the items referred to in clause (a) above, any and all costs and expenses (including reasonable counsel fees and all other expenses reasonably incurred in investigating, preparing or defending any litigation or proceeding, commenced or threatened) payable to a Third Party.

1.26 "Major Markets." Major Markets means, collectively, the United States, France, Germany, Italy, Spain, and the United Kingdom.

1.27 "Manufacture" or "Manufacturing." Manufacture or Manufacturing means activities directed to making, having made, producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and storage of a product.

1.28 "Marketing Approval." Marketing Approval means any and all approvals (including supplements, amendments, and post-marketing approvals), licenses, registrations or authorizations of any Regulatory Authority that are necessary to market and/or sell a drug or biologic product in a country or jurisdiction for one or more uses.

1.29 "NDA." NDA means a New Drug Application, as defined in the United States Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301, et. seq., as it may be amended from time to time, including the rules, regulations, guidance, guidelines, and requirements promulgated or issued thereunder), filed with the FDA with respect to a Compound or Product, or an equivalent application filed with the Regulatory Authority of a country in the Territory other than the United States, and all amendments and supplements thereto.

1.30 "Net Sales." Net Sales means the gross amounts billed or invoiced by Processa, or any of its Affiliates, to any Third Party that is not a Sublicensee with respect to sales of Products in the Territory, calculated in the same manner as reported in such Person's audited financial statements, less the following to the extent actually incurred or allocated in accordance with Processa's or its Affiliates' customary accounting practices consistently and generally applied:

(a) Volume, cash or trade discounts, credits or allowances not to exceed thirty five percent (35%) of the billed or invoiced amount, including discounts in the form of inventory management fees paid to wholesalers and distributors all to the extent such discounts are included in the invoices and actually granted, but excluding commissions for commercialization;

(b) Credits, refunds or allowances granted upon returns, rejections or recalls and for retroactive price reductions or billing errors;

(c) Freight, postage, shipping, and insurance costs incurred in transporting the applicable Products to the extent that such items are applicable to such sale and are separately itemized and invoiced and actually paid as evidenced by invoices, receipts or other appropriate documents;

(d) Amounts paid (including rebates and chargeback payments or credits or other equivalents thereof) to formularies, government or government agency programs, trade customers, managed health care organizations and pharmacy benefit managers (or equivalents thereof) to obtain listing or purchase of the applicable Products not to exceed thirty-five (35%) of the billed or invoiced amount;

(e) Bad debts, uncollectible amounts, and collection costs relating to the sale of Products that are actually written off; and

(f) To the extent not reimbursed by a third party, taxes, tariffs, duties or other governmental charges (other than income taxes) levied on, absorbed, or otherwise imposed on the sales, transportation, delivery, use, exportation, or importation of the applicable Products.

Sales of Products between Processa and its Affiliates or Sublicensees for resale shall be excluded from the computation of Net Sales. Subject to Section 7.6, all sales by a Sublicensee shall also be excluded from the computation of Processa Net Sales. Disposal or use of Products at or below cost for regulatory, Development or charitable purposes, such as clinical trials, compassionate use, named patient use, or indigent patient programs, shall not be deemed a sale hereunder.

With respect to any sale of any Product in a given country for any substantive consideration other than monetary consideration on arm's length terms (which has the effect of reducing the invoiced amount below what it would have been in the absence of such non-monetary consideration), for purposes of calculating the Net Sales under this Agreement, such Product shall be deemed to be sold exclusively for cash at the average Net Sales price charged to Third Parties for cash sales in such country during the applicable reporting period (or if there were only *de minimis* cash sales in such country, at the fair market value as determined in good faith based on pricing in comparable markets).

If a Product is sold as part of a Combination Product, Net Sales will be the product of (x) Net Sales of the Combination Product calculated as above (*i.e.*, calculated as for a non-Combination Product) and (y) the fraction (A/(A+B)), where:

(i) A is the average selling price of the Product comprising a Compound as the sole therapeutically active ingredient during the most recently completed Calendar Quarter during which such non-Combination Product was sold in such country; and

(ii) B is the average selling price in such country of products containing the Other API contained in the Combination Product as the sole therapeutically active ingredient when sold separately during the most recently completed Calendar Quarter during which such products were sold in such country.

If both A and B cannot be determined by reference to non-Combination Product sales as described above, then Net Sales for purposes of determining Royalty payments will be calculated as above, but the average selling price in the above equation shall be determined by mutual agreement reached in good faith by the Parties prior to the end of the accounting period in question based on an equitable method of determining same that takes into account, in the applicable country, variations in dosage units and the relative fair market value of each therapeutically active ingredient in the Combination Product. If the Parties are unable to reach such an agreement prior to the end of the applicable accounting period, then the Parties will refer such matter to a jointly selected Third Party with expertise in the pricing of pharmaceutical products that is not an employee, consultant, legal advisor, officer, director or stockholder of, and does not have any conflict of interest with respect to, either Party for resolution, which will be final and binding on the Parties.

1.31 "Party." Party means either Yuhan or Processa; "Parties" means both Yuhan and Processa.

1.32 "Patent Rights." Patent Rights means all patent applications, patents, certificates of invention, applications for certificates of invention and priority patent filings, including any continuations, continuations-in-part, renewals, requests for continued examination and divisions of any such patents and patent applications, any patents or certificates of invention issuing from any of the foregoing, any extensions, reissues, reexaminations, substitutions, confirmations, registrations, revalidations, revisions, additions or supplementary patent certificates thereto, and all foreign counterparts thereof.

1.33 "Person." Person means any natural person or any corporation, company, partnership, joint venture, firm, Governmental Authority, or other entity, including a Party.

1.34 "Phase 1 Clinical Trial." Phase 1 Clinical Trial means a single randomized, placebo, or active controlled human clinical trial which provides for the first introduction into humans of a product, conducted in normal volunteers or patients to get information on product safety, tolerability, immunogenicity, pharmacological activity, or pharmacokinetics, as more fully defined in 21 C.F.R. § 312.21(a) (or analogous regulations of an applicable Regulatory Authority outside the U.S.).

1.35 "Phase 2 Clinical Trial." Phase 2 Clinical Trial means, a single randomized, placebo, or active controlled human clinical trial of any product, the principal purposes of which are the evaluation of the efficacy of such product for a particular indication in the target patient population and a determination of the common side-effects and risks associated with the product in the dosage range to be prescribed and to obtain sufficient information about the efficacy for such pharmaceutical product in the disease or condition being studied to permit the design and dose of such product in a Phase 2 Clinical Trial, as described in 21 C.F.R. § 312.21(b) (or analogous regulations of an applicable Regulatory Authority outside the U.S.). Phase 2 Clinical Trial shall include any Phase 2a or Phase 2b Clinical Trial.

1.36 "Phase 3 Clinical Trial." Phase 3 Clinical Trial means a single randomized, placebo or active controlled human clinical trial of any product on sufficient numbers of patients that is designed to demonstrate statistically that such product is safe and efficacious for its intended use, to evaluate the risk-benefit relationship of the product, and to define warnings, precautions and adverse reactions that are associated with such product in the dosage range to be prescribed, as described in 21 C.F.R. § 312.21(c) (or analogous regulations of an applicable Regulatory Authority outside the U.S.), and that is intended to support Regulatory Approval of such product.

1.37 "Pivotal Clinical Trial." Pivotal Clinical Trial shall mean (a) a Phase 3 Clinical Trial that is intended by Company or its Affiliates or Sublicensees to be submitted (together with any other registration trials that are prospectively planned when such Phase 3 Clinical Trial is Initiated) for Regulatory Approval in the United States or the EU, or (b) any other Clinical Trial that is intended by Company or its Affiliates or Sublicensees to establish that a Product is safe and efficacious for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with such pharmaceutical product in the dosage range to be prescribed, which Clinical Trial is a registration trial intended by Company or its Affiliates or Sublicensees to be sufficient for filing an application for a Regulatory Approval for such product in the United States or another country or some or all of an extra-national territory, solely as evidenced by the acceptance for filing for a Regulatory Approval for such Product after completion of such Clinical Trial.

1.38 "Planned Public Offering." Planned Public Offering means Processa's planned capital raise for the up-list to Nasdaq or the NYSE pursuant to the sale of shares pursuant to the Form S-1 Registration Statement (File No. 333-235511), as amended.

1.39 "Processa Intellectual Property." Processa Intellectual Property means, collectively, Processa Know-How and Processa Patent Rights.

1.40 "Processa Know-How." Processa Know-How means all Know-How Controlled as of the Effective Date or thereafter during the Term by Processa or any of its Affiliates (other than any Know-How included in Joint Intellectual Property) that is used by Processa or any of its Affiliates in the Development, Manufacture or Commercialization of any Compound or Product; provided, however, that, if Processa is acquired by a Third Party, "Processa Know-How" shall exclude any Know-How that (a) is Controlled by such Third Party or the Affiliates of such Third Party (other than Processa and the Persons that were Processa's Affiliates immediately prior to the closing of such acquisition transaction (such Affiliates, "Processa Pre-Existing Affiliates")) ("Processa Excluded Affiliates") and (b) was not Controlled by Processa or any of the Processa Pre-Existing Affiliates immediately prior to the closing of such acquisition transaction; provided further that, if, after the closing of such acquisition, any such Processa Excluded Affiliate has or acquires Control of any Know-How that is necessary or useful to Develop, Manufacture or Commercialize any Compound or Product and that is used to Develop, Manufacture or Commercialize any such Compound or Product, such additional Know-How that is Controlled by such Processa Excluded Affiliate shall be included in Processa Know-How.

1.41 "Processa Patent Rights." Processa Patent Rights means all Patent Rights in the Territory Controlled as of the Effective Date or thereafter during the Term by Processa or any of its Affiliates (other than Joint Patent Rights) that Cover any Compound or Product and are used by Processa or any of its Affiliates in the Development, Manufacture or Commercialization of any Compound or Product; provided, however, that, if Processa is acquired by a Third Party, "Processa Patent Rights" shall exclude any Patent Rights that (a) are Controlled by such Third Party or the Affiliates of such Third Party (other than Processa and Processa Pre-Existing Affiliates) and (b) were not Controlled by Processa or any of the Processa Pre-Existing Affiliates immediately prior to the closing of such acquisition transaction; provided further that, if, after the closing of such acquisition, any such Processa Excluded Affiliate has or acquires Control of any Patent Right that Covers the Development, Manufacture or Commercialization of any Compound or Product and that is used to Develop, Manufacture or Commercialize any such Compound or Product, such additional Patent Right that is Controlled by such Processa Excluded Affiliate shall be included in Processa Patent Rights.

1.42 "Product." Product means any pharmaceutical preparation containing one or more Compounds either as its only active ingredient(s) or as part of a Combination Product. For the avoidance of doubt, nothing in this Agreement grants to Processa or Yuhan any right or license under any Patent Rights or Know-How Controlled by Yuhan or Processa, respectively, with respect to any Other API.

1.43 "Regulatory Approval." Regulatory Approval means an approval by the applicable Regulatory Authority of an NDA and any other approval, license, registration, permit, notification or authorizations (or waiver) of the applicable Regulatory Authority, which is necessary for the Manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale, or other Commercialization of pharmaceutical products in a given country or regulatory jurisdiction, other than any pricing or reimbursement approval.

1.44 "Regulatory Authority." Regulatory Authority means any Governmental Authority with responsibility for granting licenses or approvals necessary for the Development, Manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale or other Commercialization of pharmaceutical products in a country or regulatory jurisdiction, including but limited to the FDA or EMA.

1.45 "Regulatory Documentation." Regulatory Documentation means: (i) all applications for Regulatory Approval; (ii) all Regulatory Approvals, including INDs, CTAs and Marketing Approvals; (iii) all supporting documents created for, referenced in, submitted to or received from an applicable Regulatory Authority relating to any of the applications or Regulatory Approvals described in clauses (i) or (ii), including drug master files (or any equivalent thereof outside the U.S.), annual reports, regulatory drug lists, advertising and promotion documents filed or shared with Regulatory Authorities, adverse event files, safety reports, inspection reports, documents with regard to clinical data, complaint files and Manufacturing records and any supplements thereto; and (iv) all correspondence made to, made with or received from any Regulatory Authority (including written and electronic mail correspondence and minutes from meetings, discussions, or conferences (whether in person or by audio conference or videoconference)).

1.46 "Regulatory Exclusivity." Regulatory Exclusivity means exclusive marketing rights or data protection or other exclusivity rights conferred by any Regulatory Authority with respect to a Product in a country or regulatory jurisdiction within the Territory, other than a Patent Right, including orphan drug exclusivity, pediatric exclusivity, and rights conferred in the United States under the Hatch-Waxman Act.

1.47 "Right of Cross-Reference." Right of Cross-Reference means an authorization that permits an applicable Regulatory Authority in a country to rely on the relevant information (by cross-reference, incorporation by reference or otherwise) contained in Regulatory Documentation (and any data contained therein) filed with such Regulatory Authority with respect to such Party's compound or product, as necessary to conduct a Clinical Trial, to support Regulatory Approval of a product, to support a label expansion, or to support a further indication in such country or as otherwise expressly permitted or required under this Agreement to enable a Party to exercise its rights or perform its obligations hereunder, and, without the disclosure of underlying Confidential Information to such Party.

1.48 "Senior Executive." Senior Executive means, with respect to Yuhan, the CEO of Yuhan, or his or her designee, and, with respect to Processa, the CEO of Processa, or his or her designee. "Senior Executives" means the applicable officers of Yuhan and Processa.

1.49 "Share Issuance Agreement." Share Issuance Agreement means the Share Issuance Agreement entered into by Yuhan and Processa as of August 19, 2020, a copy of which is set forth as Schedule 1.49.

1.50 "Sublicensee." Sublicensee means a Third Party that has been granted a sublicense under the rights granted to Processa pursuant to Section 2.1 of this Agreement, beyond the mere right to purchase Compound or Product Manufactured by or on behalf of Processa or its Affiliates.

1.51 "Territory." Territory means all countries of the world except for Manufacturing and Commercialization rights in South Korea.

1.52 "Third Party." Third Party means any Person other than Yuhan or Processa or any of their respective Affiliates.

1.53 "U.S." U.S. means the United States of America, including its territories and possessions.

1.54 "Valid Claim." Valid Claim means any claim of (a) an issued and unexpired patent within the Yuhan Patent Rights, Processa Patent Rights, or Joint Patent Rights that has not been revoked or held unenforceable or invalid by a final decision of a court or other Governmental Authority of competent jurisdiction, or that has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise; or (b) a patent application within the Yuhan Patent Rights, Processa Patent Rights, or Joint Patent Rights; provided that such a claim within a patent application has not been canceled, withdrawn, or abandoned or been pending for more than seven (7) years from the date of its first priority filing in the applicable country. For clarity, a claim of a patent that, pursuant to clause (b), had ceased to be a Valid Claim before it issued but that subsequently issues and is otherwise described by clause (a), shall again be considered to be a Valid Claim once it issues until it is no longer considered a Valid Claim in accordance with clause (a).

1.55 "Yuhan Intellectual Property." Yuhan Intellectual Property means the Yuhan Know-How and the Yuhan Patent Rights.

1.56 "Yuhan Know-How." Yuhan Know-How means all Know-How that is Controlled by Yuhan or any of its Affiliates as of the Effective Date or thereafter during the Term (other than any Know-How included in Joint Intellectual Property) that is necessary or useful to Develop, Manufacture or Commercialize any Compound or Product; provided, however, that, if Yuhan is acquired by a Third Party, "Yuhan Know-How" shall exclude any Know-How that (a) is Controlled by such Third Party or the Affiliates of such Third Party (other than Yuhan and the Persons that were Yuhan's Affiliates immediately prior to the closing of such acquisition transaction (such Affiliates, "Yuhan Pre-Existing Affiliates")) ("Yuhan Excluded Affiliates") and (b) was not Controlled by Yuhan or any of the Yuhan Pre-Existing Affiliates immediately prior to the closing of such acquisition transaction; provided further that, if, after the closing of such acquisition, any such Yuhan Excluded Affiliate has or acquires Control of any Know-How that is necessary or useful to Develop, Manufacture or Commercialize any Compound or Product and that is used to Develop, Manufacture or Commercialize any such Compound or Product, such additional Know-How that is Controlled by such Yuhan Excluded Affiliate shall be included in Yuhan Know-How.

1.57 "Yuhan Patent Rights." Yuhan Patent Rights means all Patent Rights in the Territory that are Controlled by Yuhan or any of its Affiliates as of the Effective Date or thereafter during the Term (other than Joint Patent Rights) that Cover any Compound or Product. The Yuhan Patent Rights existing as of the Effective Date are set forth on Schedule 1.57; provided, however, that, if Yuhan is acquired by a Third Party, "Yuhan Patent Rights" shall exclude any Patent Rights that (a) are Controlled by such Third Party or the Affiliates of such Third Party (other than Yuhan and Yuhan Pre-Existing Affiliates) and (b) were not Controlled by Yuhan or any of the Yuhan Pre-Existing Affiliates immediately prior to the closing of such acquisition transaction; provided further that, if, after the closing of such acquisition, any such Yuhan Excluded Affiliate has or acquires Control of any Patent Right that Covers the Development, Manufacture or Commercialization of any Compound or Product and that is used to Develop, Manufacture or Commercialize any such Compound or Product, such additional Patent Right that is Controlled by such Yuhan Excluded Affiliate shall be included in Yuhan Patent Rights.

1.58 Additional Definitions. Each of the following definitions is set forth in the Section of this Agreement indicated below:

| **Definition:** | **Section:** |
|---|---|
| Abandoned Patents | Section 8.2(a) |
| Agents | Section 9.1 |
| Commercialization Plan | Section 5.2 |
| Confidential Information | Section 9.2 |
| Confidentiality Agreement | Section 9.2 |
| Courts | Section 13.1 |
| Deadlocked Matter | Section 3.5(e) |
| Development Milestone Payments | Section 7.2 |
| Development Plan | Section 6.1(a) |
| Effective Date | Preamble |
| Indemnified Party | Section 11.3(a) |
| Indemnifying Party | Section 11.3(a) |
| Infringement Claim | Section 8.3(a) |
| Joint Inventions | Section 8.1(b) |
| Joint Patent Rights | Section 8.2(b) |
| Late Payment Notice | Section 7.12 |
| Milestone Shares | Section 7.2 |
| Other API | Section 1.6 |
| Paragraph IV Claim | Section 8.8(a) |
| PCYU Board | Section 3.5(a) |
| Product Liability Claims | Section 11.1(b) |
| Processa | Preamble |
| Processa Excluded Affiliates | Section 1.40 |
| Processa Parties | Section 11.2 |
| Processa Pre-Existing Affiliates | Section 1.40 |
| Processa Sole Inventions | Section 8.1(a) |
| ROFN Notice | Section 4.2 |
| ROFN Response | Section 4.2 |
| Royalties | Section 7.5(a) |
| Royalty Floor | Section 7.5(d) |
| Royalty Rate | Section 7.5(a) |
| Royalty Term | Section 7.5(b) |
| Sales Milestone Payment | Section 7.4 |
| Sublicense Considerations | Section 7.6(a) |
| Sublicense Materials | Section 2.1(c) |
| Sublicense Payments | Section 7.6 |
| Sublicensee Intellectual Property | Section 2.1(c) |
| Taxes | Section 7.9 |
| Term | Section 12.1 |
| Third Party Claims | Section 11.1 |
| Third Party Patent Licenses | Section 7.5(c) |
| Upfront Fee | Section 7.1 |
| Worldwide Annual Accrued Net Sales | Section 7.4 |
| Yuhan | Preamble |
| Yuhan Excluded Affiliates | Section 1.56 |
| Yuhan Parties | Section 11.1 |
| Yuhan Pre-Existing Affiliates | Section 1.56 |
| Yuhan Sole Inventions | Section 8.1(a) |

1.59 Captions; Certain Conventions; Construction. All headings and captions herein are for convenience only and shall not be interpreted as having any substantive meaning. The Schedules to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. Unless otherwise expressly provided herein or the context of this Agreement otherwise requires:

(a) words of any gender include each other gender;

(b) words such as "herein," "hereof," and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear;

(c) words using the singular shall include the plural, and vice versa;

(d) the words "include," "includes" and "including" shall be deemed to be followed by the phrase "but not limited to", "without limitation", "inter alia" or words of similar import;

(e) the word "or" shall be deemed to include the word "and" (*i.e.*, shall mean "and/or")

(f) references to "Article," "Section," "subsection," "paragraph," "clause," or other subdivision, or to a Schedule, without reference to a document, are to the specified provision or Schedule of this Agreement; and

(g) references to "$" or "dollars" shall be references to U.S. Dollars.

This Agreement shall be construed as if the Parties drafted it jointly.

## ARTICLE II
## GRANTS OF RIGHTS

2.1 Licenses.

(a) License. Subject to the terms of this Agreement, Yuhan shall, and hereby does, grant to Processa an exclusive (even as to Yuhan and its Affiliates), royalty-bearing right and license, including the right to sublicense in accordance with Section 2.1(b), under the Yuhan Intellectual Property and Yuhan's interest in the Joint Intellectual Property, to Develop, Manufacture, use and Commercialize, including filing for, obtaining and maintaining Regulatory Approval for, Products in the Field in the Territory.

(b) License Back. Subject to the terms of this Agreement and in order to facilitate Yuhan's right to Develop (solely to obtain Marketing Approval), Manufacture and Commercialize Products in South Korea, Processa shall, and hereby does, grant to Yuhan an exclusive (even as to Processa and its Affiliates), royalty-bearing and sublicensable right and license (i) to access and use any data generated by or on behalf of Processa in the Development of Products for the Territory, including all data included in any regulatory submission; and (ii) under any Processa Intellectual Property, and Processa's interest in the Joint Intellectual Property directed to modifications or improvements to the Yuhan Intellectual Property, in each case ((i) and (ii)) for the sole purpose of obtaining Marketing Approval for, and Manufacturing and Commercializing the Products in South Korea only. Yuhan shall pay Processa a royalty equal to three percent (3%) of Net Sales (by Yuhan or its Affiliates, or its or their sublicensees) of such Products Covered by Processa Patents in South Korea (starting from the First Commercial Sale of such Product made by Yuhan in South Korea, to be calculated in accordance with Sections 7.5(a) through 7.5(d), but without any reference to Section 7.6, applied *mutatis mutandis* as if such Net Sales were made by Yuhan, and as if the Royalty Term were until the expiration or invalidation of the last Valid Claim in the Processa Patents Covering such Patent in South Korea). Upon the expiration or invalidation of the last Valid Claim in the Processa Patents Covering such Patent in South Korea, the licenses granted to Yuhan under this Section 2.1(b) shall become non-exclusive, fully-paid-up, perpetual, and irrevocable.

(c) Sublicenses. From the Effective Date, Processa shall have the right to grant sublicenses under the licenses to Yuhan Intellectual Property and Yuhan's interest in the Joint Intellectual Property granted to Processa under Section 2.1(a) to its Affiliates and to Third Parties, such sublicense rights being subject to Yuhan's prior written approval (which may not be unreasonably withheld or delayed) with respect to Third Parties; provided, however, that (i) any such sublicense shall be subject to all applicable terms and conditions of this Agreement; (ii) any Sublicensee to whom Processa discloses Confidential Information shall enter into an appropriate written agreement obligating such Sublicensee to be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are no less restrictive than the obligations in ARTICLE IX; (iii) Processa shall at all times be responsible for the performance of such Sublicensee; and (iv) Processa shall, prior to granting any sublicense to a Sublicensee under this Agreement, provide Yuhan with a copy of such sublicense agreement. Each agreement with each Sublicensee must include grants of rights sufficient to enable Processa to grant substantially the rights set forth in Sections 12.7(b) through 12.7(f) with respect to (1) all Know-How and Patent Rights (including all applicable pre-clinical and clinical data, including pharmacology and biology data; Manufacturing documents and materials; and Manufacturing technologies) Controlled by such Sublicensee during the Term and used by such Sublicensee in the Development, Manufacture or Commercialization of any Compound or Product (collectively, "Sublicensee Intellectual Property"); (2) all filings with Regulatory Authorities in the Territory relating to Compounds and Products and Regulatory Approvals relating to Compounds and Products held by such Sublicensee, including related correspondence with Regulatory Authorities; (3) all Manufacturing agreements to which such Sublicensee is a party that are related to Compounds or Products; (4) all of such Sublicensee's inventory of Compounds and Products existing as of the applicable date; and (5) all trademarks owned by such Sublicensee and used solely in connection with the Products, along with all associated goodwill ((1) – (5), collectively, "Sublicense Materials").

2 . 2 Rights Retained by the Parties. Any rights of Yuhan or Processa, as the case may be, not expressly granted to the other Party under the provisions of this Agreement shall be retained by such Party.

2.3 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement, including the licenses granted under Sections 2.1 or 12.7(e) to Patent Rights and Know-How (including any data included in the Know-How), are and will otherwise be deemed to be for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined in Section 101(35A) of the Bankruptcy Code. Each Party will retain and may fully exercise all of its respective rights and elections under the Bankruptcy Code. The Parties agree that each Party, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code or any other provisions of applicable Law outside the United States that provide similar protection for "intellectual property."

2 . 4 Transfer of Yuhan Material and Know-How. Within ninety (90) days after the Effective Date, Yuhan shall transition Yuhan Know-How to Processa and provide Processa with reasonable amounts of consultation regarding the transferred Yuhan Know-How. In addition, Yuhan will transfer all material and copies of documentation in English to Processa related to the Product including but not limited to (a) documents including communications, reports, white papers and supporting material, lab or study notes, Manufacturing documents, and similar material, (b) know-how related to the Development of the Product, and (c) Regulatory Approvals or clearances or submissions.

## ARTICLE III
## DEVELOPMENT & GOVERNANCE

3 . 1 General. From the Effective Date, and subject to the terms of this Agreement, including the requirements of ARTICLE VI, with input from the PCYU Board (defined in Section 3.5), Processa (or its Affiliates or Sublicensees) shall control and be solely responsible for the Development of and regulatory activities with respect to Compounds and Products in the Field in the Territory, including all costs and expenses relating thereto (excluding the costs and expenses of Yuhan appointed members of the PCYU Board). If Processa requests Yuhan's cooperation outside of the PCYU Board as described above, the Parties shall mutually agree in advance on a budget therefor, and Processa shall reimburse Yuhan for any expenses incurred by Yuhan under this Section 3.1 within thirty (30) days after receiving an invoice therefor.

3.2 Exchange of Information Regarding Development. At least once each Calendar Year, beginning on the Effective Date and ending on the date on which Processa obtains the first Regulatory Approval for a Product in the United States and the first Regulatory Approval for a Product in another Major Market, Processa shall provide Yuhan with a reasonably detailed report describing Processa's Development activities and the summary results thereof with respect to all Compounds and Products.

3.3 Right of Cross Reference. Processa hereby grants to Yuhan an option for an irrevocable and perpetual, fully paid-up, transferable right of access and Right of Cross-Reference to all Regulatory Documentation and Regulatory Approvals for the Compound and Products anywhere in the Territory for purposes of Development, Manufacture and Commercialization in South Korea. Yuhan may exercise such option and shall obtain such rights upon giving written notice to Processa and paying a one-time fee of two hundred fifty thousand dollars ($250,000). Upon Yuhan's exercise of the option, Processa shall grant such rights to Yuhan and shall cooperate fully to make the benefits of such Regulatory Documentation and Regulatory Approvals available to Yuhan or its designee, including by providing a signed statement to such effect.

3.4 Recalls. In the event that any Regulatory Authority issues or requests a recall or takes a similar action in connection with a Product in the Territory, or in the event either Party determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal in the Territory, the Party notified of such recall or similar action, or the Party that desires such recall or similar action, shall within 24 hours, advise the other Party thereof by telephone, facsimile or email. Processa, in consultation with Yuhan, through the PCYU Board, shall decide whether to conduct a recall in any market in the Territory (except in the case of a government mandated recall, when Processa may act without such advance notice but, shall notify Yuhan as soon as possible) and the manner in which any such recall shall be conducted (and in the event of any disagreement regarding a recall in the Territory, the approach that is more conservative shall control). Each Party will make available to the other Party, upon request, all of such Party's (and its Affiliates') pertinent records that such other Party may reasonably request to assist such other Party in effecting any recall.

3.5 Processa Yuhan Advisory Board.

(a) General; Responsibilities. Within thirty (30) days after the Effective Date, the Parties will establish a Processa Yuhan Advisory Board (the "PCYU Board") to oversee and coordinate the Parties' activities under this Agreement to the extent provided in this Agreement. The PCYU Board shall:

(i) oversee the Development Plan to ensure that the goals and direction of the plan are identified and achieved and to advise on courses of action to achieve the goal and direction of the plan;

(ii) on at least an annual basis, review the then-current Development Plan, and review, comment on, on approve (or reject) any proposed amendments to the then-current Development Plan;

(iii) not oversee nor provide approval for the everyday operations of and decisions by Processa that are required to demonstrate the safety and efficacy of the Compound and Products in order to obtain Regulatory Approval within any country in the Territory;

(iv) not oversee nor provide approval for the regulatory science process used by Processa for the Compound and Products in order to obtain Regulatory Approval within any country in the Territory; and

(v) perform such other functions, in each case as expressly assigned to the PCYU and set forth in this Agreement or as mutually agreed upon by the Parties in writing.

(b) Composition. The PCYU Board initially shall be composed of at least four (4) members, two (2) of whom shall be representatives appointed by Processa and two (2) of whom shall be representatives appointed by Yuhan. Each PCYU Board member shall have the requisite experience and seniority to enable such representative to make decisions on behalf of the Party who appointed such member with respect to the issues falling within the jurisdiction of the PCYU Board. Neither Party shall appoint any representative to the PCYU Board that is not an employee or member of the Board of Directors of such Party or its Affiliates without the prior written consent of the other Party. Processa shall appoint one (1) of its representatives as the chairperson of the PCYU Board. The size of the PCYU Board may be changed from time to time by written agreement of the Parties; provided that the PCYU Board shall at all times include an equal number of representatives of each Party. Each Party may replace its PCYU Board representatives at any time upon written notice to the other Party. An employee of Processa and not an official member of the PCYU Board may also be appointed by Processa as Secretary to take notes and provide minutes for the Board. This Secretary shall not have any voting privileges within the PCYU Board.

(c) Meetings. Unless otherwise agreed by the Parties, the PCYU Board shall hold meetings (a) at least once per Calendar Quarter or more often as its members may determine until the filing of an IND for the Compound and (b) twice per Calendar Year thereafter until the first anniversary of the First Commercial Sale in the Territory for the Product. PCYU Board meetings may be held in person or by any means of telecommunications as the members deem necessary or appropriate, including telephone, video conference or similar means in which each participant can hear what is said, and be heard, by the other participants. If a meeting is held in person, PCYU Board members may, in lieu of attending in person, attend by any means of telecommunications in which each participant can hear what is said, and be heard, by the other participants. A quorum of the PCYU Board shall exist whenever there is present at a meeting at least one (1) representative appointed by each Party. Employees or consultants of either Party who are not members of the PCYU Board may attend meetings of the PCYU Board; provided that: (i) such attendees shall not vote in the decision-making process of the PCYU Board; (ii) such attendees shall be bound in writing by obligations of confidentiality and non-use equivalent to those set forth in ARTICLE IX; and (iii) a consultant of a Party may attend a meeting only with prior notice to and consent of the other Party, which shall not be unreasonably withheld or delayed; *provided further that* any PCYU Board meetings that includes representatives of either Party who are not PCYU Board members may, at the request of any PCYU Board member, include a closed session consisting of only PCYU Board members. Except as provided in the prior sentence, individuals who are not members of the PCYU Board may not attend a meeting of the PCYU Board without the prior consent of both Parties. Each Party shall be responsible for its own expenses of participating in the PCYU Board.

(d) Minutes. As soon as reasonably practicable and in any event no fewer than fifteen (15) Business Days prior to each meeting, Processa shall disclose to Yuhan any proposed agenda items together with all appropriate information with respect to such proposed agenda items. The chairperson of the PCYU Board shall prepare and circulate to all members of the PCYU Board for review draft minutes of each PCYU Board meeting within an appropriate time after such meeting, but in no event later than the next meeting of the PCYU Board. The Parties shall approve in writing the minutes of each meeting promptly.

(e) Decision-Making. The PCYU Board shall make decisions and take action by consensus of the members present at a meeting at which a quorum exists, with each Party having a single vote, regardless of the number of representatives of such Party in attendance at such meeting. If the PCYU Board does not reach consensus on any matter within its authority (a "Deadlocked Matter"), the Deadlocked Matter will be referred to the Senior Executive of Processa or his/her designee as the final decision-making authority with respect to such Deadlocked Matter provided that Processa shall not have any such final decision-making authority with respect to a Deadlocked Matter that would require Yuhan to incur any additional costs or expenses, or otherwise materially adversely impact Yuhan's rights and obligations under this Agreement. In addition, if the PCYU Board recommends changes to the development that require a change in budget, staffing, or external payments, the Senior Executive of Processa shall be the final decision-making authority to approve or not approve the PCYU Board recommendation(s).

(f) Authority. The PCYU Board shall have only such powers as are specifically delegated to it under this Agreement, and for clarity the PCYU Board shall not have any authority or ability to: (1) modify, amend, or waive the terms or conditions of this Agreement, including the milestone payment provisions, license rights provisions and delegations of authority provisions; (2) determine whether or not a breach of this Agreement has occurred; (3) make any decision that, under the terms of this Agreement, requires Yuhan's or Processa's consent, approval or agreement or the consent, approval or agreement of both Parties; or (4) require Yuhan or Processa to conduct any activities in contravention of, or outside the scope of, this Agreement.

(g) Sublicensee; Dissolution. If Processa grants sublicenses to Sublicensees for the Development, Manufacture, or Commercialization of the Product in the Field in any Major Market, Processa will provide Yuhan with copies of all correspondence with such Sublicensee, and shall invite Yuhan to attend all meetings with such Sublicensee. Subject to the foregoing, if Processa grants sublicenses to Sublicensees for the Development, Manufacture and Commercialization of the Product in the Field in all countries in the Territory, upon Yuhan's written request the PCYU Board shall dissolve.

## ARTICLE IV
## SUPPLY

4.1 Initial Clinical Supply. Yuhan shall, upon Processa's request, use its current inventory to supply Processa with its requirements of the Compound and Product for all non-clinical studies, the first Phase 1 Clinical Trial, and first Phase 2 Clinical Trial to be conducted by Processa subject to the terms and conditions set forth in a clinical supply agreement to be executed by the Parties. The price for such initial clinical study supply shall be composed of Yuhan's manufacturing cost. The Parties may agree on additional activities to be performed by Yuhan for Processa in relation to the Compound and the Product under a clinical supply agreement to be negotiated in good faith by the Parties.

4.2 ROFN For Further Supply. Yuhan shall have an exclusive right of first negotiation for a supply agreement for any supply of the Compound and Product to Processa for Development and Commercialization in the Territory other than as described in Section 4.1 as long as the Yuhan manufacturing site, control labs and storage facilities meet the GMP requirements of the Regulatory Authorities for the clinical protocols or the Regulatory Authorities where the Product is commercially sold. Processa shall notify Yuhan in writing of Processa's intention to negotiate for such supply agreement (the "ROFN Notice"). If Yuhan desires to negotiate for such supply agreement, Yuhan shall so notify Processa in writing (the "ROFN Response") within thirty (30) days of receipt of the ROFN Notice. Upon Processa's receipt of the ROFN Response, Yuhan and Processa shall negotiate in good faith for such supply agreement, for up to one hundred and twenty (120) calendar days from the date of the ROFN Response (without guaranteeing success in reaching an agreement).

## ARTICLE V
## COMMERCIALIZATION

5.1 General. From the Effective Date, and subject to the terms of this Agreement, including the requirements of ARTICLE VI, Processa (or its Affiliates or Sublicensees) shall control and be solely responsible for the Commercialization of Products in the Field in the Territory, including all costs and expenses relating thereto.

5.2 Commercialization Plans. During the Royalty Term with respect to each Product, at least thirty (30) days prior to the commencement of each Calendar Year, Processa shall provide Yuhan, for Yuhan's review and comments, a summary of the planned Commercialization activities to be conducted by or on behalf of Processa and its Affiliates and Sublicensees with respect to such Product in each country in the Territory during such Calendar Year (each such plan, a "Commercialization Plan"). Processa, its Affiliates and Sublicensees shall consider Yuhan's comments in good faith and shall not unreasonably decline to implement or incorporate any comments of Yuhan regarding any aspect of the Commercialization Plan.

## ARTICLE VI
## DILIGENCE

6.1 Commercially Reasonable Efforts. During the Term, Processa shall, directly or through its Affiliates or Sublicensees, use Commercially Reasonable Efforts, from and after the Effective Date, to Develop and obtain Regulatory Approval for one (1) Product in the Field in the U.S. and in one (1) other Major Market, and, upon obtaining Regulatory Approval, Processa shall, directly or through its Affiliates or Sublicensees, use Commercially Reasonable Efforts to Commercialize the Product. Without limiting or derogating from the foregoing, Processa, by itself or through its Affiliates or Sublicensees, shall meet each of the following milestones within the respective time periods set forth herein:

(a) Prepare a first draft of the Product Development plan (the "Development Plan") which incorporates, in good faith, Yuhan's review and comment within ninety (90) days after the Effective Date;

(b) Request FDA pre-IND meeting for the Product within six (6) months from the Effective Date of this Agreement;

(c) Dose the first patient in a Phase 2A Clinical Trial with the Product within twenty-four (24) months from the Effective Date of this Agreement;

(d) Dose the first patient with the Product in a Phase 2B Clinical Trial, Phase 3 Clinical Trial or other Pivotal Clinical Trial within forty-eight (48) months from the Effective Date of this Agreement;

(e) Achieve First Commercial Sale of a Product within twelve (12) months from the date a Regulatory Approval for such Product is obtained.

6.2 Termination for Failure to Meet Diligence Obligation. If, at any time during the Term, Processa fails to timely achieve any of the foregoing milestones, or if Yuhan reasonably believes that Processa (itself and through its Affiliates and Sublicensees) has not complied with its obligations under Section 6.1 to Develop one (1) Compound or Product in the Field in the U.S. for any consecutive nine (9) month period following the Effective Date, Yuhan shall provide written notice to Processa specifying the nature of such reasonable belief, and Yuhan may terminate this Agreement pursuant to Section 12.4.

## ARTICLE VII
## FINANCIAL PROVISIONS

7.1 Upfront Fee. In partial consideration for the rights granted to Processa hereunder, within ten (10) Business Days following the Effective Date, Processa shall issue to Yuhan, for no additional consideration, the number of Processa common shares equivalent to USD $2,000,000 at a price of $8.00 per share, subject to adjustment in and otherwise in accordance with, the terms and conditions of the Share Issuance Agreement (the "Upfront Fee"), which Upfront Fee shall be non-refundable and non-creditable. Notwithstanding the foregoing, if Processa does not complete the Planned Public Offering before January 31, 2021, the number of shares of Processa common stock issued in connection with the Upfront Fee will be adjusted in accordance with the Share Issuance Agreement.

7.2 Development Milestone Payments. Processa shall make the following one-time, non-refundable, non-creditable development milestone payments (the "Development Milestone Payments") in the form of cash and issuance of Processa common shares (the "Milestone Shares") to Yuhan as set forth in Section 7.2(a) or 7.2(b) below. For avoidance of doubt, in no event shall both Section 7.2(a) and 7.2(b) apply.

(a) The milestones, payments and share issuances set forth in this Section 7.2(a) shall apply only in the event that (i) Yuhan and/or its Affiliates purchase $3.0 million or more of the shares of common stock sold by Processa in the Planned Public Offering, or (ii) if the Planned Public Offering does not occur by January 31, 2021, Yuhan and/or its Affiliates provide an amount equal to or greater than $3.0 million of equity funding, on terms to be mutually agreed, to assist in the Development and Regulatory Approval of the Product (for clarity, Processa shall not use such funding for any purpose other than in the Development and Regulatory Approval of the Product):

| Development Milestone | Payment |
|---|---|
| 1st Patient Dosed in 1st Pivotal Trial | Milestone Shares Equivalent to $1,000,000* |
| Last Patient Dosed 1st Pivotal Trial | Milestone Shares Equivalent to $1,500,000* |
| 1st NDA Approval | $4,000,000 |
| 2nd NDA Approval | $3,000,000 |
| Ex-US 1st Approval | $2,000,000 |
| Ex-US 2nd Approval | $2,000,000 |

(b) The milestones, payments and share issuances set forth in this Section 7.2(b) shall apply only if both of the following occur: (i) Yuhan and/or its Affiliates do not invest in the Processa Planned Public Offering or purchases less than $3.0 million of the shares of common stock sold by Processa in the Planned Public Offering, and (ii) if the Planned Public Offering does not occur by January 31, 2021, Yuhan and/or its Affiliates do not otherwise provide equity funding, on terms to be mutually agreed to assist in the Development and Regulatory Approval of the Product, or provide less than $3.0 million (in aggregate when combined with any amounts invested pursuant to clause (i) above) of funding to assist in the Development and Regulatory Approval of the Product (for clarity, Processa shall not use such funding for any purpose other than in the Development and Regulatory Approval of the Product):

| **Development Milestone** | **Payment** |
|---|---|
| 1st Patient Dosed in 1st Pivotal Trial | Milestone Shares Equivalent to $200,000 |
| Last Patient Dosed 1st Pivotal Trial | Milestone Shares Equivalent to $200,000 |
| 1st NDA Approval | $2,000,000 |
| 2nd NDA Approval | $2,000,000 |
| Ex-US 1st Approval | $2,000,000 |
| Ex-US 2nd Approval | $2,000,000 |

*The number of common shares of Processa issued in connection with the achievement of each milestone set forth in the Tables 7.2(a) and 7.2(b) above shall be determined in accordance with the Share Issuance Agreement.

7.3 Development and Commercialization Costs. For clarity, following the Effective Date, Processa shall be solely responsible for all costs it incurs in Developing and Commercializing Compounds and Products, including all Manufacturing costs (excluding any compensation or expenses incurred by the Yuhan appointed members of the PCYU Board).

7.4 Sales Milestone Payments. Processa shall pay Yuhan the one-time, non-refundable, non-creditable sales milestone payments set forth in the table below (the "Sales Milestone Payments") within thirty (30) days after the end of the first Calendar Year during which the total Net Sales accrued during such Calendar Year in the Territory (the "Worldwide Annual Accrued Net Sales") first reach the values indicated below. For clarity, each Sales Milestone Payment will apply once and only once when the milestone is first achieved. Thereafter, the Sales Milestone Payment will no longer apply. In addition, if more than one milestone is achieved in a Calendar Year, all associated Sales Milestone Payments will be paid. For illustration purposes, if at a given Calendar Year Worldwide Annual Accrued Net Sales first reach $100,000,000 (without having reached $50,000,000 prior to such Calendar Year); the Sales Milestone Payment for such Calendar Year will be $7,500,000 ($2,500,000 plus $5,000,000). If in the next Calendar Year Worldwide Annual Accrued Net Sales first reach $250,000,000; the Sales Milestone Payment for such Calendar Year will be $12,500,000 because the Milestone Payment for $50,000,000 and $100,000,000 has already been achieved and each Sales Milestone Payment will apply once and only once. The calculation of Worldwide Annual Accrued Net Sales and the corresponding Sales Milestone Payments shall exclude all sales made by a Sublicensee in the event that Processa receives Sublicense Consideration on account of a specific Product in a specific Territory from such Sublicensee for which Processa is required to pay Yuhan the applicable percentage of the Sublicense Consideration as set forth in Section 7.6.

| **Worldwide Annual Accrued Net Sales** | **Payment** |
|---|---|
| ≥ $50M | $2,500,000 |
| ≥ $100M | $5,000,000 |
| ≥ $250M | $12,500,000 |
| ≥ $500M | $25,000,000 |
| ≥ $1 Billion | $50,000,000 |
| ≥ $2 Billion | $100,000,000 |
| ≥ $5 Billion | $200,000,000 |

7.5 Product Royalties.

(a) Royalty Rate. Processa shall pay Yuhan royalties equal to seven percent (7%) (the "Royalty Rate") on the aggregate Net Sales of Products in the Territory (collectively, "Royalties") during each Calendar Year to Yuhan on a Product-by-Product basis. Notwithstanding the foregoing, with respect to Net Sales by Sublicensees, the Royalties shall exclude all sales made by a Sublicensee in the event that Processa receives Sublicense Consideration on account of a specific Product in a specific Territory from such Sublicensee for which Processa is required to pay Yuhan the applicable percentage of the Sublicense Consideration as set forth in Section 7.6.

(b) Royalty Term and Adjustments. Processa's Royalty obligations to Yuhan under this Section 7.5 shall commence on a country-by-country and Product-by-Product basis on the Effective Date and shall expire on a country-by-country basis and Product-by-Product basis on the later of (i) expiration or invalidation of the last Valid Claim Covering such Product in such country or (ii) the tenth (10th) anniversary of the date of the First Commercial Sale by Processa or any of its Affiliates or Sublicensees (except as provided above) to a non-Sublicensee Third Party of such Product in such country (the "Royalty Term"); provided that, during any period within the Royalty Term remaining after the expiration of all Valid Claims Covering such Product in such country and all Regulatory Exclusivity as to such Product in such country, the Royalties payable as to such Product in such country under this Section 7.5 shall be reduced to fifty percent (50%) of the Royalties otherwise payable as to such Product in such country pursuant to Section 7.5. Such Royalty reduction will be calculated by determining the portion of total Net Sales of the relevant Product in a Calendar Quarter that is attributable to the applicable country in which such reduction applies, and by determining the total Royalties without reduction, and then reducing to fifty percent (50%) the applicable portion (based on Net Sales) of total Royalties attributable to the country in which such reduction applies. Upon the expiration of the Royalty Term with respect to each Product in each country, the licenses granted to Processa under Section 2.1(a) shall become non-exclusive, fully-paid–up, perpetual and irrevocable with respect to such Product in such country.

(c) Third Party Payments. If, in the opinion of patent counsel mutually acceptable to both Processa and Yuhan, in order to Develop, Manufacture, use or Commercialize a Product in the Field in a country of the Territory without infringing any third party intellectual property rights relating to the Yuhan Intellectual Property, Processa or its Affiliate or Sublicensee is obligated to obtain a license or comparable grant of rights (*e.g.*, a covenant not to sue) under any Patent Rights from a Third Party ("Third Party Patent Licenses") and pay a royalty under such Third Party Patent License with respect to such Product in such country, then, subject to Section 7.5, forty percent (40%) of such royalties actually paid by Processa, its Affiliates or Sublicensees shall be creditable against Royalties payable to Yuhan hereunder with respect to such Product in such country; provided that, (i) if Processa is obligated to enter into any Third Party Patent License, Processa shall use Commercially Reasonable Efforts to minimize the royalties owed by Processa under such Third Party Patent License; and (ii) for any creditable amounts permitted under the Section 7.5(c) but that are not applied in a given Calendar Quarter as a result of the Royalty Floor set forth in Section 7.5(d), Processa may carry forward and apply such amounts against Royalties due in up to four (4) subsequent Calendar Quarters, or until the amount of such reduction has been fully applied against Royalties due to Yuhan, whichever is earlier (in each case subject to Section 7.5(d)).

(d) Royalty Floor. In no event shall the Royalty reductions described in Sections 7.5(b) and 7.5(c), alone or together, reduce the Royalties payable by Processa for a given Calendar Quarter during the Royalty Term for a Product in a particular country in the Territory to less than fifty percent (50%) of the amounts otherwise payable by Processa for such Calendar Quarter pursuant to Section 7.5(a) (the "Royalty Floor").

7.6 Sublicense. If Processa sublicenses the Product, Yuhan shall receive the applicable percentage of any Sublicense Consideration, as described in this Section 7.6 (the "Sublicense Payments"). The percentages described in this Section 7.6 shall apply to all Sublicense Consideration. Notwithstanding the foregoing, in the event that Processa receives Sublicense Consideration on account of a specific Product in a specific Territory, then in such case Processa shall be required to pay Yuhan the applicable Sublicense Payment, but such Sublicense Consideration shall not be taken into account when calculating Development Milestone Payments (Section 7.2) or Sales Milestone Payments (Section 7.4) or Royalties (Section 7.5). To clarify, three example scenarios are presented:

Example 1: If Processa Develops the Product in multiple Territories and licenses out the commercial sales to Sublicensee in all Territories such that Processa does not sell any of the product. The financial terms of ARTICLE VII would then be the following: Sections 7.2-7.3 would apply, Sections 7.4-7.5 would no longer apply, and Section 7.6 would apply for any funds from Sublicense Consideration for the Sublicensee Territories using the table in this Section 7.6. The percentage in the table would apply to all financial considerations from the Sublicensee such as upfront fees, any milestones payments, and royalties.

Example 2: If Processa Develops and Commercializes the Product in US while Sublicensing the Product for Development and Commercialization in other territories. The financial terms of ARTICLE VII would then be the following: Sections 7.2 – 7.3 would apply, Sections 7.4-7.5 would only apply to Territories in which Processa Commercializes the Product, and Section 7.6 would apply for any funds from Sublicense Consideration for the Sublicensee Territories using the table in this Section 7.6. The percentage in the table would apply to all financial considerations from the Sublicensee such as upfront fees, any milestones payments, and royalties.

Example 3: If Processa sublicenses the Product prior to Phase 3 trial and Sublicensee completes Development, obtains Regulatory Approval, and Commercializes the Product. The financial terms of ARTICLE VII would then be the following: for Sections 7.2 – 7.3 Processa would pay for milestones that it has completed, the remaining milestones of Sections 7.2 – 7.3 not completed by Processa would no longer apply, Sections 7.4-7.5 would not apply, and Section 7.6 would apply for any funds from Sublicense Consideration for the Sublicensee Territories using the table in this Section 7.6. The percentage in the table would apply to all financial considerations from the Sublicensee such as upfront fees, any milestones payments, and royalties.

( a ) Sublicense Considerations shall mean any payments or other consideration that Processa or its Affiliates receive as a direct result of the grant of a sublicense or an option to obtain such sublicense, including without limitation license fees, license option fees, milestone payments, license maintenance fees, equity, and royalty on Sublicensee sales, provided that in the event that Processa or its Affiliates receive non-monetary consideration in connection with a sublicense, Sublicense Considerations shall be calculated based on the fair market value of such consideration or transaction, assuming an arm's length transaction made in the ordinary course of business. Notwithstanding the foregoing, Sublicense Considerations shall not include amounts expressly dedicated to, and actually expended by the Sublicensee to reimburse Processa and its Affiliates for, the Development of Products, up to the sum of the actual external costs incurred by Processa and its Affiliates for such activities.

(b) Processa shall pay Yuhan the Sublicense Payments within thirty (30) days after the receipt of the Sublicense Consideration. Depending on when the applicable sublicense agreement enters into force Processa shall pay to Yuhan the percentage defined in the following Table:

| **Sublicense Effective Date** | **Sublicense Payment Percentage** |
|---|---|
| Before 1st Phase 2a Clinical Trial FPFV | 80% |
| Before 1st Phase 2b Clinical Trial FPFV | 50% |
| After 1st Phase 2b Clinical Trial FPFV but Before 1st Phase 3 Clinical Trial FPFV | 40% |
| After 1st Phase 3 Clinical Trial FPFV | 30% |

7.7 Reports; Payments. Within thirty (30) days after the end of each Calendar Quarter commencing from the earlier of (a) the First Commercial Sale of a Product; or (b) the grant of a sublicense or receipt of Sublicense Consideration, Processa shall furnish Yuhan with a quarterly report ("Periodic Report") detailing, at a minimum, the following information for the applicable Calendar Quarter, each listed by Product and by country of sale: (i) the total number of units of Product sold by Company, its Affiliates and Sublicensees for which Royalties are owned to Yuhan hereunder, including a breakdown of the number and type of Products sold, (ii) gross amounts received for all such sales, (iii) deductions by type taken from Net Sales as specified herein, (iv) Net Sales, (v) Royalties, Development Milestone Payments and Sales Milestone Payments owed to Yuhan, listed by category, (vi) Sublicense Consideration received during the preceding Calendar Quarter and sublicense fees due to Yuhan, (vii) the currency in which the sales were made, including the computations for any applicable currency conversions, (viii) invoice dates and all other data enabling the Royalties and sublicense fees payable to be calculated accurately and (ix) a detailed summary of progress against each development and regulatory milestone set forth in Section 7.2 and each sales milestone set forth in Section 7.4, and an estimate of the timing of the achievement of the next applicable milestone. Once the events set forth in sub-section (a) or (b), above, have occurred, Periodic Reports shall be provided to Yuhan whether or not Royalties, Development Milestone Payments, Sales Milestone Payments or sublicense fees are payable for a particular Calendar Quarter. In addition to the foregoing, upon Yuhan's reasonable request, Processa will provide to Yuhan such other information as may be reasonably requested by Yuhan, and will otherwise cooperate with Yuhan as reasonably necessary, to enable Yuhan to verify Processa's compliance with the payment and related obligations under this Agreement, including verification of the calculation of amounts due to Yuhan under this Agreement and of all financial information provided or required to be provided in the Periodic Reports. Concurrently with each such report, Processa shall pay to Yuhan all amounts payable by it under Sections 7.4, 7.5, and 7.6.

7.8 Books and Records; Audit Rights. Processa shall keep complete and accurate records of the underlying revenue and expense data relating to the calculations of Net Sales and payments required by Sections 7.4, 7.5, and 7.6. Yuhan shall have the right, once annually at its own expense, to have an independent, certified public accounting firm, selected by Yuhan and reasonably acceptable to Processa, review any such records of Processa in the location(s) where such records are maintained by Processa upon reasonable notice (which shall be no less than fourteen (14) days prior notice) and during regular business hours and under obligations of strict confidence, for the sole purpose of verifying the basis and accuracy of payments made under Sections 7.4, 7.5, and 7.6 within the thirty-six (36) month period preceding the date of the request for review. The report of such accounting firm shall be limited to a certificate stating whether any report made or payment submitted by Processa during such period is accurate or inaccurate and the actual amounts of Net Sales, and Royalties due, for such period. Processa shall receive a copy of each such report concurrently with receipt by Yuhan. Should such inspection lead to the discovery of a discrepancy to Yuhan's detriment, Processa shall pay within five (5) Business Days after its receipt from the accounting firm of the certificate the amount of the discrepancy plus interest calculated in accordance with Section 7.12. Yuhan shall pay the full cost of the review unless the underpayment is greater than five percent (5%) of the amount due for any applicable Calendar Year, in which case Processa shall pay the reasonable cost charged by such accounting firm for such review. Any overpayment by Processa revealed by an examination shall be fully creditable against future payments.

7.9 Tax Matters. Except as expressly provided below, no payments to be made to Yuhan by Processa hereunder shall be reduced by or on account of any taxes, levies, imposts, duties, charges, assessments or fees (collectively, "Taxes"). Notwithstanding the immediately preceding sentence, if any applicable Law requires (with due regard to any relief to which Yuhan may be entitled) that Taxes be deducted and withheld from any payment made to Yuhan by Processa under this Agreement, Processa shall (a) deduct those Taxes, together with any interest and penalties properly assessed thereon, from such payment or from any other payment owed by Processa hereunder; (b) transmit the amounts so deducted to the proper Governmental Authority; (c) send evidence of the requirement together with proof of due transmission of the amounts described in clause (b) to Yuhan promptly following such payment; and (d) remit to Yuhan the net amount of such payment after taking account of such deduction. In determining whether to deduct any amount hereunder and prior to making such deduction, Processa shall contact Yuhan and take due account of all documentation supplied by Yuhan, and of other facts known to Processa, supporting a reduction in any Tax otherwise required to be deducted, or a credit therefor or refund thereof. Processa will reasonably cooperate with Yuhan in respect of Tax matters relating to payments made by Processa to Yuhan under this Agreement and any disputes with a Governmental Authority regarding such matters, including without limitation: (y) complying with reasonable requests from Yuhan to change the form, place or other circumstances of payments to be made to Yuhan by Processa under this Agreement so as to reduce the incidence of Taxes on such payments or recover any Taxes imposed on such payments (any such recovery to be for the benefit of Yuhan); and (z) in connection with any official or unofficial audit or contest relating to such payments.

7.10 Payment Method and Currency Conversion. All payments shall be made in U.S. dollars in immediately available funds via either a bank wire transfer, an ACH (automated clearing house) mechanism, or any other means of electronic funds transfer, at Processa's election, to Yuhan's bank account, or to such other bank account as Yuhan shall designate in a notice at least ten (10) days before the payment is due. For the purposes of determining the amount of any Royalties due for the relevant Calendar Quarter under Section 7.5, the amount of Net Sales in any foreign currency shall be converted into U.S. dollars in accordance with the average of the closing exchange rates reported in *The Wall Street Journal* (U.S., Eastern Edition) for the first, middle and last Business Days of the applicable reporting period for the payment due.

7.11 Blocked Payments. If by reason of applicable Laws in any country in the Territory, it becomes impossible or illegal for Processa or its Affiliates or Sublicensees to transfer, or have transferred on its behalf Royalties or other payments to Yuhan or to Processa or its Affiliates or Sublicensees, Processa shall promptly notify Yuhan of the conditions preventing such transfer. To the extent any payments to Yuhan cannot be transferred pursuant to the preceding sentence, such amounts shall be deposited in local currency in the relevant country to the credit of Yuhan in a recognized banking institution designated by Yuhan or, if none is designated by Yuhan within a period of thirty (30) days, in a recognized banking institution selected by Processa or its Affiliate or Sublicensee, as the case may be, and identified in a notice given to Yuhan. If so deposited in a foreign country, Processa shall provide, or cause its Affiliate or Sublicensee to provide, reasonable cooperation to Yuhan so as to allow Yuhan to assume control over such deposit as promptly as practicable.

7.12 Late Payments. If a Party shall fail to make a timely payment pursuant to the terms of this Agreement, the other Party shall provide written notice of such failure to the non-paying Party (a "Late Payment Notice"), and interest shall accrue on the past due amount starting on the date of the Late Payment Notice at the U.S. dollar prime lending rate as reported in The Wall Street Journal effective for the date that payment was due (as published in The Wall Street Journal) plus five percent (5%) per annum, computed for the actual number of days after the date of the Late Payment Notice that the payment was past due.

## ARTICLE VIII
## INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION AND RELATED MATTERS

8.1 Ownership of Inventions.

(a) Sole Inventions. Yuhan shall exclusively own all inventions relating to any Compound or Product or its Manufacture or use made solely by Yuhan, its employees, agents, and consultants ("Yuhan Sole Inventions"). Processa shall exclusively own all inventions relating to any Compound or Product or its Manufacture or use made solely by Processa, its employees, agents, and consultants in each case independently of and without using any Yuhan Intellectual Property or Joint Inventions ("Processa Sole Inventions").

(b) Joint Inventions. The Parties shall jointly own all inventions relating to any Compound or Product or its Manufacture or use (i) made jointly by employees, agents and consultants of Processa, on the one hand, and employees, agents and consultants of Yuhan, on the other hand, or (ii) made solely by Processa, its employees, agents, and consultants by using or referencing Yuhan Intellectual Property or Joint Inventions, in each case ((i) and (ii)) on the basis of each Party having an undivided interest in the whole ("Joint Inventions"). Joint Inventions may only be used in accordance with and subject to the terms and conditions of this Agreement.

(c) Inventorship. For purposes of determining whether an invention is a Processa Sole Invention, a Yuhan Sole Invention or a Joint Invention, questions of inventorship shall be resolved in accordance with United States patent Laws.

8.2 Prosecution and Maintenance of Patent Rights.

(a) Prosecution of Yuhan Patent Rights. With respect to Yuhan Patent Rights, Yuhan and Processa shall cooperate in good faith in connection with the continued prosecution and maintenance by Processa of such Yuhan Patent Rights in any countries in the Territory (including South Korea). Processa shall control prosecution and maintenance of such Yuhan Patent Rights. The out-of-pocket costs and expenses incurred by Processa after the Effective Date to obtain, prosecute and maintain Yuhan Patent Rights shall be borne one hundred percent (100%) by Processa. Processa shall file international patent applications, or designate for national filing and file, in all countries selected by Processa taking into account, in good faith, any comments from Yuhan. Yuhan shall promptly (as soon as commercially practicable) deliver to Processa copies of all official correspondence, on an "as-is" basis, existing as of the Effective Date with the applicable patent and trademark offices in the Territory relating to the Yuhan Patent Rights and, after the Effective Date Processa shall promptly provide Yuhan drafts of all proposed filings and correspondence to any patent authority with respect to the Yuhan Patent Rights for Yuhan's review and comment prior to the submission of such proposed filings and correspondences. Processa shall keep Yuhan informed of the status of all pending patent applications that pertain to any Compound or Product. Processa, its agents and attorneys shall not unreasonably decline to implement or incorporate any comments of Yuhan regarding any aspect of such patent prosecutions. Processa shall not abandon any Yuhan Patent Rights (the "Abandoned Patents") without at least ninety (90) days' prior notice to Yuhan. If Processa decides to abandon any Yuhan Patent Rights, Yuhan shall have the option to continue to prosecute and maintain the Abandoned Patents in Yuhan's name and at Yuhan's sole expense.

(b) Prosecution of Joint Patent Rights. Processa shall be responsible for obtaining, prosecuting, and/or maintaining patents and patent applications, in any countries in the Territory (including South Korea), Covering Joint Inventions ("Joint Patent Rights"). Processa shall control prosecution and maintenance of such Joint Patent Rights. The out-of-pocket costs and expenses incurred to obtain, prosecute and maintain Joint Patent Rights shall be borne one-hundred percent (100%) by Processa. Processa shall promptly provide Yuhan drafts of all proposed filings and correspondence to any patent authority with respect to the Joint Patent Rights for Yuhan's review and comment (which comments shall be considered reasonably and in good faith) prior to the submission of such proposed filings and correspondences. Processa shall keep Yuhan informed of the status of all pending Joint Patent Rights. Processa, its agents and attorneys shall not unreasonably decline to implement or incorporate any comments of Yuhan regarding any aspect of such patent prosecutions. Processa shall not abandon any Joint Patent Right without at least ninety (90) days' prior notice to Yuhan. If Processa decides to abandon any Joint Patent Right, Yuhan shall have the option to continue to prosecute and maintain such Joint Patent Right jointly in both Parties' names, at Yuhan's sole expense.

(c) Prosecution of Processa Patent Rights. Processa has the sole right, but not the responsibility, to obtain, prosecute, and/or maintain the Processa Patent Rights. Processa shall keep Yuhan informed of the status of all pending Processa Patent Rights. Processa shall promptly provide Yuhan drafts of all proposed filings and correspondence to any patent authority with respect to the Processa Patent Rights for Yuhan's review and comment (which comments shall be considered reasonably and in good faith) prior to the submission of such proposed filings and correspondences. Processa, its agents and attorneys shall not unreasonably decline to implement or incorporate any comments of Yuhan regarding any aspect of such patent prosecutions. Processa shall not abandon any Processa Patent Right without at least ninety (90) days' prior notice to Yuhan. If Processa decides to abandon any Processa Patent Right, Yuhan shall have the option to continue to prosecute and maintain such Processa Patent Right jointly in both Parties' names, at Yuhan's sole expense.

(d) Cooperation. Each Party agrees to cooperate fully in the preparation, filing, prosecution, and maintenance of Yuhan Patent Rights, Joint Patent Rights, and Processa Patent Rights, pursuant to this Section 8.2 and in the obtaining and maintenance of any patent term extensions, supplementary protection certificates, pediatric extensions, and their equivalent with respect thereto. Such cooperation includes: (i) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, so as enable the other Party to apply for and to prosecute patent applications in any country as permitted by this Section 8.2; and (ii) promptly informing the other Party of any matters coming to such Party's attention that may affect the preparation, filing, prosecution, or maintenance of any such patent applications.

8.3 Third Party Infringement.

(a) Notice. Each Party shall promptly report in writing to the other Party during the Term any known or suspected (i) infringement of any of the Yuhan Patent Rights, Processa Patent Rights or Joint Patent Rights, or (ii) unauthorized use or misappropriation of any of the Yuhan Know-How, Processa Sole Invention or Joint Inventions, in the case of either clause (i) or clause (ii), that could reasonably be expected to impact the (A) Development, Manufacture, use or Commercialization of a Compound or Product, or (B) scope of the rights licensed to such Party under ARTICLE II (an "Infringement Claim"), of which such Party becomes aware, and shall provide the other Party with all available evidence supporting such Infringement Claim.

(b) Initial Right to Enforce.

(i) Enforcement by Processa. Subject to Section 8.3(c)(i), Processa (itself or through its Affiliate or Sublicensee) shall have the first right, but not the obligation, to initiate a suit, or take other appropriate action that it believes is reasonably required to protect (*i.e.*, prevent or abate actual or threatened infringement or misappropriation of) or otherwise enforce the Yuhan Intellectual Property and Joint Intellectual Property with respect to an Infringement Claim anywhere in the Territory and the Processa Intellectual Property with respect to an Infringement Claim anywhere in the world; provided, however, that Processa shall (x) consult with Yuhan in good faith with respect to any claim that any Yuhan Patent Right, Processa Patent Right in South Korea or Joint Patent Right is invalid or unenforceable and (y) implement any reasonable comment from Yuhan regarding any aspect of defending against any such claim described in clause (x). Any such suit by Processa shall be brought either in the name of Yuhan or its Affiliate, the name of Processa or its Affiliate, or the names of Processa, Yuhan and their respective Affiliates, as may be required by the Law of the forum. For this purpose, Yuhan shall execute such legal papers and cooperate in the prosecution of such suit, including providing full access to documents, information and witnesses as reasonably requested by Processa in connection with such suit, as may be reasonably requested by Processa; provided that Processa shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by Yuhan in connection with such cooperation. For clarity, as between Yuhan and Processa, (A) Yuhan shall have the sole right, but not the obligation, to protect Yuhan Intellectual Property against any suspected misappropriation or infringement that does not constitute an Infringement Claim and (B) the Parties shall jointly determine by mutual agreement whether and how to protect Joint Intellectual Property against any suspected misappropriation or infringement that does not constitute an Infringement Claim, and the provisions of this ARTICLE VIII shall not apply with respect thereto.

(ii) Enforcement by Yuhan. Subject to Section 8.3(c)(ii), Yuhan (itself or through its Affiliate) shall have the first right, but not the obligation, to initiate a suit, or take other appropriate action that it believes is reasonably required to protect (*i.e.*, prevent or abate actual or threatened infringement or misappropriation of) or otherwise enforce the Yuhan Intellectual Property and Joint Intellectual Property with respect to an Infringement Claim in South Korea; provided, however, that Yuhan shall (x) consult with Processa in good faith with respect to any claim that any Yuhan Patent Right or Joint Patent Right is invalid or unenforceable and (y) implement any reasonable comment from Processa regarding any aspect of defending against any such claim described in clause (x). Any such suit by Yuhan shall be brought either in the name of Yuhan or its Affiliate, the name of Processa or its Affiliate, or the names of Processa, Yuhan and their respective Affiliates, as may be required by the Law of the forum. For this purpose, Processa shall execute such legal papers and cooperate in the prosecution of such suit, including providing full access to documents, information and witnesses as reasonably requested by Yuhan in connection with such suit, as may be reasonably requested by Yuhan; provided that Yuhan shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by Processa in connection with such cooperation. For clarity, as between Yuhan and Processa, (A) Yuhan shall have the sole right, but not the obligation, to protect Yuhan Intellectual Property in the Territory and (B) the Parties shall jointly determine by mutual agreement whether and how to protect Joint Intellectual Property against any suspected misappropriation or infringement that does not constitute an Infringement Claim, and the provisions of this ARTICLE VIII shall not apply with respect thereto.

(c) Step-In Right.

(i) Step-In by Yuhan. If Processa does not initiate a suit or take other appropriate action that it has the initial right to initiate or take with respect to an Infringement Claim pursuant to Section 8.3(b)(i) related to the Yuhan Intellectual Property and Joint Intellectual Property in the Territory or related to the Processa Intellectual Property anywhere in the world, then Yuhan may, in its discretion, provide Processa with notice of Yuhan's intent to initiate a suit or take other appropriate action. If Yuhan provides such notice and Processa does not initiate a suit or take such other appropriate action within thirty (30) days after receipt of such notice from Yuhan, then Yuhan shall have the right to initiate a suit or take other appropriate action that it believes is reasonably required to protect the Yuhan Intellectual Property, Joint Intellectual Property or Processa Intellectual Property. Any suit by Yuhan shall be either in the name of Yuhan or its Affiliate, the name of Processa or its Affiliate, or the names of Processa, Yuhan, and their respective Affiliates, as may be required by the Law of the forum. For this purpose, Processa shall execute such legal papers and cooperate in the prosecution of such suit, including providing full access to documents, information and witnesses as reasonably requested by Yuhan in connection with such suit, as may be reasonably requested by Yuhan; provided that Yuhan shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by Processa in connection with such cooperation.

(ii) Step-In by Processa. If Yuhan does not initiate a suit or take other appropriate action that it has the initial right to initiate or take with respect to an Infringement Claim pursuant to Section 8.3(b)(ii), then Processa may, in its discretion, provide Yuhan with notice of Processa's intent to initiate a suit or take other appropriate action. If Processa provides such notice and Yuhan does not initiate a suit or take such other appropriate action within thirty (30) days after receipt of such notice from Processa, then Processa shall have the right to initiate a suit or take other appropriate action that it believes is reasonably required to protect the Processa Intellectual Property and Joint Intellectual Property with respect to an Infringement Claim. Any suit by Processa shall be either in the name of Yuhan or its Affiliate, the name of Processa or its Affiliate, or the names of Processa, Yuhan, and their respective Affiliates, as may be required by the Law of the forum. For this purpose, Yuhan shall execute such legal papers and cooperate in the prosecution of such suit, including providing full access to documents, information and witnesses as reasonably requested by Processa in connection with such suit, as may be reasonably requested by Yuhan; provided that Processa shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by Yuhan in connection with such cooperation.

( d ) Conduct of Certain Actions; Costs. The Party initiating suit or taking other action with respect to an Infringement Claim shall have the sole and exclusive right to select counsel for, and otherwise control, any suit or action initiated by it pursuant to Section 8.3(b) or Section 8.3(c). The initiating Party shall assume and pay all of its own out-of-pocket costs incurred in connection with any litigation or proceedings initiated by it pursuant to Sections 8.3(b) and 8.3(c), including the fees and expenses of the counsel selected by it. The other Party shall have the right to participate, but not control, and be represented in, any such suit by its own counsel at its own expense.

( e ) Recoveries. Except as otherwise agreed by the Parties as part of a cost-sharing arrangement,any damages, settlements, accounts of profits, or other financial compensation recovered from a Third Party by the Party that assumes control over enforcing any Infringement Claim shall be allocated between the Parties as follows:

(i) first, to reimburse the Parties' actual out-of-pocket expenses (including reasonable counsel fees and expenses) incurred in pursuing such Infringement Claim;

(ii) second, if Processa controlled the assertion of the Infringement Claim, (1) any remaining amount that represents compensatory damages relating to any Compound or Product Commercialized in the Territory other than South Korea (including lost sales or lost profits) shall be deemed Net Sales of Processa less an amount equal to Royalty payments to Yuhan on such deemed Net Sales in accordance with the Royalty provisions of Section 7.5, which amount shall be paid to Yuhan, and (2) any remaining amount that represents compensatory damages relating to any Compound or Product Commercialized in South Korea (including lost sales or lost profits) shall be deemed Net Sales of Yuhan less an amount equal to Royalty payments to Processa on such deemed Net Sales in accordance with the Royalty provisions of Section 2.1(b), which amount shall be paid to Processa; and any remaining amount that represents punitive damages shall be shared equally by the Parties; and

(iii) third, if Yuhan controlled the assertion of the Infringement Claim, any remaining amount following reimbursement of expenses under clause 8.3(e)(i) shall be retained by Yuhan.

8.4 Patent Invalidity Claim. Each of the Parties shall promptly notify the other in the event of any legal or administrative action by any Third Party against a Yuhan Patent Right, Processa Patent Right or Joint Patent Right of which it becomes aware, including any nullity, revocation, reexamination or compulsory license proceeding. Processa shall have the first right, but not the obligation, to defend against any such action involving a Yuhan Patent Right, Processa Patent Right or Joint Patent Right, and the costs of any such defense shall be at Processa's expense. If Processa does not defend against any such action involving such Yuhan Patent Right, Processa Patent Right or Joint Patent Right, then Yuhan shall have the right, but not the obligation, to defend such action and any such defense shall be at Yuhan's expense. Upon request of the Party that defends against any such action involving a Yuhan Patent Rights, Processa Patent Right or Joint Patent Right, the other Party agrees to join in any such action and to cooperate reasonably with the defending Party, including providing full access to documents, information and witnesses as reasonably requested by the defending Party in connection with such action, provided that the defending Party shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by the other Party in connection with such cooperation.

8.5 Claimed Infringement. Each of the Parties shall promptly notify the other in the event a Party becomes aware that the practice by either Party of the Yuhan Patent Rights infringes, or is suspected or alleged to infringe, the intellectual property rights of any Third Party in the Territory, and shall promptly provide the other Party with any notice it receives or has received from a Third Party related to such suspected, alleged or actual infringement.

8.6 Patent Term Extensions. Processa shall have the exclusive right and obligation to seek patent term extensions or supplemental patent protection, including supplementary protection certificates, in each country in the Territory in relation to the Products at Processa's expense. Yuhan and Processa shall cooperate in connection with all such activities, and Processa, its agents and attorneys will give due consideration to all timely suggestions and comments of Yuhan regarding any such activities; provided that all final decisions shall be made by Processa.

8.7 Patent Marking. Processa shall comply with the patent marking statutes in each country in the Territory in which any Product is sold by Processa, its Affiliates, or its Sublicensees. Yuhan shall comply with the patent marking statutes in South Korea for any Product that is sold by Yuhan, its Affiliates, or its Sublicensees.

8.8 Certification under Drug Price Competition and Patent Restoration Act.

(a) Notice. If a Party becomes aware of any certification filed pursuant to 21 U.S.C. § 355(b)(2)(A) or 355(j)(2)(A)(vii)(IV) or its successor provisions, or any similar provision in any country other than the U.S., claiming that any Yuhan Patent Rights, Processa Patent Rights or Joint Patent Rights are invalid or otherwise unenforceable, or that infringement will not arise from the manufacture, use, import or sale of a product by a Third Party (a "Paragraph IV Claim"), such Party shall promptly notify the other Party in writing within five (5) Business Days after its receipt thereof.

(b) Control of Response; Recoveries. Processa shall have the first right, but not the obligation, to initiate and control patent infringement litigation for any Paragraph IV Claim; provided, however, that Processa shall (i) consult with Yuhan in good faith with respect to any claim that any Yuhan Patent Right, Processa Patent Right or Joint Patent Right is invalid or unenforceable and (ii) implement any comment from Yuhan regarding any aspect of defending against any such claim. Any suit by Processa shall be brought either in the name of Yuhan or its Affiliate, the name of Processa or its Affiliate, or the names of Processa, Yuhan, and their respective Affiliates, as may be required by the Law of the forum. For this purpose, Yuhan shall execute such legal papers and cooperate in the prosecution of such suit, including providing full access to documents, information and witnesses, as may be reasonably requested by Processa; provided that Processa shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by Yuhan in connection with such cooperation. If Processa elects not to assume control over litigating any Paragraph IV Claim, Processa shall notify Yuhan as soon as practicable but in any event not later than ten (10) days before the first action required to litigate such Paragraph IV Claim so that Yuhan may, but shall not be required to, assume sole control over litigating such Paragraph IV Claim using counsel of its own choice. Any suit by Yuhan shall be either in the name of Yuhan or its Affiliate, the name of Processa or its Affiliate, or the names of Processa, Yuhan, and their respective Affiliates, as may be required by the Law of the forum. For this purpose, Processa shall execute such legal papers and cooperate in the prosecution of such suit, including providing full access to documents, information and witnesses, as may be reasonably requested by Yuhan; provided that Yuhan shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by Processa in connection with such cooperation. Any compensation recovered as a result of such litigation shall be allocated as set forth in Section 8.3(e) above.

8.9 Privileged Communications. In furtherance of this Agreement, it is expected that Processa and Yuhan will, from time to time, disclose to one another privileged communications with counsel, including opinions, memoranda, letters, and other written, electronic and verbal communications. Such disclosures are made with the understanding that they shall remain confidential, that they will not be deemed to waive any applicable attorney-client or attorney work product or other privilege and that they are made in connection with the shared community of legal interests existing between Yuhan and Processa, including the community of legal interests in avoiding infringement of any valid, enforceable patents of Third Parties and maintaining the validity of Yuhan Patent Rights, Processa Patent Rights and Joint Patent Rights.

8.10 Settlement. Neither Party shall unilaterally enter into any settlement or compromise of any suit, action or proceeding under this ARTICLE VIII that would in any manner alter, diminish, or be in derogation of the other Party's rights under this Agreement without the prior written consent of such other Party, which shall not be unreasonably withheld or delayed.

**ARTICLE IX**
**CONFIDENTIAL INFORMATION**

9 . 1 Treatment of Confidential Information. During the Term and for five (5) years thereafter, each Party shall maintain Confidential Information (as defined in Section 9.2) of the other Party in confidence, and shall not disclose, divulge or otherwise communicate such Confidential Information to others (except for agents, directors, officers, employees, consultants, subcontractors, licensees, sublicensees, partners, Affiliates, and advisers who have a need to know such information to perform obligations or exercise rights on behalf of such Party (collectively, "Agents") under obligations of confidentiality no less stringent than those set forth in this ARTICLE IX) or use it for any purpose other than in connection with the Development, Manufacture, use or Commercialization of Compounds or Products pursuant to this Agreement or otherwise to accomplish the purposes of this Agreement, including exercising its rights or performing its obligations hereunder, and each Party shall exercise Commercially Reasonable Efforts to prevent and restrain the unauthorized disclosure of such Confidential Information by any of its Agents, which efforts shall be at least as diligent as those generally used by such Party in protecting its own confidential and proprietary information, and in any event no less than reasonable efforts. Each Party will be responsible for any breach of this ARTICLE IX by its Agents. Either receiving Party may disclose Confidential Information of the disclosing Party (a) to Governmental Authorities in order to comply with applicable Laws, respond to inquiries, requests or investigations by Governmental Authorities, including filing, prosecuting or maintaining Patent Rights as permitted by this Agreement; (b) to comply with the regulations or requirements of any stock exchange; (c) to the extent useful to Develop, Manufacture, use or Commercialize any Compound or Product, including making regulatory filings for any Compound or Product, in accordance with this Agreement; (d) to the extent necessary or useful in order to defend or prosecute litigation; and (e) to potential and actual *bona fide* investors, acquirors and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition or collaboration; provided that (x) with respect to any disclosure in accordance with Section 9.1(a), (b) or (d), the receiving Party shall promptly provide prior notice of such disclosure to the disclosing Party and use Commercially Reasonable Efforts to avoid or minimize the degree of such disclosure, (y) with respect to any disclosure in accordance with Section 9.1(a) or (d), the receiving Party will use efforts to secure confidential treatment of such Confidential Information at least as diligent as such Party would use to protect its own confidential information, but in no event less than reasonable efforts, and (z) with respect to any disclosure in accordance with Section 9.1(e),the receiving Party shall obtain the same confidentiality obligations from any Third Parties to which it discloses the Confidential Information of the disclosing Party as it obtains with respect to its own similar types of confidential information, and in any event such obligations shall be no less stringent than those set forth in this ARTICLE IX.

9 . 2 Confidential Information. "Confidential Information" means all trade secrets or other proprietary information, including any proprietary data and materials (whether or not patentable or protectable as a trade secret), that is disclosed by a Party to the other Party. All information disclosed prior to the Effective Date by Yuhan and/or Yuhan's Affiliate to Processa pursuant to the Confidentiality Agreement effective as of April 22, 2020, as amended through the Effective Date (the " Confidentiality Agreement"), shall be deemed "Confidential Information" of Yuhan. Notwithstanding the foregoing, there shall be excluded from the foregoing definition of Confidential Information any of the foregoing that:

(a) either before or after the date of the disclosure to the receiving Party is lawfully disclosed to the receiving Party by a Third Party without any violation of any obligation to the other Party; or

(b) either before or after the date of the disclosure to the receiving Party, becomes published or generally known to the public through no fault or omission on the part of the receiving Party or its Agents; or

(c) is independently developed by or for the receiving Party without reference to or reliance upon the disclosing Party's Confidential Information as demonstrated by contemporaneous written records of the receiving Party.

9.3 Publications. The Parties recognize the desirability of publishing and publicly disclosing the results of clinical trials of pharmaceutical products. Accordingly, subject to coordination through designated representatives of each Party, Processa shall be free to publicly disclose the results of clinical trials involving Compounds or Products, subject to prior review by Yuhan for issues of patentability and protection of its Confidential Information, in a manner consistent with all Laws applicable to Processa and best industry practices. In addition, if Processa intends to publish articles in scientific or medical journals or to make presentations of the results of clinical trials involving Compounds or Products, Processa shall provide Yuhan through the designated representatives of each Party at its earliest opportunity with any proposed abstracts, manuscripts or summaries of presentations that cover the results of Development of any Compound or Product. Yuhan shall respond promptly through its designated representative, and in any event no later than thirty (30) days after receipt of such proposed publication or presentation, or such shorter period as may be required by the publication. If timely requested by Yuhan, Processa agrees to allow a reasonable period (not to exceed sixty (60) days) to permit filings for patent protection and to otherwise address issues of Confidential Information or related competitive harm to the reasonable satisfaction of Yuhan. In addition, Processa will consider in good faith any comments furnished by Yuhan to Processa during such period. Processa shall be responsible to assure that its Affiliates and licensees agree to, and comply with, equivalent undertakings in favor of Yuhan. Yuhan and its Affiliates may make any publication or public disclosure of any data concerning the Compounds or Products that existed as of the Effective Date, provided that Yuhan provides Processa at least thirty (30) days (or such shorter period as may be required by the publication) to review such publication or public disclosure, allows a reasonable period (not to exceed sixty (60) days) to permit filings for patent protection and to otherwise address issues of Confidential Information or related competitive harm to the reasonable satisfaction of Processa, and reasonably considers any timely comments provided by Processa with respect to such publication or public disclosure. Yuhan shall not, and shall cause each of its Affiliates, licensees, and sublicensees not to, make any other publications or public disclosures regarding the Compounds or Products without Processa's prior written consent. If Processa consents to Yuhan making such publications, Yuhan shall provide Processa a reasonable opportunity to comment on any such publications and such comments shall not be unreasonably rejected. All publications involving Compounds or Products shall include appropriate acknowledgement consistent with standard scientific practice of any contributions of each Party to the results being publicly disclosed.

9.4 Press Releases and Other Disclosures. The Parties recognize that each Party may from time to time desire to issue press releases and make other public statements or disclosures regarding the subject matter of this Agreement. In such event, the Party desiring to issue a press release or make a public statement or disclosure shall provide the other Party with a copy of the proposed press release, statement or disclosure for review and approval in advance (except that neither Party shall have any obligation to disclose or approve the disclosure of Confidential Information except to the extent required or permitted pursuant to this ARTICLE IX). No other public statement or disclosure concerning the existence or terms of this Agreement shall be made, either directly or indirectly, by either Party, without first obtaining the written approval of the other Party. Once any public statement or disclosure has been approved in accordance with this Section 9.4, then either Party may appropriately communicate information contained in such permitted statement or disclosure. Notwithstanding the foregoing provisions of this Section 9.4 this ARTICLE IX, a Party may (a) disclose the existence and terms of this Agreement where required, as reasonably determined by the disclosing Party, by applicable Law, by applicable stock exchange regulation or by order or other ruling of a competent court and (b) disclose the existence and terms of this Agreement under obligations of confidentiality no less stringent than those set forth in this ARTICLE IX to agents, advisors, contractors, licensees, sublicensees, and *bona fide* investors, acquirors and other financial or commercial partners, and to potential agents, advisors, contractors, licensees, sublicensees, and *bona fide* investors, acquirors and other financial or commercial partners. To the extent a Party determines in good faith that it is required by applicable Law to publicly file, register or notify this Agreement with a Governmental Authority, including public filings pursuant to securities Laws, it shall provide a proposed redacted form of the Agreement to the other Party a reasonable amount of time prior to filing for the other Party to review such draft and propose changes to such proposed redactions. The Party making such filing, registration or notification shall incorporate any proposed changes timely requested by the other Party, absent a reasonable basis for not making such changes, and shall use Commercially Reasonable Efforts to seek confidential treatment for any terms that the other Party timely requests be kept confidential, to the extent such confidential treatment is reasonably available consistent with applicable Law. Each Party shall be responsible for its own legal and other external costs in connection with any such filing, registration, or notification.

9.5 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that a Party would suffer upon unauthorized disclosure, use, or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages would not be a sufficient remedy for any breach of this ARTICLE IX. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this ARTICLE IX.

## ARTICLE X
## REPRESENTATIONS, WARRANTIES AND COVENANTS

10.1 Yuhan's Representations. Yuhan hereby represents and warrants as of the Effective Date as follows:

(a) Yuhan has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder. The execution, delivery, and performance of this Agreement has been duly and validly authorized and approved by all necessary corporate action on the part of Yuhan. Yuhan has taken all other action required by Law, its certificate of incorporation or by-laws, or any agreement to which it is a party or by which it or its assets are bound, to authorize such execution, delivery, and performance. Assuming due authorization, execution, and delivery on the part of Processa, this Agreement constitutes a legal, valid, and binding obligation of Yuhan, enforceable against Yuhan in accordance with its terms.

(b) The execution and delivery of this Agreement by Yuhan do not require Yuhan to obtain any permit, authorization or consent from any Governmental Authority or from any other Person which has not been obtained prior to the Effective Date, and such execution and delivery by Yuhan will not result in the breach of or give rise to any termination of, rescission, renegotiation or acceleration under or trigger any other rights under any agreement or contract to which Yuhan may be a party that relates to the Yuhan Patent Rights or the Yuhan Know-How.

(c) Schedule 1.57 is a complete and correct list of all Patent Rights owned by Yuhan as of the Effective Date that Cover any Compound or Product. No Patent Right that covers any Compound or Product has been licensed to Yuhan.

(d) Yuhan is the legal and beneficial owner of all the Patent Rights identified on Schedule 1.57. To Yuhan's knowledge, all assignments to Yuhan of ownership rights relating to such Patent Rights are valid and enforceable and free and clear of any liens, security interests or other similar encumbrances that would impair or limit the license rights granted under this Agreement. All of the Patent Rights listed identified on Schedule 1.57 that are issued patents are in full force and effect, and all applicable filing, maintenance and other fees required to be paid to a patent office with respect to the Patent Rights listed identified on Schedule 1.57 have been timely paid. Yuhan has the right to grant the licenses granted by it in this Agreement and has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the Yuhan Intellectual Property in a manner that conflicts with any rights granted to Processa hereunder.

(e) There is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry, or investigation of any nature, civil, criminal, regulatory, or otherwise, in law or in equity, pending or, to Yuhan's knowledge, threatened against Yuhan in connection with the Compounds or Products or any Yuhan Patent Rights, Yuhan Know-How or against or relating to the transactions contemplated by this Agreement. Yuhan has not received any written notice from a Third Party that the Development of any Compound or Product conducted by Yuhan has infringed or misappropriated, or that any Development or Commercialization of any Compound or Product will infringe or misappropriate, any Patent Rights or Know-How of any Third Party.

(f) No claim or action has been brought or, to Yuhan's knowledge, threatened by any Third Party alleging that the Yuhan Patent Rights are invalid or unenforceable, and no Yuhan Patent Rights are the subject of any litigation, interference, post-grant review, opposition, cancellation or other proceeding challenging the validity or enforceability of the Yuhan Patent Rights.

(g) Neither Yuhan nor, to the knowledge of Yuhan, any of its directors, officers, employees, agents or subcontractors has been convicted of any crime or engaged in any conduct that has resulted in, or would reasonably be expected to result, in debarment by the FDA under 21 U.S.C. § 335a or any similar state or foreign Law.

10.2 Processa's Representations. Processa hereby represents and warrants as of the Effective Date as follows:

(a) Processa has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder. The execution, delivery, and performance of this Agreement has been duly and validly authorized and approved by all necessary corporate action on the part of Processa. Processa has taken all other action required by Law, its certificate of incorporation or by-laws or any agreement to which it is a party or by which it or its assets are bound to authorize such execution, delivery and (subject to obtaining all necessary governmental approvals with respect to the Development, Manufacture, use and Commercialization of Compounds and Products) performance. Assuming due authorization, execution, and delivery on the part of Yuhan, this Agreement constitutes a legal, valid, and binding obligation of Processa, enforceable against Processa in accordance with its terms.

(b) The execution and delivery of this Agreement by Processa will not violate any U.S. Law or, to Processa's knowledge, any Law of any Governmental Authority outside the U.S.

(c) There is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to the knowledge of Processa, threatened against Processa in connection with or relating to the transactions contemplated by this Agreement.

(d) The execution and delivery of this Agreement do not require Processa to obtain any permit, authorization or consent from any Governmental Authority or from any other Person, and such execution and delivery by Processa will not result in the breach of or give rise to any termination of, rescission, renegotiation or acceleration under or trigger any other rights under any agreement or contract to which Processa may be a party that relates to the Products, Processa Patent Rights or Processa Know-How.

(e) Neither Processa nor, to the knowledge of Processa, any of its directors, officers, employees, agents or subcontractors has been convicted of any crime or engaged in any conduct that has resulted in, or would reasonably be expected to result, in debarment by the FDA under 21 U.S.C. § 335a or any similar state or foreign Law.

10.3 Yuhan Covenants. Yuhan covenants and agrees during the Term that, subject to Processa's, its Affiliates' and Sublicensees' performance of their obligations under this Agreement:

(a) Yuhan shall not grant to any Third Party any rights that would be inconsistent or conflict with Processa's rights hereunder.

(b) Subject to Section 13.7, Yuhan shall not assign, transfer, convey, or otherwise encumber its right, title, and interest in the Yuhan Intellectual Property in a manner that conflicts with any rights granted to Processa hereunder.

10.4 Processa Covenants.

(a) Processa shall conduct, and shall cause its contractors and consultants to conduct, all of their activities contemplated under this Agreement in accordance with all applicable Laws of the country in which such activities are conducted, including applicable requirements of "good laboratory practices," "good clinical practices," and "good manufacturing practices," as applicable, as defined by the FDA.

(b) Subject to Section 13.7, Processa shall not assign, transfer, convey, or otherwise encumber its right, title, and interest in the Processa Intellectual Property in a manner that conflicts with any rights granted hereunder to Yuhan upon termination.

10.5 No Warranty. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED. IN PARTICULAR, BUT WITHOUT LIMITATION, EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY CONCERNING WHETHER ANY OF THE COMPOUNDS OR PRODUCTS ARE FIT FOR ANY PARTICULAR PURPOSE OR SAFE FOR HUMAN CONSUMPTION.

## ARTICLE XI
## INDEMNIFICATION

11.1 Indemnification in Favor of Yuhan. Processa shall indemnify, defend and hold harmless the Yuhan Parties from and against any and all Losses incurred, suffered or sustained by any of the Yuhan Parties or to which any of the Yuhan Parties becomes subject as a result of any Third Party claim, action, suit, proceeding, liability or obligation (which in no event includes any claim by any Processa Party or any Yuhan Party) (collectively, "Third Party Claims") arising out of, relating to or resulting from:

(a) any misrepresentation or breach of any representation, warranty, covenant or agreement made by Processa in this Agreement; or

(b) the Development Manufacture or Commercialization of Compounds or Products by Processa, its Affiliates or Sublicensees, including all Third Party Claims involving death or bodily injury caused or allegedly caused by the use of such a Compound or Product, and even if such a Compound or Product is altered for use for a purpose not intended (any and all such Third Party Claims "Product Liability Claims"); or

(c) any actual or alleged infringement of any trademark, Patent Right or other intellectual property right, or misappropriation of any trade secret, of any Third Party as a result of the Development, Manufacture or Commercialization of Compounds or Products by Processa, its Affiliates or Sublicensees; or

(d) the gross negligence or willful misconduct of any of the Processa Parties (as hereinafter defined) in connection with Processa's performance of this Agreement.

For purposes of this ARTICLE XI, "Yuhan Parties" means Yuhan, its Affiliates and their respective agents, directors, officers, licensees, sublicensees and employees.

The indemnification obligations set forth in this Section 11.1 shall not apply to the extent that any Loss is the result of (i) a breach of any representation, warranty, covenant, or agreement made by Yuhan in this Agreement or (ii) the gross negligence or willful misconduct of any applicable Yuhan Party.

11.2 Indemnification in Favor of Processa. Yuhan shall indemnify, defend and hold harmless the Processa Parties from and against any and all Losses incurred, suffered or sustained by any of the Processa Parties or to which any of the Processa Parties becomes subject as a result of any Third Party Claim arising out of, relating to or resulting from:

(a) any misrepresentation or breach of any representation, warranty, covenant or agreement made by Yuhan in this Agreement; or

(b) the Development, Manufacture or Commercialization of Compounds or Products by Yuhan, its Affiliates, licensees (excluding Processa) or sublicensees prior to the execution of this Agreement and after any termination of this Agreement, including all Product Liability Claims arising out of any such pre-Agreement, post-termination Development, Manufacture or Commercialization by Yuhan, its Affiliates, licensees (excluding Processa) or sublicensees; or

(c) any actual or alleged infringement of any trademark, Patent Right or other intellectual property right, or misappropriation of any trade secret, of any Third Party as a result of the Development, Manufacture or Commercialization of Compounds or Products by Yuhan, its Affiliates, licensees (excluding Processa) or sublicensees prior to the execution of this Agreement and after any termination of this Agreement; or

(d) the gross negligence or willful misconduct of any of the Yuhan Parties in connection with Yuhan's performance of this Agreement.

For purposes of this ARTICLE XI, "Processa Parties" means Processa, its Affiliates and their respective agents, directors, officers, licensees, sublicensees and employees.

The indemnification obligations set forth in this Section 11.2 shall not apply to the extent that any Loss is the result of (i) a breach of any representation, warranty, covenant, or agreement made by Processa in this Agreement, or (ii) the gross negligence or willful misconduct of any applicable Processa Party.

11.3 General Indemnification Procedures.

(a) A Yuhan Party or Processa Party seeking indemnification pursuant to this ARTICLE XI (an " Indemnified Party") shall give prompt notice to the Party from whom such indemnification is sought (the "Indemnifying Party") of the commencement or assertion of any Third Party Claim in respect of which indemnity may be sought hereunder, shall give the Indemnifying Party such information with respect to any indemnified matter as the Indemnifying Party may reasonably request, and shall not make any admission concerning any Third Party Claim, unless such admission is required by applicable Law or legal process, including in response to questions presented in depositions or interrogatories. Any admission made by the Indemnified Party or the failure to give such notice shall relieve the Indemnifying Party of any liability hereunder only to the extent that the ability of the Indemnifying Party to defend such Third Party Claim is prejudiced thereby (and no admission required by applicable Law or legal process shall be deemed to result in prejudice). The Indemnifying Party shall assume and conduct the defense of such Third Party Claim, with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party. Subject to the initial and continuing satisfaction of the terms and conditions of this ARTICLE XI by the Indemnifying Party, the Indemnifying Party shall have full control of such Third Party Claim, including settlement negotiations and any legal proceedings. If the Indemnifying Party does not assume the defense of such Third Party Claim in accordance with this Section 11.3, the Indemnified Party may defend the Third Party Claim. If both Parties are Indemnifying Parties with respect to the same Third Party Claim, the Parties shall determine by mutual agreement, within twenty (20) days following their receipt of notice of commencement or assertion of such Third Party Claim (or such lesser period of time as may be required to respond properly to such claim), which Party shall assume the lead role in the defense thereof. Should the Indemnifying Parties be unable to mutually agree on which of them shall assume the lead role in the defense of such Third Party Claim, both Indemnifying Parties shall be entitled to participate in such defense through counsel of their respective choosing.

(b) Any Indemnified Party or Indemnifying Party not managing the defense of a Third Party Claim shall have the right to participate in (but not control), at its own expense (subject to the immediately succeeding sentence), the defense. The Indemnifying Party managing the defense shall not be liable for any litigation cost or expense incurred, without its consent, by the Indemnified Party where the action or proceeding is under the control of such Indemnifying Party; provided, however, that, if the Indemnifying Party managing the defense fails to take reasonable steps necessary to defend such Third Party Claim, the Indemnified Party may assume its own defense, and the Indemnifying Party managing the defense will be liable for all reasonable costs or expenses paid or incurred in connection therewith.

(c) The Indemnifying Party shall not, except with the consent of the Indemnified Party, consent to a settlement of, or the entry of any judgment against, an Indemnified Party arising from any Third Party Claim to the extent such settlement or judgment involves equitable or other non-monetary relief from the Indemnified Party. No Party shall, without the prior written consent of the other Party or the Indemnified Party, enter into any compromise or settlement that commits the other Party or the Indemnified Party to take, or to forbear to take, any action.

(d) The Parties shall cooperate in the defense or prosecution of any Third Party Claim and shall furnish such records, information and testimony, and attend such conferences, discovery proceedings, hearings, trials and appeals, as may be reasonably requested in connection therewith; provided, however, that the Indemnifying Party shall reimburse the Indemnified Party for any out-of-pocket expenses actually and reasonably incurred in connection with any such cooperation.

(e) Any indemnification hereunder shall be made net of any insurance proceeds actually recovered by the Indemnified Party from unaffiliated Third Parties; provided, however, that if, following the payment to the Indemnified Party of any amount under this ARTICLE XI, such Indemnified Party recovers any such insurance proceeds in respect of the claim for which such indemnification payment was made, the Indemnified Party shall promptly pay an amount equal to the amount of such proceeds (but not exceeding the amount of such net indemnification payment) to the Indemnifying Party.

(f) The Parties agree and acknowledge that the provisions of this ARTICLE XI represent the Indemnified Party's exclusive recourse with respect to any Losses for Third Party Claims for which indemnification is provided to the Indemnified Party under this ARTICLE XI.

11.4 Insurance. During the Term, for so long as a Third Party Claim may be brought for which Processa must indemnify Yuhan pursuant to Section 11.1, Processa shall obtain and maintain, at its sole cost and expense, product liability insurance in amounts that are reasonable and customary in the pharmaceutical industry, but in no event less than $5 million per occurrence or claim, and $10 million in the aggregate, or a comparable program of self-insurance. Such product liability insurance shall insure against all liability, including product liability and property damage arising out of the Development, use or Commercialization of Compounds and Products by Processa, its Affiliates, or Sublicensees in the Territory. Without limiting the generality of the foregoing, Processa shall maintain comprehensive general liability insurance, including product liability insurance, to cover its activities and, unless its Affiliates and Sublicensees maintain comparable coverage, the activities of its Affiliates and Sublicensees, with respect to Compounds and Products. Processa shall provide satisfactory evidence of adequate insurance coverage to Yuhan upon the request of Yuhan, and upon any cancellation, non-renewal, replacement, or material change in such insurance.

## ARTICLE XII
## TERM AND TERMINATION

12.1 Term. The term of this Agreement (the "Term") shall commence on the Effective Date and, unless earlier terminated as provided in this ARTICLE XII, shall continue in full force and effect until the expiration of the last Royalty Term. In the Territory, on a country-by-country and Product-by-Product basis, upon the expiration of the Royalty Term in such country with respect to such Product, Processa shall have a fully paid-up, perpetual, irrevocable, non-exclusive license under the Yuhan Intellectual Property and Yuhan's interest in the Joint Intellectual Property with respect to such Product in such country.

12.2 Termination for Convenience. Processa shall have the right upon sixty (60) days prior written notice to Yuhan to terminate this Agreement in its entirety for any reason.

12.3 Termination for Cause. In the event of a material breach of this Agreement by a Party, the other Party may give the Party in default notice requiring it to cure such default, which notice shall specify the nature of the breach. If such material breach is not cured within forty-five (45) days after receipt of such notice (or within fifteen (15) days in the case of a payment breach), the notifying Party shall be entitled (without prejudice to any other rights conferred on it by this Agreement or under applicable Law) to terminate this Agreement by giving written notice to the defaulting Party. The right of either Party to terminate this Agreement as set forth in this Section 12.3 shall not be affected in any way by its waiver of, or failure to take action with respect to, any previous default.

12.4 Additional Termination by Yuhan. In the event that Yuhan has provided written notice to Processa pursuant to Section 6.2, if Processa does not respond to Yuhan in writing within ninety (90) days of receipt of such notice from Yuhan and reasonably demonstrate in such response compliance with Processa's obligations under Section 6.1, Yuhan shall be entitled (without prejudice to any other rights conferred on it by this Agreement or under applicable Law) to terminate this Agreement by giving written notice to Processa.

12.5 Termination for Insolvency. This Agreement may be terminated by a Party upon written notice to the other Party if (a) the other Party shall make an assignment for the benefit of its creditors, file a petition in bankruptcy, petition or apply to any tribunal for the appointment of a custodian, receiver or trustee for it or a substantial part of its assets, or shall commence any proceeding under any bankruptcy, reorganization, readjustment of debt, dissolution or liquidation law or statute of any jurisdiction, whether now or hereafter in effect; or (b) if there shall have been filed against the other Party any such *bona fide* petition or application, or any such proceeding shall have been commenced against it, in which an order for relief is entered or that remains undismissed or unstayed for a period of ninety (90) days or more; or (c) if the other Party by any act or omission shall consent to, approve of or acquiesce in any such petition, application or proceeding or order for relief or the appointment of a custodian, receiver or trustee for it or any substantial part of its assets, or shall suffer any such custodianship, receivership or trusteeship to continue undischarged or unstayed for a period of ninety (90) days or more. Termination shall be effective upon the date specified in such notice.

12.6 Termination for Challenge of Patent Rights. If a Party or any of the Party's Affiliates or Sublicensees commences an action in any court or tribunal of competent jurisdiction that challenges, opposes or disputes the validity, enforceability or patentability of any of the other Party's Patent Rights that are the subject of this Agreement, or any of the claims thereof, or supports or assists any Third Party that commences such an action in any such court or tribunal, the other Party shall have the right to terminate this Agreement upon notice to the Party; provided, however, that the other Party shall not have a right to terminate if the challenge is brought by a Sublicensee, either directly or indirectly through any Third Party, and the Party or the Affiliate, as the case may be, terminates such Sublicensee's sublicense rights hereunder within thirty (30) days after becoming aware of such challenge.

12.7 Consequences of Termination. If this Agreement (x) is terminated by Yuhan under Section 12.3, 12.4, 12.5 or 12.6, (y) is terminated by Processa under Section 12.2, or (z) is terminated by Processa under Section 12.3 or 12.5, then the licenses granted to Processa in Section 2.1 and, except as provided in this Section 12.7 and Sections 12.8 and 12.9 (and any Articles and Sections referenced therein), all other rights and obligations of the Parties under this Agreement shall terminate. Upon a termination described in clause (x) (but not clause (y) or (z)) of this Section 12.7, clause (a) shall apply, and, upon a termination described in clause (x) or (y) (but not clause (z)), Processa shall grant, and shall cause any applicable Affiliate to grant, Yuhan any combination of the following clauses (b) through (f) elected by Yuhan:

(a) Sublicenses. Yuhan hereby grants, effective automatically upon any termination of this Agreement by Yuhan pursuant to Section 12.3, 12.4, 12.5 or 12.6, a direct license to each then-existing Sublicensee, provided that (i) such Sublicensee is not in breach under the applicable sublicense, (ii) such Sublicensee's failure to comply with the terms of its sublicense or other actions or omissions were not a basis for such termination, and (iii) such Sublicensee continues to satisfy all obligations under this Agreement applicable to such sublicense, including the diligence obligations set forth in ARTICLE VI and all payment obligations under the then-existing Sublicensee agreement (except that such payments for the sublicenses shall be made directly to Yuhan), from and after the date that such direct license becomes effective. For clarity, Yuhan shall not be bound to any responsibility or liability of Processa under its sublicense agreements that has already accrued at the time of such termination of this Agreement by Yuhan pursuant to Section 12.3, 12.4, 12.5, or 12.6, or that is attributable to a period prior to such termination

( b ) Regulatory Matters. Ownership of all filings with Regulatory Authorities in the Territory relating to Compounds and Products and Regulatory Approvals relating to Compounds and Products held Processa or its Affiliates or applicable Sublicensees, including related correspondence with Regulatory Authorities, and Processa shall provide copies thereof to Yuhan;

(c) Pre-clinical and Clinical Matters. Possession of all pre-clinical and clinical data, including pharmacology and biology data, within the Processa Know-How and applicable Sublicensee Intellectual Property;

(d) Manufacturing Matters. At Yuhan's option, to be exercised no later than the later of (x) thirty (30) days after the Effective Date of termination or (y) thirty (30) days after Yuhan's receipt of the applicable Manufacturing agreements,

(i) use of Commercially Reasonable Efforts by Processa and its Affiliates and applicable Sublicensees to effect the assignment of each Manufacturing agreement specific and exclusive to Compounds or Products to Yuhan, if such agreement is then in effect and such assignment is permitted under such agreement or by the applicable Third Party; provided that Processa and its applicable Affiliates and applicable Sublicensees shall be released to the extent the applicable Third Party will permit from any obligation arising out of such agreement following such assignment and Yuhan shall execute such documentation reasonably satisfactory to Processa to effectuate such agreement; provided further that if any such agreement is specific but not exclusive to Compounds or Products, or is not assigned to Yuhan for any reason, Processa will discuss in good faith with Yuhan terms upon which Processa and its Affiliates and applicable Sublicensees shall use Commercially Reasonable Efforts to provide Yuhan with the benefits of such agreement to the extent it relates to Compounds or Products for a limited period of time (not to exceed six (6) months) and upon payment of a reasonably acceptable fee to Processa;

(ii) for a period of up to six (6) months following the Effective Date of termination, (A) cooperation with Yuhan in reasonable respects to transfer Manufacturing documents and materials within the Processa Know-How and applicable Sublicensee Intellectual Property that are used (at the time of the termination) by Processa or its Affiliates or applicable Sublicensees exclusively in the Manufacture of Compounds and Products to the extent such Manufacturing documents and materials are not obtained by Yuhan pursuant to the assignment of agreements pursuant to paragraph (i) above, and (B) cooperation with Yuhan to provide Yuhan with reasonable access to and right to use such Manufacturing documents and materials in Processa's or its Affiliates' or applicable Sublicensees' possession or Control to the extent they relate to, but are not used exclusively in, the Manufacture of Compounds and Products, subject to appropriate confidentiality and limitation on use protections applicable to for Manufacturing documents and materials;

(iii) for a period of up to six (6) months following the Effective Date of termination, (A) cooperation with Yuhan in reasonable respects to transfer Manufacturing technologies within the Processa Intellectual Property and applicable Sublicensee Intellectual Property that are used (at the time of the termination) by Processa or its Affiliates or applicable Sublicensees exclusively in the Manufacture of Compounds and Products, and (B) cooperation with Yuhan to provide Yuhan with reasonable access to and right to use such Manufacturing technologies Controlled by Processa or its Affiliates (other than Processa Excluded Affiliates) or applicable Sublicensees to the extent they relate to, but are not used exclusively in, the Manufacture of Compounds and Products and that Processa or such Affiliates or Sublicensees are permitted to provide such access to Yuhan; provided that Yuhan shall reimburse Processa for Processa's reasonable out-of-pocket expenses to provide such requested assistance, to the extent such Manufacturing technologies are not obtained by Yuhan pursuant to the assignment of agreements pursuant to paragraph (i) above; and

(iv) sale of Processa's or its Affiliates' or applicable Sublicensees' then-existing inventory of Compounds and Products to Yuhan, at Processa's or its applicable Affiliates' or applicable Sublicensees' cost of Manufacture, but only if the following conditions have been met: (A) such Compounds and Products meet the applicable release specifications; and (B) Processa does not reasonably believe the continued use of such Compounds and Products causes safety concerns;

(e) License Grant. At Yuhan's option, to be exercised by written notice to Processa no later than thirty (30) days after the Effective Date of termination, a worldwide license, with the right to sublicense, under the Processa Patent Rights, Processa Know-How, Processa's interest in the Joint Intellectual Property, and applicable Sublicensee Intellectual Property, solely to make, have made, use, sell, offer for sale and import Compounds and Products in the Field that were Developed or Commercialized prior to the Effective Date of termination, which license would be, at Yuhan's election, either (i) non-exclusive, fully paid-up, non-royalty-bearing, irrevocable and perpetual or (ii) exclusive and royalty-bearing subject to mutual agreement by Yuhan and Processa on commercially reasonable terms; provided that, notwithstanding the foregoing, with respect to any Processa Patent Rights or Processa Know-How that Processa acquired from a Third Party (by license or otherwise), or any applicable Sublicensee Intellectual Property that the applicable Sublicensee(s) acquired from a Third Party (by license or otherwise), Processa or the applicable Sublicensee(s) shall only be required to grant to Yuhan a license to such Processa Patent Rights, Processa Know-How or Sublicensee Intellectual Property to the extent permitted under the applicable agreement with such Third Party, and Yuhan shall pay Processa or such Sublicensee or such Third Party, as determined by Processa, any payment due to such Third Party relating to the Compounds and Products; provided further that Yuhan shall execute such documentation reasonably satisfactory to Processa to effectuate such agreement; and if the license granted to Yuhan is exclusive, Yuhan shall have the same enforcement rights with respect to any Processa Patent Rights and Patent Rights within the Sublicensee Intellectual Property that exclusively Cover Products that are licensed to Yuhan pursuant to this Section 12.7(e) as Processa has with respect to Infringement Claims pursuant to Section 8.3 (to the extent that Processa or the applicable Sublicensee(s) have such rights with respect to such Processa Patent Rights or Patent Rights within the Sublicensee Intellectual Property, as applicable), provided that any enforcement of Processa Patent Rights, Joint Patent Rights or Patent Rights within the Sublicensee Intellectual Property that Cover subject matter other than such Products shall be performed by Yuhan only with the consultation and prior agreement of Processa or the applicable Sublicensee, which such agreement shall not unreasonably withheld, delayed or conditioned.

( f ) Assignment of Trademarks. Assign to Yuhan all of Processa's or its applicable Sublicensees' right, title and interest in any trademark owned by Processa or its Affiliates or applicable Sublicensees and used solely in connection with the Products, along with all associated goodwill.

12.8 Effect of Termination or Expiration; Accrued Rights and Obligations. Termination or expiration of this Agreement for any reason shall not release either Party from any liability that, at the time of such termination or expiration, has already accrued or that is attributable to a period prior to such termination (including payment obligations accrued prior to the Effective Date of termination or expiration pursuant to ARTICLE VII) nor preclude either Party from pursuing any right or remedy it may have hereunder or at Law or in equity with respect to any breach of this Agreement.

12.9 Survival. The rights and obligations set forth in this Agreement shall extend beyond the Term or termination or expiration of this Agreement only to the extent expressly provided for in this Agreement or to the extent required to give effect to a termination or expiration of this Agreement or the consequences of a termination or expiration of this Agreement as expressly provided for in this Agreement. Without limiting the generality of the foregoing, it is agreed that the provisions of ARTICLE I, Sections 2.2, 2.3, 7.8 (only for thirty-six (36) months after expiration or termination), 7.9, 7.10, 7.11, 7.12, 8.1, 8.9, 9.1, 9.2, 9.5, 10.5, ARTICLE XI, and Sections 12.1 (last sentence as to any such license that became perpetual and irrevocable prior to expiration or termination), 12.7, 12.8, 12.9 and ARTICLE XIII shall survive expiration or termination of this Agreement for any reason.

## ARTICLE XIII
## MISCELLANEOUS

13.1 Governing Law; Jurisdiction. This Agreement shall be governed by and interpreted in accordance with the laws of the state of New York, without regard to its conflicts of laws rules. Each Party (a) irrevocably submits to the exclusive jurisdiction in the state court sitting in New York (collectively, the "Courts"), for purposes of any action, suit or other proceeding arising out of this Agreement, and (b) agrees not to raise any objection at any time to the laying or maintaining of the venue of any such action, suit or proceeding in any of the Courts, irrevocably waives any claim that such action, suit or other proceeding has been brought in an inconvenient forum and further irrevocably waives the right to object, with respect to such action, suit or other proceeding, that such Court does not have any jurisdiction over such Party. Either Party may serve any process required by such Courts by way of notice under this Agreement. Notwithstanding anything to the contrary in this Section 13.1, each Party shall have the right to institute judicial proceedings against the other Party or anyone acting by, through, or under such other Party, in any court of competent jurisdiction, in order to enforce the instituting Party's rights hereunder through reformation of contract, specific performance, injunction, or similar equitable relief.

13.2 Dispute Resolution. In the event of a dispute arising out of or relating to this Agreement, either Party shall provide written notice of the dispute to the other, in which event the dispute shall be referred to the Senior Executives of each Party, for attempted resolution by good faith negotiations within twenty (20) days after such notice is received. In the event the Senior Executives do not resolve such dispute within the allotted twenty (20) days, either Party may, after the expiration of the twenty (20) day period, seek to resolve the dispute in accordance with Section 13.1.

13.3 Waiver. Waiver by a Party of a breach hereunder by the other Party shall not be construed as a waiver of any succeeding breach of the same or any other provision. No delay or omission by a Party to exercise or avail itself of any right, power, or privilege that it has or may have hereunder shall operate as a waiver of any right, power, or privilege by such Party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.

13.4 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address specified in this Section 13.4 and shall be: (a) delivered personally; (b) sent by registered or certified mail, return receipt requested, postage prepaid; (c) sent via a reputable nationwide overnight courier service; or (d) sent by facsimile or other electronic transmission. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service, or when transmitted with confirmation of receipt, if transmitted by facsimile or other electronic transmission (if such transmission is on a Business Day; otherwise, on the next Business Day following such transmission).

Notices to Processa shall be addressed to:

Processa Pharmaceuticals, Inc.
7380 Coca Cola Drive, Suite 106
Hanover, MD 21076
Attn: Wendy Guy, Chief Administrative Officer
Email: wguy@processapharmaceuticals.com

Notices to Yuhan shall be addressed to:

Yuhan Corporation
74, Noryangjin-ro, Dongjak-gu
Seoul, Republic of Korea, 06927
Attention: Taejin Yoon, Head of Global Business Development
Email: tyoon@yuhan.co.kr
Facsimile: 82-2-828-0086

Yuhan Corporation
74, Noryangjin-ro, Dongjak-gu
Seoul, Republic of Korea, 06927
Attention: Han K. Kim, Head of Global Operations
Email: hkkim@yuhan.co.kr
Facsimile: 82-2-828-0086

Either Party may change its address by giving notice to the other Party in the manner provided above.

13.5 Entire Agreement. This Agreement (including Schedules) contains the complete understanding of the Parties with respect to the subject matter of this Agreement and supersedes all prior understandings and writings between the Parties relating to such subject matter.

13.6 Severability. If any provision of this Agreement is held unenforceable by a court or tribunal of competent jurisdiction because it is invalid or conflicts with any Law of any relevant jurisdiction, the validity of the remaining provisions shall not be affected. In such event, the Parties shall negotiate a substitute provision that, to the extent possible, accomplishes the original business purpose.

13.7 Assignment. Neither this Agreement nor any right or obligation hereunder may be assigned or otherwise transferred by any Party without the consent of the other Party; provided, however, that any Party may, without such consent, assign this Agreement, in whole or in part: (a) to any of its respective Affiliates,provided that such Affiliate has acknowledged and confirmed in writing that effective as of such assignment, such Affiliate shall be bound by this Agreement to the identical extent applicable to the assigning Party; or (b) to any successor in interest by way of merger, acquisition or sale of all or substantially all of its business or assets relating to the subject matter of this Agreement, provided that such successor (if the applicable Party is not the surviving entity in such transaction) agrees in writing to be bound by the terms of this Agreement to the identical extent applicable to the assigning Party. Any purported assignment in violation of this Section 13.7 shall be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement.

13.8 Counterparts; Exchange by Facsimile. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and that together shall constitute one and the same instrument. Such counterparts may be exchanged by facsimile or PDF (provided that each executed counterpart is transmitted in one complete transmission or electronic mail message). Where there is an exchange of executed counterparts by facsimile or PDF, each Party shall be bound by the Agreement notwithstanding that original copies of the Agreement may not be exchanged immediately. The Parties shall cooperate after execution of the Agreement and exchange by facsimile or PDF to ensure that each Party obtains an original executed copy of this Agreement with reasonable promptness.

13.9 Force Majeure. No Party shall be liable for failure of or delay in performing obligations set forth in this Agreement, and no Party shall be deemed in breach of its obligations, if such failure or delay is due to a pandemic, natural disaster, explosion, fire, flood, tornadoes, thunderstorms, earthquake, war, terrorism, riots, embargo, losses or shortages of power, labor stoppage, substance or material shortages, damage to or loss of product in transit not due to a failure by such Party or its Affiliates to exercise reasonable care, events caused by reason of Laws of any Governmental Authority, events caused by acts or omissions of a Third Party not induced or solicited by such Party or its Affiliates, or any other cause reasonably beyond the control of such Party or its Affiliates; provided that such Party uses Commercially Reasonable Efforts to overcome the difficulties created by such force majeure event and to resume performance of its obligations as soon as practicable.

13.10 Third Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party other than a Yuhan Party or a Processa Party, as applicable, that is an Indemnified Party under ARTICLE XI, and no Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against either Party.

13.11 Relationship of the Parties. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other, except as expressly provided in this Agreement. Neither Party shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said other Party's approval. For all purposes and notwithstanding any other provision of this Agreement to the contrary, the legal relationship under this Agreement of each Party to the other Party shall be that of independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint venturers between the Parties.

13.12 Performance by Affiliates. To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations.

13.13 No Consequential or Punitive Damages. NEITHER PARTY WILL BE LIABLE FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, OR PUNITIVE DAMAGES, INCLUDING LOST PROFITS, ARISING FROM OR RELATING TO THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTHING IN THIS SECTION 13.13 IS INTENDED TO LIMIT OR RESTRICT (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY UNDER THIS AGREEMENT WITH RESPECT TO THIRD PARTY CLAIMS, OR (B) DAMAGES TO WHICH A PARTY MAY BE ENTITLED FOR BREACH OF CONFIDENTIALITY AND LIMITATION ON USE OBLIGATIONS SET FORTH IN THIS AGREEMENT, OR (C) DAMAGES TO WHICH A PARTY MAY BE ENTITLED FOR THE WILLFUL MISCONDUCT, INTENTIONAL BREACH OR FRAUD OF THE OTHER PARTY.

*[Signature page follows]*

IN WITNESS WHEREOF, the Parties have signed this License Agreement as of the Effective Date.

**PROCESSA PHARMACEUTICALS, INC.**

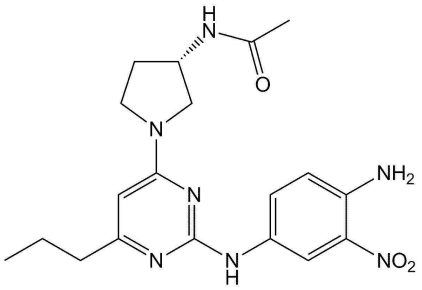
By: 
Name: David Young
Title: CEO

**YUHAN CORPORATION**

By: 
Name: Jung Hee Lee
Title: CEO and President

**Schedule 1.10**
**Compound**

(S)-N-(1-(2-((4-amino-3-nitrophenyl)amino)-6-propylpyrimidin-4-yl)pyrrolidin-3-yl)acetamide



Schedule 1.10-1

**Schedule 1.49**
**Form of Share Issuance Agreement**

**SHARE ISSUANCE AGREEMENT**

THIS SHARE ISSUANCE AGREEMENT (this "**Agreement**"), is made as of August 19, 2020, by and between Yuhan Corporation (the "**Yuhan**"), and Processa Pharmaceuticals, Inc., a Delaware corporation (the "**Company**").

WHEREAS, concurrently with the entering into of this Agreement, the Company and Yuhan are entering into that certain License Agreement (the "**License Agreement**");

WHEREAS, pursuant to the terms and subject to the conditions set forth in this Agreement and the License Agreement, the Company desires to issue to Yuhan, and Yuhan desires to acquire from the Company, at the Closing (as defined below) 250,000 shares (the "**Initial Shares**") of the Company's common stock ("**Common Stock**") as the Upfront Fee (as defined in the License Agreement);

WHEREAS, pursuant to the terms and subject to the conditions set forth in this Agreement and the License Agreement, the Company will issue to Yuhan, and Yuhan will acquire from the Company, the Milestone Shares (as defined below) and the Additional Shares (as defined below);

NOW, THEREFORE, in consideration of the foregoing recitals, the mutual representations, warranties, promises and obligations in the License Agreement and the following mutual representations, warranties, promises and obligations, and for other good and valuable consideration, the adequacy and sufficiency of which are hereby acknowledged, Yuhan and the Company agree as follows:

1. Definitions.

1.1 Defined Terms. When used in this Agreement, the following terms shall have the respective meanings specified therefor below:

"**Affiliate**" has the meaning set forth in the License Agreement.

"**Agreement**" means as set forth in the Preamble, including all exhibits, schedules and appendices attached hereto.

"**Beneficially Own**" or "**Beneficially Owned**", and words of similar import have the meaning assigned to such terms pursuant to Rule 13d-3 under the Exchange Act.

"**Business Day**" has the meaning set forth in the License Agreement.

"**Common Stock Equivalents**" means any options, warrants or other securities or rights convertible into or exercisable or exchangeable for, whether directly or following conversion into or exercise or exchange for other options, warrants or other securities or rights, shares of Common Stock.

"**Contract**" means, with respect to any Person, any written or oral contracts, agreements, deeds, mortgages, indentures, bonds, loans, leases, subleases, licenses, sublicense, statements of work, instruments, notes, commitments, commissions, undertakings, arrangements and understandings to which such Person is a party or by which any of its properties or assets are subject.

"**Development Milestone Payments**" has the meaning set forth in the License Agreement.

"**Disposition**" or "**Dispose of**" means (a) pledge, sale, contract to sell, sale of any option or Contract to purchase, purchase of any option or Contract to sell, grant of any option, right or warrant for the sale of, or other disposition of or transfer of any shares of Common Stock, or any Common Stock Equivalents, including, without limitation, any "short sale" or similar arrangement, or (b) swap, hedge, derivative instrument or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of shares of Common Stock, whether any such swap or transaction is to be settled by delivery of securities, in cash or otherwise.

"**Exchange Act**" means the Securities Exchange Act of 1934, as amended.

"**Governmental Authority**" has the meaning set forth in the License Agreement.

"**IPO Price**" means the price per share at which the Company sells its Common Stock in the Planned Public Offering to the public.

"**Last Round Purchase Price**" means the lowest price per share at which the Company sold its capital stock in any transaction(s) conducted with the principal purpose of raising capital that occurs after the date of this Agreement, pursuant to which the Company issues and sells shares of its capital stock for immediate cash proceeds. For avoidance of doubt, the Last Round Purchase Price shall not include shares issued pursuant to an equity compensation plan or in connection with a license or other transaction with a third party.

"**Law**" or "**Laws**" has the meaning set forth in the License Agreement.

"**Material Adverse Effect**" means a material adverse effect on the business, assets (including intangible assets), liabilities, financial condition, property or results of operations of the Company.

"**Material Contract**" means all Contracts that are required to be filed as exhibits by the Company with the SEC pursuant to Items 601(b)(4) and 601(b)(10) of Regulation S-K promulgated by the SEC.

"**Milestone Shares**" has the meaning set forth in the License Agreement.

"**Organizational Documents**" means (a) the Amended and Restated Certificate of Incorporation of the Company, as amended and restated from time to time and as in effect as of the date of this Agreement, and (b) the Bylaws of the Company as in effect as of the date of this Agreement.

"**Party**" means either Yuhan or Processa; "**Parties**" means both Yuhan and Processa.

"**Permitted Transferee**" means an Affiliate of Yuhan; provided, however, that no such Person shall be deemed a Permitted Transferee for any purpose under this Agreement unless: (a) the Permitted Transferee, prior to or simultaneously with any Disposition, shall have agreed in writing to be subject to and bound by all restrictions and obligations set forth in this Agreement as though it were Yuhan hereunder, and (b) Yuhan acknowledges that it continues to be bound by all restrictions and obligations set forth in this Agreement.

"**Person**" has the meaning set forth in the License Agreement.

"**Planned Public Offering**" has the meaning set forth in the License Agreement.

"**Prospectus**" means the prospectus (including any preliminary, final or summary prospectus) included in any Registration Statement, all amendments and supplements to such prospectus and all other material incorporated by reference in such prospectus.

"**Register**," "**Registered**" and "**Registration**" means a registration effected by preparing and filing (a) a Registration Statement in compliance with the Securities Act (and any post-effective amendments filed or required to be filed) and the declaration or ordering of effectiveness of such Registration Statement, or (b) a Prospectus and/or Prospectus supplement in respect of an appropriate effective Registration Statement.

"**Registrable Securities**" means the Shares; provided, that any Shares will cease to be Registrable Securities when such Shares (without regard to any other shares owned) (A) have been sold or otherwise Disposed of or (B) may be sold under Rule 144 without regard to volume restrictions.

"**Registration Statement**" means a registration statement of the Company that covers the resale of any Registrable Securities pursuant to the provisions of Appendix 1 filed with, or to be filed with, the SEC under the rules and regulations promulgated under the Securities Act, including the related Prospectus, amendments and supplements to each such registration statement or Prospectus, including pre- and post-effective amendments, all exhibits thereto, financial information and all other material incorporated by reference or deemed to be incorporated by reference in such registration statement.

"**Rule 144"** means Rule 144 under the Securities Act.

"**Second Adjustment Target Share Amount**" means a number of shares of Common Stock equal to the quotient of $2,000,000 divided by the lowest of (a) the VWAP Purchase Price, (b) the price per share at which Common Stock is sold in the Late Public Offering, and (c) the Last Round Purchase Price (if the Company executed a capital raising transaction in addition to the Late Public Offering), of the period after January 31, 2021 until the Late Public Offering.

"**Securities Act**" means the Securities Act of 1933, as amended.

"**Shares**" means the Initial Shares, the Additional Shares, and all Milestone Shares.

"**Shelf Registration Statement**" means a "shelf" registration statement of the Company that covers all Registrable Securities (when and if issued, but not prior to such issuance) on Form S-3 and under Rule 415 under the Securities Act or, if the Company is not then eligible to file on Form S-3, on another eligible form under the Securities Act, such as Form S-1, or any successor rule that may be adopted by the SEC, including without limitation any such registration statement filed pursuant to Appendix 1 and all amendments and supplements to such "shelf" registration statement, including, post-effective amendments, in each case, including the Prospectus contained therein, all exhibits thereto and any document incorporated by reference therein.

"**Subsidiary**" means any corporation, association trust, limited liability company, partnership, joint venture or other business association or entity (a) at least 50% of the outstanding voting securities of which are at the time owned or controlled directly or indirectly by the Company or (b) with respect to which the Company possesses, directly or indirectly, the power to direct or cause the direction of the affairs or management of such Person.

"**Target Share Amount**" means (i) if the Planned Public Offering has been consummated, a number of shares of Common Stock equal to the quotient of $2,000,000 divided by the IPO Price; provided, however, that the Target Share Amount shall be no less than 181,818 and (ii) if the Planned Public Offering has not been consummated, a number of shares of Common Stock equal to the quotient of $2,000,000 divided by the lowest of (a) the VWAP Purchase Price, (b) the Last Round Purchase Price as of January 31, 2021 (if the Company has executed a capital raising transaction), and (c) $8.00.

"**Tax**" or "**Taxes**" shall mean all federal, state, local, and foreign income, excise, gross receipts, gross income, ad valorem, profits, gains, property, capital, sales, transfer, use, payroll, employment, severance, withholding, duties, intangibles, franchise, backup withholding, value-added, and other taxes imposed by a Governmental Authority, together with all interest, penalties and additions to tax imposed with respect thereto.

"**Third Party**" means any Person other than Yuhan, the Company, or any Affiliate of Yuhan or the Company.

"**Trading Market**" means the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, the New York Stock Exchange or the NYSE MKT, or, prior to consummation of the Planned Public Offering, the OTCQB® Market.

"**Transactions**" means the issuance of the Shares by the Company, and the acquisition of the Shares by Yuhan, in accordance with the terms hereof, and any other transactions contemplated by this Agreement and the License Agreement.

"**Transaction Agreements**" means this Agreement and the License Agreement.

"**Underwriter**" means, with respect any Underwritten Offering, a securities dealer(s) who purchases any Registrable Securities as a principal in connection with a distribution of such Registrable Securities.

"**Underwritten Offering**" means a public offering of securities Registered under the Securities Act in which an Underwriter participates in the distribution of such securities, including on a firm commitment basis for reoffer and resale to the public, including any such offering that is a "bought deal" or a block trade.

"**VWAP Purchase Price**" means the volume-weighted average price of a share of Common Stock (weighted by the total daily trading volume for that day, as quoted on the electronic financial news service of Bloomberg L.P. or, if such quote is not then available, then on the electronic financial news service of Thomson Reuters) on the Trading Market over the most recent 45 days in which at least one share of Common Stock was traded.

2. Purchase and Sale of Common Stock. Subject to the terms and conditions of this Agreement and the License Agreement, at the Closing, the Company shall issue to Yuhan and Yuhan shall acquire from the Company the Initial Shares.

3. Closing Date; Deliveries.

3.1 Closing Date. The closing of the acquisition and issuance of the Initial Shares hereunder (the "**Closing**") shall be held by electronic exchange of signature pages on the date within ten (10) Business Days following the effective date of the License Agreement or at such other time and date as the Parties may mutually agree in writing. The date the Closing occurs is hereinafter referred to as the "**Closing Date**."

3.2 Deliveries. At the Closing, the Company shall deliver or cause to be delivered to Yuhan the Initial Shares in certificated form or maintained in restricted book-entry form at the Company's transfer agent (at Yuhan's cost). At any time Additional Shares or Milestone Shares are to be delivered pursuant to this Agreement, the Company shall deliver or cause to be delivered to Yuhan such Shares certificated form or maintained in restricted book-entry form at the Company's transfer agent (at Yuhan's cost).

4. Adjustments.

4.1 Forfeiture of Initial Shares. In the event the Company consummates the Planned Public Offering at an IPO Price greater than $8.00, a number of Initial Shares equal to 250,000 minus the Target Share Amount shall be automatically forfeited. In the event of such forfeiture, Yuhan agrees to work in good faith with the Company to take any actions reasonably necessary to effect and document such forfeiture.

4.2 Issuance of Additional Shares on or before January 31, 2021. In the event the Company consummates the Planned Public Offering at an IPO Price less than $8.00, or if the Company does not consummate the Planned Public Offering on or before January 31, 2021, the Company shall, for no additional consideration, immediately issue a number of shares of Common Stock to Yuhan equal to the Target Share Amount minus 250,000.

4.3 Issuance of Additional Shares after January 31, 2021. In the event the Company does not consummate the Planned Public Offering on or before January 31, 2021, but consummates a capital raise for the up-list to Nasdaq or the NYSE pursuant to the sale of shares pursuant to the Form S-1 registration statement (the "**Late Public Offering**") after January 31, 2021, the Company shall, for no additional consideration, immediately issue a number of shares of Common Stock to Yuhan equal to the Second Adjustment Target Share Amount minus the number of shares issued pursuant to Section 4.2 (if any) minus 250,000 (any shares of Common Stock issued pursuant to Section 4.2 or this Section 4.3, the "**Additional Shares**").

5 . Milestone Shares. The Company shall issue Milestone Shares to Yuhan on each date that a Development Milestone Payment is due pursuant to the License Agreement. If the Planned Public Offering has been consummated, the number of Milestone Shares shall be equal to the dollar amount set forth in the License Agreement applicable to the Development Milestone achieved divided by the VWAP Purchase Price as calculated on the date the Development Milestone Payment is due. If the Planned Public Offering has not been consummated, the number of Milestone Shares shall be equal to the dollar amount set forth in the License Agreement applicable to the Development Milestone achieved divided by the lesser of (i) the VWAP Purchase Price as calculated on the date the Development Milestone Payment is due and (ii) the Last Round Purchase Price (if applicable) as of the date the Development Milestone Payment is due.

6 . Representations and Warranties of the Company. The Company hereby represents and warrants to Yuhan that the following representations are true and complete as of the date hereof and as of the Closing, except as otherwise indicated herein or in a SEC Report (as defined below):

6 . 1 Organization. The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. The Company has all requisite corporate power and authority to enter into this Agreement, to issue the Shares and to perform its obligations under and to carry out the Transactions contemplated by this Agreement. The Company is duly qualified as a foreign corporation to transact business and is in good standing in each jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except whether the failure to so qualify or be in good standing would not, individually or in the aggregate, constitute a Material Adverse Effect. The Company is not in violation of, in conflict with, or in default under its Organizational Documents in any material respect. True and correct copies of the Organizational Documents, as in effect on the date of this Agreement, are attached as exhibits to the Company's SEC Reports.

6.2 Authorization.

(a) All requisite corporate action on the part of the Company required by applicable Law for the authorization, execution and delivery by the Company of this Agreement and the performance of all obligations of the Company hereunder and thereunder, including the authorization, issuance and delivery of the Shares, has been taken.

(b) This Agreement has been duly executed and delivered by the Company, and upon the due execution and delivery of this Agreement by Yuhan, it will constitute valid and legally binding obligations of the Company, enforceable against the Company in accordance with its terms, except as limited by: (i) applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance and other Laws of general application relating to or affecting enforcement of creditors' rights generally; and (ii) as limited by Laws relating to the availability of specific performance, injunctive relief or other equitable remedies (the exceptions set forth in (i) and (ii), the "**Enforceability Exceptions**").

(c) On or prior to the date hereof, the Board of Directors of the Company has duly adopted resolutions, among other things, authorizing and approving each of the Transaction Agreements and the Transactions.

6.3 No Conflicts. Except as set forth in a written notice provided by the Company to Yuhan prior to the execution of this Agreement and referencing this Section 6.3, the execution, delivery and performance of this Agreement, and compliance with the provisions hereof, and the issuance of the Shares by the Company do not and shall not: (a) subject to receipt of the Required Approvals, violate any provision of applicable Law or any ruling, writ, injunction, order, permit, judgment or decree of any Governmental Authority to which the Company is subject, (b) result in any encumbrance upon any of the Shares, other than restrictions on resale pursuant to securities laws or as set forth in this Agreement, (c) result in a default, modification, acceleration of payment or termination under, give any Person a right of termination or cancellation under, result in the loss of a benefit or imposition of any obligation under, any Material Contract, or (d) violate or conflict with any of the provisions of the Organizational Documents, except, in the case of subsections (a) and (c) as would not, individually or in the aggregate, constitute a Material Adverse Effect.

6.4 No Approval. No consent, approval, authorization or other order of, or filing with, or notice to, any Governmental Authority is required to be obtained or made by the Company or any of its Subsidiaries in connection with the authorization, execution and delivery by the Company of this Agreement or with the authorization, issuance and sale by the Company of the Shares, or the consummation of the Transactions, except (a) such filings as may be required to be made with the Securities and Exchange Commission (the "**SEC**") and with any state blue sky or securities regulatory authority, which filings shall be made in a timely manner in accordance with all applicable Laws; and (b) those that have been made or obtained prior to the date of this Agreement (the items referred to in clauses (a) and (b), the "**Required Approvals**").

6 . 5 Valid Issuance of Shares. When issued, sold and delivered in accordance with the terms hereof, the Shares will be duly authorized, validly issued, fully paid and nonassessable, free from any liens, encumbrances or restrictions on transfer, including preemptive rights, rights of first refusal, purchase option, call option, subscription right or other similar rights, other than as arising pursuant to this Agreement, as a result of any action by Yuhan or under federal or state securities Laws. Assuming the accuracy of the representations and warranties of Yuhan in this Agreement and subject to the Required Approvals, the Shares will be issued in compliance with all applicable federal and state securities Laws.

6.6 Company SEC Reports.

(a) The Company has filed or furnished, as applicable, all reports, schedules, forms, statements and other documents required to be filed or furnished by it with the SEC pursuant to the reporting requirements of the Exchange Act (all of the foregoing filed prior to the date of this Agreement and all exhibits included therein and financial statements and schedules thereto and documents (other than exhibits) incorporated by reference therein, collectively, the "**Company SEC Reports**"), each of which complied at the time of filing in all material respects with all applicable requirements of the Securities Act and the Exchange Act, as applicable, in each case as in effect on the dates such forms reports and documents were filed. As of its respective date, and if amended, as of the date of the last such amendment, no Company SEC Report, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. All Material Contracts to which the Company or any Subsidiary is a party, or to which the property or assets of the Company or any Subsidiary are subject, that are required to be included as part of or specifically identified in the Company SEC Reports, are so included or specifically identified. True and complete copies of the Company SEC Reports are available for public access via the SEC's EDGAR system (excluding schedules, exhibits and any redacted information).

(b) As of their respective dates, the consolidated financial statements included or incorporated in the Company SEC Reports (the "**Financial Statements**"), and the related notes, complied as to form in all material respects with applicable accounting requirements and the published rules and regulations of the SEC with respect thereto. The Financial Statements and the related notes have been prepared, in all material respects, in accordance with accounting principles generally accepted in the United States, consistently applied, during the periods involved (except (i) as may be otherwise indicated in the Financial Statements or the notes thereto, or (ii) in the case of unaudited interim statements, to the extent they may not include footnotes, may be condensed or summary statements or may conform to the SEC's rules and instructions for Quarterly Reports on Form 10-Q) and fairly present in all material respects the consolidated financial position and the results of the operations of the Company and its Subsidiaries, retained earnings (loss), and cash flows, as the case may be, for the periods then ended (subject, in the case of unaudited statements, to normal and recurring year-end audit adjustments).

(c) Except as noted in the SEC Reports, the Company has established and maintains disclosure controls and procedures (as defined in Rules 13a-15 and 15d-15 under the Exchange Act) that (i) are designed to ensure that material information relating to the Company, including each consolidated Subsidiary, is made known to the Company's principal executive officer and its principal financial officer by others within those entities, particularly during the periods in which the periodic reports required under the Exchange Act are being prepared; and (ii) have been evaluated by management of the Company for effectiveness as of the end of the Company's most recent fiscal quarter.

7. Representations and Warranties of Yuhan. Yuhan hereby represents and warrants to the Company as of the date hereof as follows:

7.1 Organization. Yuhan is a corporation duly organized, validly existing and in good standing under the laws of the Republic of Korea. Yuhan has all requisite power and authority to enter into this Agreement, to purchase the Shares and to perform its obligations under and to carry out the Transactions.

7.2 Authorization. All requisite corporate action on the part of Yuhan, required by applicable Law for the authorization, execution and delivery by Yuhan of this Agreement and the performance of all of its obligations hereunder, including the acquisition of the Shares, has been taken. This Agreement has been duly executed and delivered by Yuhan, and upon the due execution and delivery thereof by the Company, will constitute valid and legally binding obligations of Yuhan, enforceable against Yuhan in accordance with its terms, except as limited by the Enforceability Exceptions.

7.3 No Conflicts. The execution, delivery and performance of this Agreement and compliance with the provisions thereof, by Yuhan do not and shall not: (a) violate any provision of applicable Law or any ruling, writ, injunction, order, permit, judgment or decree of any Governmental Authority, or (b) violate or conflict with any of the provisions of Yuhan's organizational documents (including any articles or memoranda of organization or association, charter, by-laws or similar documents), except as would not materially impair or affect in a material adverse manner the ability of Yuhan to consummate the Transactions and perform its obligations under this Agreement.

7.4 No Approval. No consent, approval, authorization or other order of any Governmental Authority is required to be obtained by Yuhan in connection with the authorization, execution and delivery of any of this Agreement or with the subscription for and purchase of the Shares.

7.5 Acquisition Entirely for Own Account. The Shares shall be acquired for investment for Yuhan's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and as of the date hereof, Yuhan has no present intention of selling, granting any participation or otherwise distributing the Shares. Yuhan, either alone or together with its representatives, has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Shares, and has so evaluated the merits and risks of such investment. Yuhan is able to bear the economic risk of an investment in the Shares and, at the present time, is able to afford a complete loss of such investment.

7.6 Purchaser Status. Yuhan is as of the date hereof, and as of the date any Shares are issued under this Agreement will be, an "accredited investor" as defined in Rule 501 under the Securities Act.

7.7 Access to Information. Yuhan acknowledges that it has had the opportunity to review the Transaction Agreements and the SEC Reports and has been afforded, (i) the opportunity to ask such questions as it has deemed necessary of, and to receive answers from, representatives of the Company concerning the terms and conditions of the offering of the Shares and the merits and risks of investing in the Shares; (ii) access to information about the Company and its financial condition, results of operations, business, properties, management and prospects sufficient to enable it to evaluate its investment; and (iii) the opportunity to obtain such additional information that the Company possesses or can acquire without unreasonable effort or expense that is necessary to make an informed investment decision with respect to the investment.

7.8 Restricted Securities. Yuhan understands that the Shares, when issued, will be "restricted securities" under the federal securities Laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such Laws the Shares may be resold without registration under the Securities Act only in certain limited circumstances. Yuhan represents that it is familiar with Rule 144.

7.9 Legends. In addition to any other legend required by Law, the book-entry or certificated form of the Shares shall bear any legend required by the "blue sky" laws of any state and a restrictive legend in substantially the following form:

**THESE SECURITIES HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED. THEY MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED OR HYPOTHECATED IN THE ABSENCE OF A REGISTRATION STATEMENT IN EFFECT WITH RESPECT TO THE SECURITIES UNDER SUCH ACT OR AN OPINION OF COUNSEL SATISFACTORY TO THE ISSUER THAT SUCH REGISTRATION IS NOT REQUIRED OR UNLESS SOLD PURSUANT TO RULE 144 OF SUCH ACT.**

7.10 Acquiring Person. As of the date of this Agreement and immediately prior to the Closing, neither Yuhan nor any of its controlled Affiliates (excluding directors and officers of Yuhan who may hold securities of the Company for their personal account) Beneficially Owns, or will Beneficially Own any securities of the Company.

7.11 No General Solicitation. Yuhan is not acquiring the Shares as a result of (a) any advertisement, article, notice or other communication published in any newspaper, magazine or similar media or broadcast over television, radio or the Internet, in each case, relating to the Company, or (ii) any seminar or meeting whose attendees, including Yuhan, have been invited by any general solicitation or general advertising related to the Company.

8. Covenants.

8.1 Commercially Reasonable Best Efforts. Subject to the terms and conditions set forth in this Agreement, each Party hereto shall use its commercially reasonable best efforts to do or cause to be done all things necessary or appropriate to satisfy the conditions to the Closing and to consummate the Transactions as promptly as practicable. Without limiting the generality of the foregoing, unless the License Agreement is earlier terminated by either Party in accordance with its terms, the Company and Yuhan shall use their respective commercially reasonable best efforts to cause the Closing to occur. Each of the Company and Yuhan shall not, and shall not permit any of their respective Affiliates to, take any action that would, or that would reasonably be expected to, result in any of the conditions set forth in Section 9 or Section 10 not being satisfied.

8.2 Registration Rights. The Company hereby provides Yuhan with the registration rights set forth on Appendix 1 attached hereto, which is hereby incorporated in and made a part of this Agreement as if set forth in full herein.

8.3 Participation Rights. The Company shall, in connection with the Planned Public Offering, reserve and offer (and cause the Underwriters to reserve and offer) to Yuhan or an Affiliate designated by Yuhan, at least a number of shares of Common Stock having a value at the IPO Price of at least $3,000,000.

8.4 Facilitation of Sales Pursuant to Rule 144. For as long as Yuhan or its Affiliates Beneficially Owns any Shares, to the extent it shall be required to do so under the Exchange Act, the Company shall use commercially reasonable efforts to timely file the reports required to be filed by it under the Exchange Act or the Securities Act (including the reports under Sections 13 and 15(d) of the Exchange Act referred to in subparagraph (c)(1) of Rule 144), and shall use commercially reasonable efforts to take such further necessary action as Yuhan may reasonably request in connection with the removal of any restrictive legend on the Shares being sold at Yuhan's cost, all to the extent required from time to time to enable such holder to sell the Shares without registration under the Securities Act within the limitations of the exemption provided by Rule 144. Notwithstanding the foregoing, the Company shall not have any obligations pursuant to this section during any time when a Registration Statement covering the Shares is effective.

9. Conditions to the Company's Obligations. The obligations of the Company under Section 2 hereof are subject to the fulfillment prior to or on the Closing Date (and with respect to Section 9.1, as of each date the Company is required to issue Shares to Yuhan under this Agreement) of all of the following conditions, any of which may be waived in whole or in part by the Company.

9.1 Representations and Warranties. The representations and warranties of Yuhan contained in this Agreement and in any certificate, if any, or other writing, if any, delivered by Yuhan pursuant hereto shall be true and correct in all material respects on and as of the Closing Date, and as of each date the Company is required to issue Shares under this Agreement, except those representations and warranties qualified by materiality or Material Adverse Effect, which representations and warranties shall be true and correct in all respects, with the same effect as though such representations and warranties had been made on and as of the Closing Date or a Share issuance date, as applicable (except to the extent expressly made as of an earlier date, in which case as of such earlier date).

9.2 Performance. Yuhan shall have performed and complied in all material respects with all agreements, obligations and conditions contained in this Agreement that are required to be performed or complied with it on or before the Closing.

9.3 License Agreement. Each of the Company and Yuhan shall have executed and delivered the License Agreement, and the License Agreement shall not have been terminated and shall be effective in accordance with its terms.

10. Conditions to Yuhan's Obligations. The obligations of Yuhan under Section 2 hereof are subject to the fulfillment prior to or on the Closing Date of all of the following conditions, any of which may be waived in whole or in part by Yuhan.

10.1 Representations and Warranties. The representations and warranties of the Company contained in this Agreement and in any certificate, if any, or other writing, if any, delivered by the Company pursuant hereto shall be true and correct in all material respects on and as of the Closing Date, except those representations and warranties qualified by materiality or Material Adverse Effect, which representations and warranties shall be true and correct in all respects, with the same effect as though such representations and warranties had been made on and as of the Closing Date (except to the extent expressly made as of an earlier date, in which case as of such earlier date).

10.2 Performance. The Company shall have performed and complied in all material respects with all agreements, obligations and conditions contained in this Agreement that are required to be performed or complied with it on or before the Closing.

10.3 License Agreement. Each of the Company and Yuhan shall have executed and delivered the License Agreement, and the License Agreement shall not have been terminated and shall be effective in accordance with its terms.

10.4 No Stockholder Approval Required. No approval on the part of the stockholders of the Company shall be required in connection with the execution and delivery by the Company of this Agreement and the consummation of the Transactions.

10.5 Qualification Under State Securities Laws. All registrations, qualifications, permits and approvals, if any, required to be obtained prior to the Closing under applicable state securities laws shall have been obtained for the lawful execution, delivery and performance of this Agreement or the other Transaction Agreements, including, without limitation, the offer and sale of the Shares.

10.6 Absence of Litigation. No proceeding challenging the Transaction Agreements or the Transactions, or seeking to prohibit, alter, prevent or materially delay the Closing, shall have been instituted by any Governmental Authority.

11. Survival. The representations and warranties contained in this Agreement shall survive the Closing of the Transactions until the date that is two years following the date of this Agreement. The covenants and agreements contained in this Agreement shall survive Closing of the Transactions. The rights and remedies that may be exercised by Yuhan shall not be limited or otherwise affected by or as a result of any information furnished to, or any investigation made by or knowledge of, Yuhan or its representatives.

12. Miscellaneous.

12.1 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and interpreted in accordance with the laws of the state of New York, without regard to its conflicts of laws rules. Each Party (a) irrevocably submits to the exclusive jurisdiction in the state court sitting in New York (collectively, the "Courts"), for purposes of any action, suit or other proceeding arising out of this Agreement, and (b) agrees not to raise any objection at any time to the laying or maintaining of the venue of any such action, suit or proceeding in any of the Courts, irrevocably waives any claim that such action, suit or other proceeding has been brought in an inconvenient forum and further irrevocably waives the right to object, with respect to such action, suit or other proceeding, that such Court does not have any jurisdiction over such Party. Either Party may serve any process required by such Courts by way of notice under this Agreement. Notwithstanding anything to the contrary in this Section 12.1, each Party shall have the right to institute judicial proceedings against the other Party or anyone acting by, through, or under such other Party, in any court of competent jurisdiction, in order to enforce the instituting Party's rights hereunder through reformation of contract, specific performance, injunction, or similar equitable relief.

12.2 No Waiver, Modifications. It is agreed that no waiver by a Party hereto of any breach or default of any of the covenants or agreements set forth herein shall be deemed a waiver as to any subsequent or similar breach or default. The failure of either Party to insist on the performance of any obligation hereunder shall not be deemed a waiver of any such obligation. No amendment, modification, waiver, release or discharge to this Agreement shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

12.3 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address specified in this Section 12.3 and shall be: (a) delivered personally; (b) sent by registered or certified mail, return receipt requested, postage prepaid; (c) sent via a reputable nationwide overnight courier service; or (d) sent by facsimile or other electronic transmission. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service, or when transmitted with confirmation of receipt, if transmitted by facsimile or other electronic transmission (if such transmission is on a Business Day; otherwise, on the next Business Day following such transmission).

Notices to the Company shall be addressed to:

Processa Pharmaceuticals, Inc.
7380 Coca Cola Drive, Suite 106
Hanover, MD 21076
Attn: Wendy Guy, Chief Administrative Officer
Email: wguy@processapharmaceuticals.com

Notices to Yuhan shall be addressed to:

Yuhan Corporation
74, Noryangjin-ro, Dongjak-gu
Seoul, Republic of Korea, 06927
Attention: Taejin Yoon, Head of Global Business Development
Email: tyoon@yuhan.co.kr
Facsimile: 82-2-828-0086

Yuhan Corporation
74, Noryangjin-ro, Dongjak-gu
Seoul, Republic of Korea, 06927
Attention: Ryan Ryou, Global Operations
Email: ryan@yuhan.co.kr
Facsimile: 82-2-828-0086

Either Party may change its address by giving notice to the other Party in the manner provided above.

12.4 Entire Agreement. This Agreement (including all exhibits, schedules and annexes attached hereto) and the License Agreement contain the entire agreement among the Parties with respect to the subject matter hereof and thereof and supersede all prior and contemporaneous arrangements or understandings, whether written or oral, with respect hereto and thereto.

12.5 Headings; Nouns and Pronouns; Section References. Headings in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement. Whenever the context may require, any pronouns used herein shall include the corresponding masculine, feminine or neuter forms, and the singular form of names and pronouns shall include the plural and vice-versa. References in this Agreement to a section or subsection shall be deemed to refer to a section or subsection of this Agreement unless otherwise expressly stated.

12.6 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future Law, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid or unenforceable provision, the Parties shall negotiate in good faith a substitute legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as possible and as reasonably acceptable to the Parties.

12.7 Assignment. Except for an assignment by Yuhan of this Agreement or any rights hereunder to an Affiliate or Permitted Transferee (which assignment will not relieve Yuhan of any obligation hereunder), neither this Agreement nor any of the rights or obligations hereunder may be assigned by either Yuhan or the Company without (a) the prior written consent of Company in the case of any assignment by Yuhan or (b) the prior written consent of Yuhan in the case of an assignment by the Company.

12.8 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.

12.9 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument. In the event that any signature is delivered by facsimile transmission or by an e-mail which contains a portable document format (.pdf) file of an executed signature page, such executed signature page shall create a valid and binding obligation of the Party executing it (or on whose behalf such signature page is executed) with the same force and effect as if such executed signature page were an original thereof.

12.10 Third Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any Party hereto, except that each Affiliate of Yuhan is an express third party beneficiary entitled to enforce this Agreement directly against the Company. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any Party hereto.

12.11 No Strict Construction. This Agreement has been prepared jointly and will not be construed against either Party. No presumption as to construction of this Agreement shall apply against either Party with respect to any ambiguity in the wording of any provision(s) of this Agreement irrespective of which Party may be deemed to have authored the ambiguous provision(s).

12.12 Remedies. The rights, powers and remedies of the Parties under this Agreement are cumulative and not exclusive of any other right, power or remedy which such Parties may have under any other Contract or Law. No single or partial assertion or exercise of any right, power or remedy of a Party hereunder shall preclude any other or further assertion or exercise thereof. The Parties hereby acknowledge and agree that the rights of the Parties hereunder are special, unique and of extraordinary character, and that if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, such refusal or failure would result in irreparable injury to the Company or Yuhan as the case may be, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation. Accordingly, if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, then, in addition to any other remedy which may be available to any damaged Party at law or in equity, such damaged Party will be entitled to seek specific performance and injunctive relief, without posting bond or other security, and without the necessity of proving actual or threatened damages, which remedy such damaged Party will be entitled to seek in any court of competent jurisdiction.

12.13 Expenses. Each Party shall pay its own fees and expenses in connection with the preparation, negotiation, execution, delivery and performance of the Transaction Agreements.

12.14 WAIVER OF JURY TRIAL. IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY ANY PARTY AGAINST ANY OTHER PARTY, THE PARTIES EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVES FOREVER TRIAL BY JURY.

12.15 Equitable Adjustments. The number of Shares issuable pursuant to this Agreement shall be adjusted equitably in the event of any stock split, dividend, corporate reorganization or similar transaction.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the Parties have executed and delivered this Agreement as of the date first above written.

**Processa Pharmaceuticals, Inc.**

By: _____
Name: David Young
Title: CEO

**Yuhan Corporation**

By: _____
Name: Jung Hee Lee
Title: CEO and President

**Appendix 1**

**Registration Rights**

1. Resale Registration.

1.1 At any time following the date that is 180 days after the Planned Public Offering, upon Yuhan's written request following the issuance of the Initial Shares, the Additional Shares, or the Milestone Shares, as applicable, the Company will file a Shelf Registration Statement registering for resale the Registrable Securities under the Securities Act. The Company shall use its commercially reasonable efforts to cause such Shelf Registration Statement to become effective as promptly as practicable after filing. Until the earlier of such time as (i) all Registrable Securities included in such Shelf Registration Statement cease to be Registrable Securities or (ii) the Company is no longer eligible to maintain a Shelf Registration Statement, the Company will keep current and effective such Shelf Registration Statement and file such supplements or amendments to such Shelf Registration Statement (or file a new Shelf Registration Statement when such preceding Shelf Registration Statement expires pursuant to the rules of the SEC) as may be necessary or appropriate in order to keep such Shelf Registration Statement continuously effective and useable for the resale of Registrable Securities under the Securities Act. For avoidance of doubt, this requirement to register the shares shall not require the Company to file a registration statement for Yuhan to sell its share in an underwritten offering.

1.2 If the filing, initial effectiveness or continued use of the Shelf Registration Statement at any time would require the Company to make a public disclosure of material non-public information that the Company has a bona fide business purpose for not disclosing publicly at such time, the Company may, upon giving prompt written notice of such action to Yuhan, delay the filing or initial effectiveness of, or suspend use of, the Shelf Registration Statement (a "**Suspension**"); provided, however, that the Company shall not be permitted to exercise a Suspension more than once during any twelve (12) month period for a period not to exceed sixty (60) days. In the case of a Suspension, Yuhan agrees to suspend use of the applicable Prospectus in connection with any sale or purchase, or offer to sell or purchase, Shares, upon receipt of the notice referred to above. The Company shall immediately notify Yuhan in writing upon the termination of any Suspension, amend or supplement the Prospectus, if necessary, so it does not contain any untrue statement or omission and furnish to Yuhan such numbers of copies of the Prospectus as so amended or supplemented as Yuhan may reasonably request. The Company shall, if necessary, supplement or amend the Shelf Registration Statement, if required by law or as may reasonably be requested by Yuhan.

2. Information. The Company may require Yuhan to furnish to the Company such information regarding the distribution of the Shares and such other information relating to Yuhan and its ownership of Shares as the Company may from time to time reasonably request in writing to the extent that such information is required to be included in the Shelf Registration Statement.

3 . Expenses. All expenses incident to the registration of the Shares shall be paid by the Company, including (a) all registration and filing fees, and any other fees and expenses associated with filings required to be made with the SEC or Financial Industry Regulatory Authority, (b) all fees and expenses in connection with compliance with any securities or "Blue Sky" laws, (c) all fees and disbursements of counsel for the Company and of all independent certified public accountants or independent auditors of the Company and any of its Subsidiaries (including the expenses of any special audit and comfort letters required by or incident to such performance), (d) Securities Act liability insurance or similar insurance if the Company so desires, (e) all fees and expenses incurred in connection with the listing of the Shares on any securities exchange or quotation of the Shares on any inter-dealer quotation system, (f) all fees and expenses of any special experts or other Persons retained by the Company in connection with any registration, and (g) all of the Company's internal expenses (including all salaries and expenses of its officers and employees performing legal or accounting duties). For the avoidance of doubt, the Company shall not be required to register the Shares for an underwritten public offering by Yuhan and will not be responsible for any underwriting discounts and commissions and transfer Taxes, if any, attributable to the sale of the Shares.

4. Notice. The Company shall notify Yuhan immediately upon (a) any request by the SEC or any other Federal or state Governmental Authority for amendments or supplements to a Shelf Registration Statement or for additional information that pertains to Yuhan as a selling stockholder; (b) the issuance by the SEC of any stop order suspending the effectiveness of the Shelf Registration Statement or any order by the SEC or any other regulatory authority preventing or suspending the use of any Prospectus or the initiation or threatening of any proceedings for such purposes, (c) receipt by the Company of any notification with respect to the suspension of the qualification of the Shares for offering or sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose, or (d) the Company becoming aware that the Shelf Registration Statement or the related Prospectus contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements therein (in the case of such Prospectus, in light of the circumstances under which they were made) not misleading.

5. Indemnification.

5.1 To the extent permitted by Law, the Company will indemnify and hold harmless Yuhan, its officers, directors, agents, partners, members, stockholders and employees, as applicable, and each Person who controls Yuhan (within the meaning of the Securities Act or the Exchange Act), and the officers, directors, agents, partners, members, stockholders and employees of each such controlling Person, from and against any and all losses, claims, liabilities, damages, deficiencies, assessments, fines, judgments, fees, costs (including, without limitation, reasonable costs of preparation and reasonable attorneys' fees) and expenses (collectively "**Losses**") (joint or several), as incurred, to which they may become subject under the Securities Act, the Exchange Act or other federal or state law, insofar as such Losses (or actions in respect thereof) arise out of, relate to, or are based upon any of the following statements, omissions or violations (collectively a "**Violation**") by the Company: (a) any untrue statement or alleged untrue statement of a material fact contained in the Shelf Registration Statement or incorporated by reference therein, including any Prospectus contained therein or any amendments or supplements thereto, (b) the omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading, or (c) any violation or alleged violation by the Company of the Securities Act, the Exchange Act, any state securities Law, or any rule or regulation promulgated under the Securities Act, the Exchange Act or any state securities Law in connection with the Shelf Registration Statement; and the Company will reimburse each such indemnified party for any legal or other expenses reasonably incurred by them in connection with investigating or defending any such Loss or action if it is judicially determined that there was such a Yuhan Violation; provided however, that the indemnity agreement contained in this Section 5.1 will not apply to amounts paid in settlement of any such Loss or action if such settlement is effected without the Company's consent, nor will the Company be liable in any such case for any such Loss to the extent that it arises out of or is based upon a Violation which occurs in reliance upon and in conformity with written information furnished by Yuhan and stated to be expressly for use in connection with the Shelf Registration Statement or an applicable Prospectus.

5.2 To the extent permitted by Law, Yuhan will indemnify and hold harmless the Company and each of its directors and its officers against any Losses (joint or several) to which the Company or any such director, officer, controlling Person, Underwriter or other Third Party who may become subject under the Securities Act, the Exchange Act or other federal or state law, insofar as such Losses (or actions in respect thereto) arise out of or are based upon any of the following statements: (a) any untrue statement or alleged untrue statement of a material fact contained in any Registration Statement or any other document incorporated reference therein, including any preliminary Prospectus or final Prospectus contained therein or any amendments or supplements thereto, or (b) the omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading (collectively, a "**Yuhan Violation**"), in each case to the extent (and only to the extent) that such Yuhan Violation occurs in reliance upon and in conformity with written information furnished by Yuhan under an instrument duly executed by Yuhan; and Yuhan will reimburse any legal or other expenses reasonably incurred by the Company or any such director, officer, controlling Person, Underwriter or other Third Party in connection with investigating or defending any such Loss or action if it is judicially determined that there was such a Yuhan Violation; provided, however, that the indemnity agreement contained in this Section 5.2 will not apply to amounts paid in settlement of any such Loss or action if such settlement is effected without Yuhan's consent; provided, further that the obligations of Yuhan hereunder shall be limited to an amount equal to the net proceeds it receives in such Registration.

5.3 Promptly after receipt by an indemnified party under this Section 5 of notice of the commencement of any action (including any governmental action), such indemnified party will, if a claim in respect thereof is to be made against any indemnifying party under this Section 5, deliver to the indemnifying party a written notice of the commencement thereof and the indemnifying party will have the right to participate in, and, to the extent the indemnifying party so desires, jointly with any other indemnifying party similarly noticed, to assume the defense thereof with counsel mutually satisfactory to the parties; provided, however, that an indemnified party will have the right to retain its own counsel, with the fees and expenses thereof to be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or potential differing interests between such indemnified party and any other party represented by such counsel in such proceeding. The failure to deliver written notice to the indemnifying party within a reasonable time of the commencement of any such action will relieve such indemnifying party of any liability to the indemnified party under this Section 5 to the extent, and only to the extent, prejudicial to its ability to defend such action, but the omission so to deliver written notice to the indemnifying party will not relieve it of any liability that it may have to any indemnified party otherwise than under this Section 5.

5.4 If the indemnification provided for in this Section 5 is held by a court of competent jurisdiction to be unavailable to an indemnified party with respect to any Losses referred to herein, the indemnifying party, in lieu of indemnifying such indemnified party thereunder, will to the extent permitted by applicable Law contribute to the amount paid or payable by such indemnified party as a result of such Loss in such proportion as is appropriate to reflect the relative fault of the indemnifying party, on the one hand, and of the indemnified party, on the other, in connection with the Violation(s) or Yuhan Violation(s), as applicable, that resulted in such Loss, as well as any other relevant equitable considerations. The relative fault of the indemnifying party and of the indemnified party will be determined by a court of law by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission to state a material fact relates to information supplied by the indemnifying party or by the indemnified party and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission; provided, however, that the obligations of Yuhan hereunder shall be limited to an amount equal to the net proceeds it receives in such Registration; and provided, further, that no Person guilty of fraudulent misrepresentation within the meaning of Section 11(f) of the Securities Act, shall be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation.

5.5 The obligations of the Company and Yuhan under this Section 5 will survive termination of this Agreement and the expiration or withdrawal of the Shelf Registration Statement. No indemnifying party, in the defense of any such claim or litigation, will, except with the consent of each indemnified party, consent to entry of any judgment or enter into any settlement which does not include as an unconditional term thereof the giving by the claimant or plaintiff to such indemnified party of a release from all liability in respect to such claim or litigation.

**Schedule 1.57**
**Yuhan Patent Rights**

Current as of August 12, 2020

| Patent | Description | Country | Application No. (Date) | Registration No. (Date) | Status |
|---|---|---|---|---|---|
| Compound | Diaminopyrimidine derivatives and processes for the preparation thereof | KR | 10-2012-0018933 (2012-02-24) | 10-1671348 (2016-10-26) | Granted |
| | | PCT | PCT/KR2012/001427 (2012-02-24) | WO2012-115480 (2012-08-30) | - |
| | | US | 14/001,489 (2012-02-24) | 9,890,138 (2018-02-13) | Granted |
| | | US(Div) | 15/848,760 (2012-02-24) | 10,227,330 (2019-03-12) | Granted |
| | | EP | 12750114.6 (2012-02-24) | 2678332 (2016-05-18) | Granted |
| | | JP | 2013-555369 (2012-02-24) | 5890436 (2016-02-26) | Granted |
| | | CN | 201280010406.7 (2012-02-24) | 103402997 (2015-08-26) | Granted |
| | | HK | 14101293.6 (2012-02-24) | 1188215 (2016-02-26) | Granted |
| | | AU | 2012221927 (2012-02-24) | 2012221927 (2016-08-11) | Granted |
| | | CA | 2,827,030 (2012-02-24) | 2,827,030 (2019-01-08) | Granted |
| | | BR | 11 2013 020641 1 (2012-02-24) | | Pending |
| | | MX | 13/09549 (2012-02-24) | 337477 (2016-03-07) | Granted |

| | | | | | |
|---|---|---|---|---|---|
| | | IN | 1520/MUMNP/2013<br>(2012-02-24) | | Pending |
| | | RU | 2013142187<br>(2012-02-24) | 2587493<br>(2016-05-25) | Granted |
| | | KR | 10-2012-0018926<br>(2012-02-24) | 10-1671341<br>(2016-10-26) | Granted |
| | | PCT | PCT/KR2012/001423<br>(2012-02-24) | WO2012-115478<br>(2012-08-30) | - |
| | | US | 14/001,475<br>(2012-02-24) | 9,850,227<br>(2017-12-26) | Granted |
| | | US(Div) | 15/813,741<br>(2012-02-24) | 10,640,490<br>(2020-05-05) | Granted |
| | | EP | 12749916.8<br>(2012-02-24) | 2678331<br>(2016-04-27) | Granted |
| | | JP | 2013-555368<br>(2012-02-24) | 5980236<br>(2016-08-05) | Granted |
| Compound (backup1) | Diaminopyrimidine derivatives and processes for the preparation thereof | CN | 201280010354.3<br>(2012-02-24) | 103391935<br>(2015-12-23) | Granted |
| | | HK | 14101278.5<br>(2012-02-24) | 1188214<br>(2016-11-18) | Granted |
| | | AU | 2012221925<br>(2012-02-24) | 2012221925<br>(2016-08-18) | Granted |
| | | CA | 2,827,072<br>(2012-02-24) | 2,827,072<br>(2019-01-08) | Granted |
| | | BR | 11 2013 019942 3<br>(2012-02-24) | | Pending |
| | | MX | 13/09627<br>(2012-02-24) | 336155<br>(2016-01-07) | Granted |
| | | IN | 1519/MUMNP/2013<br>(2012-02-24) | 329365<br>(2020-01-14) | Granted |
| | | RU | 2013142188<br>(2012-02-24) | 2587981<br>(2016-06-02) | Granted |

| | | | | | |
|---|---|---|---|---|---|
| Compound (backup2) | Diaminopyrimidine derivatives and processes for the preparation thereof | KR | 10-2011-0016986 (2011-02-25) | 10-1682417 (2016-11-29) | Granted |
| | | PCT | PCT/KR2012/001425 (2012-02-24) | WO2012-115479 (2012-08-30) | - |
| Compound (backup3) | Bicyclic derivatives containing pyrimidine ring and processes for the preparation thereof | KR | 10-2013-0058843 (2013-05-24) | 10-1657616 (2016-09-08) | Granted |
| | | PCT | PCT/KR2014/004636 (2014-05-23) | WO2014-189331 (2014-11-27) | - |
| Process | Novel processes for preparing a diaminopyrimidine derivative or acid addition salt thereof | KR | 10-2018-0057088 (2018-05-18) | | Pending |
| | | PCT | PCT/KR2019/005859 (2019-05-16) | WO2019-221522 (2019-11-21) | - |
| Formulation | Pharmaceutical compositions comprising a diaminopyrimidine derivative or pharmaceutically acceptable salt thereof and processes for preparing the same | KR | 10-2020-0084595 (2020-07-09) | | Pending |

**Exhibit 10.12**

***Execution Copy***

**SHARE ISSUANCE AGREEMENT**

THIS SHARE ISSUANCE AGREEMENT (this "**Agreement**"), is made as of August 19, 2020, by and between Yuhan Corporation (the "**Yuhan**"), and Processa Pharmaceuticals, Inc., a Delaware corporation (the "**Company**").

WHEREAS, concurrently with the entering into of this Agreement, the Company and Yuhan are entering into that certain License Agreement (the "**License Agreement**");

WHEREAS, pursuant to the terms and subject to the conditions set forth in this Agreement and the License Agreement, the Company desires to issue to Yuhan, and Yuhan desires to acquire from the Company, at the Closing (as defined below) 250,000 shares (the "**Initial Shares**") of the Company's common stock ("**Common Stock**") as the Upfront Fee (as defined in the License Agreement);

WHEREAS, pursuant to the terms and subject to the conditions set forth in this Agreement and the License Agreement, the Company will issue to Yuhan, and Yuhan will acquire from the Company, the Milestone Shares (as defined below) and the Additional Shares (as defined below);

NOW, THEREFORE, in consideration of the foregoing recitals, the mutual representations, warranties, promises and obligations in the License Agreement and the following mutual representations, warranties, promises and obligations, and for other good and valuable consideration, the adequacy and sufficiency of which are hereby acknowledged, Yuhan and the Company agree as follows:

1. Definitions.

1.1 Defined Terms. When used in this Agreement, the following terms shall have the respective meanings specified therefor below:

"**Affiliate**" has the meaning set forth in the License Agreement.

"**Agreement**" means as set forth in the Preamble, including all exhibits, schedules and appendices attached hereto.

"**Beneficially Own**" or "**Beneficially Owned**", and words of similar import have the meaning assigned to such terms pursuant to Rule 13d-3 under the Exchange Act.

"**Business Day**" has the meaning set forth in the License Agreement.

"**Common Stock Equivalents**" means any options, warrants or other securities or rights convertible into or exercisable or exchangeable for, whether directly or following conversion into or exercise or exchange for other options, warrants or other securities or rights, shares of Common Stock.

"**Contract**" means, with respect to any Person, any written or oral contracts, agreements, deeds, mortgages, indentures, bonds, loans, leases, subleases, licenses, sublicense, statements of work, instruments, notes, commitments, commissions, undertakings, arrangements and understandings to which such Person is a party or by which any of its properties or assets are subject.

"**Development Milestone Payments**" has the meaning set forth in the License Agreement.

"**Disposition**" or "**Dispose of**" means (a) pledge, sale, contract to sell, sale of any option or Contract to purchase, purchase of any option or Contract to sell, grant of any option, right or warrant for the sale of, or other disposition of or transfer of any shares of Common Stock, or any Common Stock Equivalents, including, without limitation, any "short sale" or similar arrangement, or (b) swap, hedge, derivative instrument or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of shares of Common Stock, whether any such swap or transaction is to be settled by delivery of securities, in cash or otherwise.

"**Exchange Act**" means the Securities Exchange Act of 1934, as amended.

"**Governmental Authority**" has the meaning set forth in the License Agreement.

"**IPO Price**" means the price per share at which the Company sells its Common Stock in the Planned Public Offering to the public.

"**Last Round Purchase Price**" means the lowest price per share at which the Company sold its capital stock in any transaction(s) conducted with the principal purpose of raising capital that occurs after the date of this Agreement, pursuant to which the Company issues and sells shares of its capital stock for immediate cash proceeds. For avoidance of doubt, the Last Round Purchase Price shall not include shares issued pursuant to an equity compensation plan or in connection with a license or other transaction with a third party.

"**Law**" or "**Laws**" has the meaning set forth in the License Agreement.

"**Material Adverse Effect**" means a material adverse effect on the business, assets (including intangible assets), liabilities, financial condition, property or results of operations of the Company.

"**Material Contract**" means all Contracts that are required to be filed as exhibits by the Company with the SEC pursuant to Items 601(b)(4) and 601(b)(10) of Regulation S-K promulgated by the SEC.

"**Milestone Shares**" has the meaning set forth in the License Agreement.

"**Organizational Documents**" means (a) the Amended and Restated Certificate of Incorporation of the Company, as amended and restated from time to time and as in effect as of the date of this Agreement, and (b) the Bylaws of the Company as in effect as of the date of this Agreement.

"**Party**" means either Yuhan or Processa; "**Parties**" means both Yuhan and Processa.

"**Permitted Transferee**" means an Affiliate of Yuhan; provided, however, that no such Person shall be deemed a Permitted Transferee for any purpose under this Agreement unless: (a) the Permitted Transferee, prior to or simultaneously with any Disposition, shall have agreed in writing to be subject to and bound by all restrictions and obligations set forth in this Agreement as though it were Yuhan hereunder, and (b) Yuhan acknowledges that it continues to be bound by all restrictions and obligations set forth in this Agreement.

"**Person**" has the meaning set forth in the License Agreement.

"**Planned Public Offering**" has the meaning set forth in the License Agreement.

"**Prospectus**" means the prospectus (including any preliminary, final or summary prospectus) included in any Registration Statement, all amendments and supplements to such prospectus and all other material incorporated by reference in such prospectus.

"**Register**," "**Registered**" and "**Registration**" means a registration effected by preparing and filing (a) a Registration Statement in compliance with the Securities Act (and any post-effective amendments filed or required to be filed) and the declaration or ordering of effectiveness of such Registration Statement, or (b) a Prospectus and/or Prospectus supplement in respect of an appropriate effective Registration Statement.

"**Registrable Securities**" means the Shares; provided, that any Shares will cease to be Registrable Securities when such Shares (without regard to any other shares owned) (A) have been sold or otherwise Disposed of or (B) may be sold under Rule 144 without regard to volume restrictions.

"**Registration Statement**" means a registration statement of the Company that covers the resale of any Registrable Securities pursuant to the provisions of Appendix 1 filed with, or to be filed with, the SEC under the rules and regulations promulgated under the Securities Act, including the related Prospectus, amendments and supplements to each such registration statement or Prospectus, including pre- and post-effective amendments, all exhibits thereto, financial information and all other material incorporated by reference or deemed to be incorporated by reference in such registration statement.

"**Rule 144"** means Rule 144 under the Securities Act.

"**Second Adjustment Target Share Amount**" means a number of shares of Common Stock equal to the quotient of $2,000,000 divided by the lowest of (a) the VWAP Purchase Price, (b) the price per share at which Common Stock is sold in the Late Public Offering, and (c) the Last Round Purchase Price (if the Company executed a capital raising transaction in addition to the Late Public Offering), of the period after January 31, 2021 until the Late Public Offering.

"**Securities Act**" means the Securities Act of 1933, as amended.

"**Shares**" means the Initial Shares, the Additional Shares, and all Milestone Shares.

"**Shelf Registration Statement**" means a "shelf" registration statement of the Company that covers all Registrable Securities (when and if issued, but not prior to such issuance) on Form S-3 and under Rule 415 under the Securities Act or, if the Company is not then eligible to file on Form S-3, on another eligible form under the Securities Act, such as Form S-1, or any successor rule that may be adopted by the SEC, including without limitation any such registration statement filed pursuant to Appendix 1 and all amendments and supplements to such "shelf" registration statement, including, post-effective amendments, in each case, including the Prospectus contained therein, all exhibits thereto and any document incorporated by reference therein.

"**Subsidiary**" means any corporation, association trust, limited liability company, partnership, joint venture or other business association or entity (a) at least 50% of the outstanding voting securities of which are at the time owned or controlled directly or indirectly by the Company or (b) with respect to which the Company possesses, directly or indirectly, the power to direct or cause the direction of the affairs or management of such Person.

"**Target Share Amount**" means (i) if the Planned Public Offering has been consummated, a number of shares of Common Stock equal to the quotient of $2,000,000 divided by the IPO Price; provided, however, that the Target Share Amount shall be no less than 181,818 and (ii) if the Planned Public Offering has not been consummated, a number of shares of Common Stock equal to the quotient of $2,000,000 divided by the lowest of (a) the VWAP Purchase Price, (b) the Last Round Purchase Price as of January 31, 2021 (if the Company has executed a capital raising transaction), and (c) $8.00.

"**Tax**" or "**Taxes**" shall mean all federal, state, local, and foreign income, excise, gross receipts, gross income, ad valorem, profits, gains, property, capital, sales, transfer, use, payroll, employment, severance, withholding, duties, intangibles, franchise, backup withholding, value-added, and other taxes imposed by a Governmental Authority, together with all interest, penalties and additions to tax imposed with respect thereto.

"**Third Party**" means any Person other than Yuhan, the Company, or any Affiliate of Yuhan or the Company.

"**Trading Market**" means the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, the New York Stock Exchange or the NYSE MKT, or, prior to consummation of the Planned Public Offering, the OTCQB® Market.

"**Transactions**" means the issuance of the Shares by the Company, and the acquisition of the Shares by Yuhan, in accordance with the terms hereof, and any other transactions contemplated by this Agreement and the License Agreement.

"**Transaction Agreements**" means this Agreement and the License Agreement.

"**Underwriter**" means, with respect any Underwritten Offering, a securities dealer(s) who purchases any Registrable Securities as a principal in connection with a distribution of such Registrable Securities.

"**Underwritten Offering**" means a public offering of securities Registered under the Securities Act in which an Underwriter participates in the distribution of such securities, including on a firm commitment basis for reoffer and resale to the public, including any such offering that is a "bought deal" or a block trade.

"**VWAP Purchase Price**" means the volume-weighted average price of a share of Common Stock (weighted by the total daily trading volume for that day, as quoted on the electronic financial news service of Bloomberg L.P. or, if such quote is not then available, then on the electronic financial news service of Thomson Reuters) on the Trading Market over the most recent 45 days in which at least one share of Common Stock was traded.

2. Purchase and Sale of Common Stock. Subject to the terms and conditions of this Agreement and the License Agreement, at the Closing, the Company shall issue to Yuhan and Yuhan shall acquire from the Company the Initial Shares.

3. Closing Date; Deliveries.

3.1 Closing Date. The closing of the acquisition and issuance of the Initial Shares hereunder (the "**Closing**") shall be held by electronic exchange of signature pages on the date within ten (10) Business Days following the effective date of the License Agreement or at such other time and date as the Parties may mutually agree in writing. The date the Closing occurs is hereinafter referred to as the "**Closing Date**."

3.2 Deliveries. At the Closing, the Company shall deliver or cause to be delivered to Yuhan the Initial Shares in certificated form or maintained in restricted book-entry form at the Company's transfer agent (at Yuhan's cost). At any time Additional Shares or Milestone Shares are to be delivered pursuant to this Agreement, the Company shall deliver or cause to be delivered to Yuhan such Shares certificated form or maintained in restricted book-entry form at the Company's transfer agent (at Yuhan's cost).

4. Adjustments.

4.1 Forfeiture of Initial Shares. In the event the Company consummates the Planned Public Offering at an IPO Price greater than $8.00, a number of Initial Shares equal to 250,000 minus the Target Share Amount shall be automatically forfeited. In the event of such forfeiture, Yuhan agrees to work in good faith with the Company to take any actions reasonably necessary to effect and document such forfeiture.

4.2 Issuance of Additional Shares on or before January 31, 2021. In the event the Company consummates the Planned Public Offering at an IPO Price less than $8.00, or if the Company does not consummate the Planned Public Offering on or before January 31, 2021, the Company shall, for no additional consideration, immediately issue a number of shares of Common Stock to Yuhan equal to the Target Share Amount minus 250,000.

4.3 Issuance of Additional Shares after January 31, 2021. In the event the Company does not consummate the Planned Public Offering on or before January 31, 2021, but consummates a capital raise for the up-list to Nasdaq or the NYSE pursuant to the sale of shares pursuant to the Form S-1 registration statement (the "**Late Public Offering**") after January 31, 2021, the Company shall, for no additional consideration, immediately issue a number of shares of Common Stock to Yuhan equal to the Second Adjustment Target Share Amount minus the number of shares issued pursuant to Section 4.2 (if any) minus 250,000 (any shares of Common Stock issued pursuant to Section 4.2 or this Section 4.3, the "**Additional Shares**").

5 . Milestone Shares. The Company shall issue Milestone Shares to Yuhan on each date that a Development Milestone Payment is due pursuant to the License Agreement. If the Planned Public Offering has been consummated, the number of Milestone Shares shall be equal to the dollar amount set forth in the License Agreement applicable to the Development Milestone achieved divided by the VWAP Purchase Price as calculated on the date the Development Milestone Payment is due. If the Planned Public Offering has not been consummated, the number of Milestone Shares shall be equal to the dollar amount set forth in the License Agreement applicable to the Development Milestone achieved divided by the lesser of (i) the VWAP Purchase Price as calculated on the date the Development Milestone Payment is due and (ii) the Last Round Purchase Price (if applicable) as of the date the Development Milestone Payment is due.

6 . Representations and Warranties of the Company. The Company hereby represents and warrants to Yuhan that the following representations are true and complete as of the date hereof and as of the Closing, except as otherwise indicated herein or in a SEC Report (as defined below):

6 . 1 Organization. The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. The Company has all requisite corporate power and authority to enter into this Agreement, to issue the Shares and to perform its obligations under and to carry out the Transactions contemplated by this Agreement. The Company is duly qualified as a foreign corporation to transact business and is in good standing in each jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except whether the failure to so qualify or be in good standing would not, individually or in the aggregate, constitute a Material Adverse Effect. The Company is not in violation of, in conflict with, or in default under its Organizational Documents in any material respect. True and correct copies of the Organizational Documents, as in effect on the date of this Agreement, are attached as exhibits to the Company's SEC Reports.

6.2 Authorization.

(a) All requisite corporate action on the part of the Company required by applicable Law for the authorization, execution and delivery by the Company of this Agreement and the performance of all obligations of the Company hereunder and thereunder, including the authorization, issuance and delivery of the Shares, has been taken.

(b) This Agreement has been duly executed and delivered by the Company, and upon the due execution and delivery of this Agreement by Yuhan, it will constitute valid and legally binding obligations of the Company, enforceable against the Company in accordance with its terms, except as limited by: (i) applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance and other Laws of general application relating to or affecting enforcement of creditors' rights generally; and (ii) as limited by Laws relating to the availability of specific performance, injunctive relief or other equitable remedies (the exceptions set forth in (i) and (ii), the "**Enforceability Exceptions**").

(c) On or prior to the date hereof, the Board of Directors of the Company has duly adopted resolutions, among other things, authorizing and approving each of the Transaction Agreements and the Transactions.

6.3 No Conflicts. Except as set forth in a written notice provided by the Company to Yuhan prior to the execution of this Agreement and referencing this Section 6.3, the execution, delivery and performance of this Agreement, and compliance with the provisions hereof, and the issuance of the Shares by the Company do not and shall not: (a) subject to receipt of the Required Approvals, violate any provision of applicable Law or any ruling, writ, injunction, order, permit, judgment or decree of any Governmental Authority to which the Company is subject, (b) result in any encumbrance upon any of the Shares, other than restrictions on resale pursuant to securities laws or as set forth in this Agreement, (c) result in a default, modification, acceleration of payment or termination under, give any Person a right of termination or cancellation under, result in the loss of a benefit or imposition of any obligation under, any Material Contract, or (d) violate or conflict with any of the provisions of the Organizational Documents, except, in the case of subsections (a) and (c) as would not, individually or in the aggregate, constitute a Material Adverse Effect.

6.4 No Approval. No consent, approval, authorization or other order of, or filing with, or notice to, any Governmental Authority is required to be obtained or made by the Company or any of its Subsidiaries in connection with the authorization, execution and delivery by the Company of this Agreement or with the authorization, issuance and sale by the Company of the Shares, or the consummation of the Transactions, except (a) such filings as may be required to be made with the Securities and Exchange Commission (the "**SEC**") and with any state blue sky or securities regulatory authority, which filings shall be made in a timely manner in accordance with all applicable Laws; and (b) those that have been made or obtained prior to the date of this Agreement (the items referred to in clauses (a) and (b), the "**Required Approvals**").

6 . 5 Valid Issuance of Shares. When issued, sold and delivered in accordance with the terms hereof, the Shares will be duly authorized, validly issued, fully paid and nonassessable, free from any liens, encumbrances or restrictions on transfer, including preemptive rights, rights of first refusal, purchase option, call option, subscription right or other similar rights, other than as arising pursuant to this Agreement, as a result of any action by Yuhan or under federal or state securities Laws. Assuming the accuracy of the representations and warranties of Yuhan in this Agreement and subject to the Required Approvals, the Shares will be issued in compliance with all applicable federal and state securities Laws.

6.6 Company SEC Reports.

(a) The Company has filed or furnished, as applicable, all reports, schedules, forms, statements and other documents required to be filed or furnished by it with the SEC pursuant to the reporting requirements of the Exchange Act (all of the foregoing filed prior to the date of this Agreement and all exhibits included therein and financial statements and schedules thereto and documents (other than exhibits) incorporated by reference therein, collectively, the "**Company SEC Reports**"), each of which complied at the time of filing in all material respects with all applicable requirements of the Securities Act and the Exchange Act, as applicable, in each case as in effect on the dates such forms reports and documents were filed. As of its respective date, and if amended, as of the date of the last such amendment, no Company SEC Report, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. All Material Contracts to which the Company or any Subsidiary is a party, or to which the property or assets of the Company or any Subsidiary are subject, that are required to be included as part of or specifically identified in the Company SEC Reports, are so included or specifically identified. True and complete copies of the Company SEC Reports are available for public access via the SEC's EDGAR system (excluding schedules, exhibits and any redacted information).

(b) As of their respective dates, the consolidated financial statements included or incorporated in the Company SEC Reports (the "**Financial Statements**"), and the related notes, complied as to form in all material respects with applicable accounting requirements and the published rules and regulations of the SEC with respect thereto. The Financial Statements and the related notes have been prepared, in all material respects, in accordance with accounting principles generally accepted in the United States, consistently applied, during the periods involved (except (i) as may be otherwise indicated in the Financial Statements or the notes thereto, or (ii) in the case of unaudited interim statements, to the extent they may not include footnotes, may be condensed or summary statements or may conform to the SEC's rules and instructions for Quarterly Reports on Form 10-Q) and fairly present in all material respects the consolidated financial position and the results of the operations of the Company and its Subsidiaries, retained earnings (loss), and cash flows, as the case may be, for the periods then ended (subject, in the case of unaudited statements, to normal and recurring year-end audit adjustments).

(c) Except as noted in the SEC Reports, the Company has established and maintains disclosure controls and procedures (as defined in Rules 13a-15 and 15d-15 under the Exchange Act) that (i) are designed to ensure that material information relating to the Company, including each consolidated Subsidiary, is made known to the Company's principal executive officer and its principal financial officer by others within those entities, particularly during the periods in which the periodic reports required under the Exchange Act are being prepared; and (ii) have been evaluated by management of the Company for effectiveness as of the end of the Company's most recent fiscal quarter.

7. Representations and Warranties of Yuhan. Yuhan hereby represents and warrants to the Company as of the date hereof as follows:

7.1 Organization. Yuhan is a corporation duly organized, validly existing and in good standing under the laws of the Republic of Korea. Yuhan has all requisite power and authority to enter into this Agreement, to purchase the Shares and to perform its obligations under and to carry out the Transactions.

7.2 Authorization. All requisite corporate action on the part of Yuhan, required by applicable Law for the authorization, execution and delivery by Yuhan of this Agreement and the performance of all of its obligations hereunder, including the acquisition of the Shares, has been taken. This Agreement has been duly executed and delivered by Yuhan, and upon the due execution and delivery thereof by the Company, will constitute valid and legally binding obligations of Yuhan, enforceable against Yuhan in accordance with its terms, except as limited by the Enforceability Exceptions.

7.3 No Conflicts. The execution, delivery and performance of this Agreement and compliance with the provisions thereof, by Yuhan do not and shall not: (a) violate any provision of applicable Law or any ruling, writ, injunction, order, permit, judgment or decree of any Governmental Authority, or (b) violate or conflict with any of the provisions of Yuhan's organizational documents (including any articles or memoranda of organization or association, charter, by-laws or similar documents), except as would not materially impair or affect in a material adverse manner the ability of Yuhan to consummate the Transactions and perform its obligations under this Agreement.

7.4 No Approval. No consent, approval, authorization or other order of any Governmental Authority is required to be obtained by Yuhan in connection with the authorization, execution and delivery of any of this Agreement or with the subscription for and purchase of the Shares.

7.5 Acquisition Entirely for Own Account. The Shares shall be acquired for investment for Yuhan's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and as of the date hereof, Yuhan has no present intention of selling, granting any participation or otherwise distributing the Shares. Yuhan, either alone or together with its representatives, has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Shares, and has so evaluated the merits and risks of such investment. Yuhan is able to bear the economic risk of an investment in the Shares and, at the present time, is able to afford a complete loss of such investment.

7.6 Purchaser Status. Yuhan is as of the date hereof, and as of the date any Shares are issued under this Agreement will be, an "accredited investor" as defined in Rule 501 under the Securities Act.

7.7 Access to Information. Yuhan acknowledges that it has had the opportunity to review the Transaction Agreements and the SEC Reports and has been afforded, (i) the opportunity to ask such questions as it has deemed necessary of, and to receive answers from, representatives of the Company concerning the terms and conditions of the offering of the Shares and the merits and risks of investing in the Shares; (ii) access to information about the Company and its financial condition, results of operations, business, properties, management and prospects sufficient to enable it to evaluate its investment; and (iii) the opportunity to obtain such additional information that the Company possesses or can acquire without unreasonable effort or expense that is necessary to make an informed investment decision with respect to the investment.

7.8 Restricted Securities. Yuhan understands that the Shares, when issued, will be "restricted securities" under the federal securities Laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such Laws the Shares may be resold without registration under the Securities Act only in certain limited circumstances. Yuhan represents that it is familiar with Rule 144.

7.9 Legends. In addition to any other legend required by Law, the book-entry or certificated form of the Shares shall bear any legend required by the "blue sky" laws of any state and a restrictive legend in substantially the following form:

**THESE SECURITIES HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED. THEY MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED OR HYPOTHECATED IN THE ABSENCE OF A REGISTRATION STATEMENT IN EFFECT WITH RESPECT TO THE SECURITIES UNDER SUCH ACT OR AN OPINION OF COUNSEL SATISFACTORY TO THE ISSUER THAT SUCH REGISTRATION IS NOT REQUIRED OR UNLESS SOLD PURSUANT TO RULE 144 OF SUCH ACT.**

7.10 Acquiring Person. As of the date of this Agreement and immediately prior to the Closing, neither Yuhan nor any of its controlled Affiliates (excluding directors and officers of Yuhan who may hold securities of the Company for their personal account) Beneficially Owns, or will Beneficially Own any securities of the Company.

7.11 No General Solicitation. Yuhan is not acquiring the Shares as a result of (a) any advertisement, article, notice or other communication published in any newspaper, magazine or similar media or broadcast over television, radio or the Internet, in each case, relating to the Company, or (ii) any seminar or meeting whose attendees, including Yuhan, have been invited by any general solicitation or general advertising related to the Company.

8. Covenants.

8.1 Commercially Reasonable Best Efforts. Subject to the terms and conditions set forth in this Agreement, each Party hereto shall use its commercially reasonable best efforts to do or cause to be done all things necessary or appropriate to satisfy the conditions to the Closing and to consummate the Transactions as promptly as practicable. Without limiting the generality of the foregoing, unless the License Agreement is earlier terminated by either Party in accordance with its terms, the Company and Yuhan shall use their respective commercially reasonable best efforts to cause the Closing to occur. Each of the Company and Yuhan shall not, and shall not permit any of their respective Affiliates to, take any action that would, or that would reasonably be expected to, result in any of the conditions set forth in Section 9 or Section 10 not being satisfied.

8.2 Registration Rights. The Company hereby provides Yuhan with the registration rights set forth on Appendix 1 attached hereto, which is hereby incorporated in and made a part of this Agreement as if set forth in full herein.

8.3 Participation Rights. The Company shall, in connection with the Planned Public Offering, reserve and offer (and cause the Underwriters to reserve and offer) to Yuhan or an Affiliate designated by Yuhan, at least a number of shares of Common Stock having a value at the IPO Price of at least $3,000,000.

8.4 Facilitation of Sales Pursuant to Rule 144. For as long as Yuhan or its Affiliates Beneficially Owns any Shares, to the extent it shall be required to do so under the Exchange Act, the Company shall use commercially reasonable efforts to timely file the reports required to be filed by it under the Exchange Act or the Securities Act (including the reports under Sections 13 and 15(d) of the Exchange Act referred to in subparagraph (c)(1) of Rule 144), and shall use commercially reasonable efforts to take such further necessary action as Yuhan may reasonably request in connection with the removal of any restrictive legend on the Shares being sold at Yuhan's cost, all to the extent required from time to time to enable such holder to sell the Shares without registration under the Securities Act within the limitations of the exemption provided by Rule 144. Notwithstanding the foregoing, the Company shall not have any obligations pursuant to this section during any time when a Registration Statement covering the Shares is effective.

9. Conditions to the Company's Obligations. The obligations of the Company under Section 2 hereof are subject to the fulfillment prior to or on the Closing Date (and with respect to Section 9.1, as of each date the Company is required to issue Shares to Yuhan under this Agreement) of all of the following conditions, any of which may be waived in whole or in part by the Company.

9.1 Representations and Warranties. The representations and warranties of Yuhan contained in this Agreement and in any certificate, if any, or other writing, if any, delivered by Yuhan pursuant hereto shall be true and correct in all material respects on and as of the Closing Date, and as of each date the Company is required to issue Shares under this Agreement, except those representations and warranties qualified by materiality or Material Adverse Effect, which representations and warranties shall be true and correct in all respects, with the same effect as though such representations and warranties had been made on and as of the Closing Date or a Share issuance date, as applicable (except to the extent expressly made as of an earlier date, in which case as of such earlier date).

9.2 Performance. Yuhan shall have performed and complied in all material respects with all agreements, obligations and conditions contained in this Agreement that are required to be performed or complied with it on or before the Closing.

9.3 License Agreement. Each of the Company and Yuhan shall have executed and delivered the License Agreement, and the License Agreement shall not have been terminated and shall be effective in accordance with its terms.

10. Conditions to Yuhan's Obligations. The obligations of Yuhan under Section 2 hereof are subject to the fulfillment prior to or on the Closing Date of all of the following conditions, any of which may be waived in whole or in part by Yuhan.

10.1 Representations and Warranties. The representations and warranties of the Company contained in this Agreement and in any certificate, if any, or other writing, if any, delivered by the Company pursuant hereto shall be true and correct in all material respects on and as of the Closing Date, except those representations and warranties qualified by materiality or Material Adverse Effect, which representations and warranties shall be true and correct in all respects, with the same effect as though such representations and warranties had been made on and as of the Closing Date (except to the extent expressly made as of an earlier date, in which case as of such earlier date).

10.2 Performance. The Company shall have performed and complied in all material respects with all agreements, obligations and conditions contained in this Agreement that are required to be performed or complied with it on or before the Closing.

10.3 License Agreement. Each of the Company and Yuhan shall have executed and delivered the License Agreement, and the License Agreement shall not have been terminated and shall be effective in accordance with its terms.

10.4 No Stockholder Approval Required. No approval on the part of the stockholders of the Company shall be required in connection with the execution and delivery by the Company of this Agreement and the consummation of the Transactions.

10.5 Qualification Under State Securities Laws. All registrations, qualifications, permits and approvals, if any, required to be obtained prior to the Closing under applicable state securities laws shall have been obtained for the lawful execution, delivery and performance of this Agreement or the other Transaction Agreements, including, without limitation, the offer and sale of the Shares.

10.6 Absence of Litigation. No proceeding challenging the Transaction Agreements or the Transactions, or seeking to prohibit, alter, prevent or materially delay the Closing, shall have been instituted by any Governmental Authority.

11. Survival. The representations and warranties contained in this Agreement shall survive the Closing of the Transactions until the date that is two years following the date of this Agreement. The covenants and agreements contained in this Agreement shall survive Closing of the Transactions. The rights and remedies that may be exercised by Yuhan shall not be limited or otherwise affected by or as a result of any information furnished to, or any investigation made by or knowledge of, Yuhan or its representatives.

12. Miscellaneous.

12.1 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and interpreted in accordance with the laws of the state of New York, without regard to its conflicts of laws rules. Each Party (a) irrevocably submits to the exclusive jurisdiction in the state court sitting in New York (collectively, the "Courts"), for purposes of any action, suit or other proceeding arising out of this Agreement, and (b) agrees not to raise any objection at any time to the laying or maintaining of the venue of any such action, suit or proceeding in any of the Courts, irrevocably waives any claim that such action, suit or other proceeding has been brought in an inconvenient forum and further irrevocably waives the right to object, with respect to such action, suit or other proceeding, that such Court does not have any jurisdiction over such Party. Either Party may serve any process required by such Courts by way of notice under this Agreement. Notwithstanding anything to the contrary in this Section 12.1, each Party shall have the right to institute judicial proceedings against the other Party or anyone acting by, through, or under such other Party, in any court of competent jurisdiction, in order to enforce the instituting Party's rights hereunder through reformation of contract, specific performance, injunction, or similar equitable relief.

12.2 No Waiver, Modifications. It is agreed that no waiver by a Party hereto of any breach or default of any of the covenants or agreements set forth herein shall be deemed a waiver as to any subsequent or similar breach or default. The failure of either Party to insist on the performance of any obligation hereunder shall not be deemed a waiver of any such obligation. No amendment, modification, waiver, release or discharge to this Agreement shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

12.3 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address specified in this Section 12.3 and shall be: (a) delivered personally; (b) sent by registered or certified mail, return receipt requested, postage prepaid; (c) sent via a reputable nationwide overnight courier service; or (d) sent by facsimile or other electronic transmission. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service, or when transmitted with confirmation of receipt, if transmitted by facsimile or other electronic transmission (if such transmission is on a Business Day; otherwise, on the next Business Day following such transmission).

Notices to the Company shall be addressed to:

Processa Pharmaceuticals, Inc.
7380 Coca Cola Drive, Suite 106
Hanover, MD 21076
Attn: Wendy Guy, Chief Administrative Officer
Email: wguy@processapharmaceuticals.com

Notices to Yuhan shall be addressed to:

Yuhan Corporation
74, Noryangjin-ro, Dongjak-gu
Seoul, Republic of Korea, 06927
Attention: Taejin Yoon, Head of Global Business Development
Email: tyoon@yuhan.co.kr
Facsimile: 82-2-828-0086

Yuhan Corporation
74, Noryangjin-ro, Dongjak-gu
Seoul, Republic of Korea, 06927
Attention: Ryan Ryou, Global Operations
Email: ryan@yuhan.co.kr
Facsimile: 82-2-828-0086

Either Party may change its address by giving notice to the other Party in the manner provided above.

12.4 Entire Agreement. This Agreement (including all exhibits, schedules and annexes attached hereto) and the License Agreement contain the entire agreement among the Parties with respect to the subject matter hereof and thereof and supersede all prior and contemporaneous arrangements or understandings, whether written or oral, with respect hereto and thereto.

12.5 Headings; Nouns and Pronouns; Section References. Headings in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement. Whenever the context may require, any pronouns used herein shall include the corresponding masculine, feminine or neuter forms, and the singular form of names and pronouns shall include the plural and vice-versa. References in this Agreement to a section or subsection shall be deemed to refer to a section or subsection of this Agreement unless otherwise expressly stated.

12.6 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future Law, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid or unenforceable provision, the Parties shall negotiate in good faith a substitute legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as possible and as reasonably acceptable to the Parties.

12.7 Assignment. Except for an assignment by Yuhan of this Agreement or any rights hereunder to an Affiliate or Permitted Transferee (which assignment will not relieve Yuhan of any obligation hereunder), neither this Agreement nor any of the rights or obligations hereunder may be assigned by either Yuhan or the Company without (a) the prior written consent of Company in the case of any assignment by Yuhan or (b) the prior written consent of Yuhan in the case of an assignment by the Company.

12.8 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.

12.9 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument. In the event that any signature is delivered by facsimile transmission or by an e-mail which contains a portable document format (.pdf) file of an executed signature page, such executed signature page shall create a valid and binding obligation of the Party executing it (or on whose behalf such signature page is executed) with the same force and effect as if such executed signature page were an original thereof.

12.10 Third Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any Party hereto, except that each Affiliate of Yuhan is an express third party beneficiary entitled to enforce this Agreement directly against the Company. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any Party hereto.

12.11 No Strict Construction. This Agreement has been prepared jointly and will not be construed against either Party. No presumption as to construction of this Agreement shall apply against either Party with respect to any ambiguity in the wording of any provision(s) of this Agreement irrespective of which Party may be deemed to have authored the ambiguous provision(s).

12.12 Remedies. The rights, powers and remedies of the Parties under this Agreement are cumulative and not exclusive of any other right, power or remedy which such Parties may have under any other Contract or Law. No single or partial assertion or exercise of any right, power or remedy of a Party hereunder shall preclude any other or further assertion or exercise thereof. The Parties hereby acknowledge and agree that the rights of the Parties hereunder are special, unique and of extraordinary character, and that if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, such refusal or failure would result in irreparable injury to the Company or Yuhan as the case may be, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation. Accordingly, if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, then, in addition to any other remedy which may be available to any damaged Party at law or in equity, such damaged Party will be entitled to seek specific performance and injunctive relief, without posting bond or other security, and without the necessity of proving actual or threatened damages, which remedy such damaged Party will be entitled to seek in any court of competent jurisdiction.

12.13 Expenses. Each Party shall pay its own fees and expenses in connection with the preparation, negotiation, execution, delivery and performance of the Transaction Agreements.

12.14 WAIVER OF JURY TRIAL. IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY ANY PARTY AGAINST ANY OTHER PARTY, THE PARTIES EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVES FOREVER TRIAL BY JURY.

12.15 Equitable Adjustments. The number of Shares issuable pursuant to this Agreement shall be adjusted equitably in the event of any stock split, dividend, corporate reorganization or similar transaction.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the Parties have executed and delivered this Agreement as of the date first above written.

**Processa Pharmaceuticals, Inc.**

By: 
Name: David Young
Title: CEO

**Yuhan Corporation**

By: 
Name: Jung Hee Lee
Title: CEO and President

**Appendix 1**

**Registration Rights**

1. Resale Registration.

1.1 At any time following the date that is 180 days after the Planned Public Offering, upon Yuhan's written request following the issuance of the Initial Shares, the Additional Shares, or the Milestone Shares, as applicable, the Company will file a Shelf Registration Statement registering for resale the Registrable Securities under the Securities Act. The Company shall use its commercially reasonable efforts to cause such Shelf Registration Statement to become effective as promptly as practicable after filing. Until the earlier of such time as (i) all Registrable Securities included in such Shelf Registration Statement cease to be Registrable Securities or (ii) the Company is no longer eligible to maintain a Shelf Registration Statement, the Company will keep current and effective such Shelf Registration Statement and file such supplements or amendments to such Shelf Registration Statement (or file a new Shelf Registration Statement when such preceding Shelf Registration Statement expires pursuant to the rules of the SEC) as may be necessary or appropriate in order to keep such Shelf Registration Statement continuously effective and useable for the resale of Registrable Securities under the Securities Act. For avoidance of doubt, this requirement to register the shares shall not require the Company to file a registration statement for Yuhan to sell its share in an underwritten offering.

1.2 If the filing, initial effectiveness or continued use of the Shelf Registration Statement at any time would require the Company to make a public disclosure of material non-public information that the Company has a bona fide business purpose for not disclosing publicly at such time, the Company may, upon giving prompt written notice of such action to Yuhan, delay the filing or initial effectiveness of, or suspend use of, the Shelf Registration Statement (a "**Suspension**"); provided, however, that the Company shall not be permitted to exercise a Suspension more than once during any twelve (12) month period for a period not to exceed sixty (60) days. In the case of a Suspension, Yuhan agrees to suspend use of the applicable Prospectus in connection with any sale or purchase, or offer to sell or purchase, Shares, upon receipt of the notice referred to above. The Company shall immediately notify Yuhan in writing upon the termination of any Suspension, amend or supplement the Prospectus, if necessary, so it does not contain any untrue statement or omission and furnish to Yuhan such numbers of copies of the Prospectus as so amended or supplemented as Yuhan may reasonably request. The Company shall, if necessary, supplement or amend the Shelf Registration Statement, if required by law or as may reasonably be requested by Yuhan.

2. Information. The Company may require Yuhan to furnish to the Company such information regarding the distribution of the Shares and such other information relating to Yuhan and its ownership of Shares as the Company may from time to time reasonably request in writing to the extent that such information is required to be included in the Shelf Registration Statement.

3 . Expenses. All expenses incident to the registration of the Shares shall be paid by the Company, including (a) all registration and filing fees, and any other fees and expenses associated with filings required to be made with the SEC or Financial Industry Regulatory Authority, (b) all fees and expenses in connection with compliance with any securities or "Blue Sky" laws, (c) all fees and disbursements of counsel for the Company and of all independent certified public accountants or independent auditors of the Company and any of its Subsidiaries (including the expenses of any special audit and comfort letters required by or incident to such performance), (d) Securities Act liability insurance or similar insurance if the Company so desires, (e) all fees and expenses incurred in connection with the listing of the Shares on any securities exchange or quotation of the Shares on any inter-dealer quotation system, (f) all fees and expenses of any special experts or other Persons retained by the Company in connection with any registration, and (g) all of the Company's internal expenses (including all salaries and expenses of its officers and employees performing legal or accounting duties). For the avoidance of doubt, the Company shall not be required to register the Shares for an underwritten public offering by Yuhan and will not be responsible for any underwriting discounts and commissions and transfer Taxes, if any, attributable to the sale of the Shares.

4. Notice. The Company shall notify Yuhan immediately upon (a) any request by the SEC or any other Federal or state Governmental Authority for amendments or supplements to a Shelf Registration Statement or for additional information that pertains to Yuhan as a selling stockholder; (b) the issuance by the SEC of any stop order suspending the effectiveness of the Shelf Registration Statement or any order by the SEC or any other regulatory authority preventing or suspending the use of any Prospectus or the initiation or threatening of any proceedings for such purposes, (c) receipt by the Company of any notification with respect to the suspension of the qualification of the Shares for offering or sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose, or (d) the Company becoming aware that the Shelf Registration Statement or the related Prospectus contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements therein (in the case of such Prospectus, in light of the circumstances under which they were made) not misleading.

5. Indemnification.

5.1 To the extent permitted by Law, the Company will indemnify and hold harmless Yuhan, its officers, directors, agents, partners, members, stockholders and employees, as applicable, and each Person who controls Yuhan (within the meaning of the Securities Act or the Exchange Act), and the officers, directors, agents, partners, members, stockholders and employees of each such controlling Person, from and against any and all losses, claims, liabilities, damages, deficiencies, assessments, fines, judgments, fees, costs (including, without limitation, reasonable costs of preparation and reasonable attorneys' fees) and expenses (collectively "**Losses**") (joint or several), as incurred, to which they may become subject under the Securities Act, the Exchange Act or other federal or state law, insofar as such Losses (or actions in respect thereof) arise out of, relate to, or are based upon any of the following statements, omissions or violations (collectively a "**Violation**") by the Company: (a) any untrue statement or alleged untrue statement of a material fact contained in the Shelf Registration Statement or incorporated by reference therein, including any Prospectus contained therein or any amendments or supplements thereto, (b) the omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading, or (c) any violation or alleged violation by the Company of the Securities Act, the Exchange Act, any state securities Law, or any rule or regulation promulgated under the Securities Act, the Exchange Act or any state securities Law in connection with the Shelf Registration Statement; and the Company will reimburse each such indemnified party for any legal or other expenses reasonably incurred by them in connection with investigating or defending any such Loss or action if it is judicially determined that there was such a Yuhan Violation; provided however, that the indemnity agreement contained in this Section 5.1 will not apply to amounts paid in settlement of any such Loss or action if such settlement is effected without the Company's consent, nor will the Company be liable in any such case for any such Loss to the extent that it arises out of or is based upon a Violation which occurs in reliance upon and in conformity with written information furnished by Yuhan and stated to be expressly for use in connection with the Shelf Registration Statement or an applicable Prospectus.

5.2 To the extent permitted by Law, Yuhan will indemnify and hold harmless the Company and each of its directors and its officers against any Losses (joint or several) to which the Company or any such director, officer, controlling Person, Underwriter or other Third Party who may become subject under the Securities Act, the Exchange Act or other federal or state law, insofar as such Losses (or actions in respect thereto) arise out of or are based upon any of the following statements: (a) any untrue statement or alleged untrue statement of a material fact contained in any Registration Statement or any other document incorporated reference therein, including any preliminary Prospectus or final Prospectus contained therein or any amendments or supplements thereto, or (b) the omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading (collectively, a "**Yuhan Violation**"), in each case to the extent (and only to the extent) that such Yuhan Violation occurs in reliance upon and in conformity with written information furnished by Yuhan under an instrument duly executed by Yuhan; and Yuhan will reimburse any legal or other expenses reasonably incurred by the Company or any such director, officer, controlling Person, Underwriter or other Third Party in connection with investigating or defending any such Loss or action if it is judicially determined that there was such a Yuhan Violation; provided, however, that the indemnity agreement contained in this Section 5.2 will not apply to amounts paid in settlement of any such Loss or action if such settlement is effected without Yuhan's consent; provided, further that the obligations of Yuhan hereunder shall be limited to an amount equal to the net proceeds it receives in such Registration.

5.3 Promptly after receipt by an indemnified party under this Section 5 of notice of the commencement of any action (including any governmental action), such indemnified party will, if a claim in respect thereof is to be made against any indemnifying party under this Section 5, deliver to the indemnifying party a written notice of the commencement thereof and the indemnifying party will have the right to participate in, and, to the extent the indemnifying party so desires, jointly with any other indemnifying party similarly noticed, to assume the defense thereof with counsel mutually satisfactory to the parties; provided, however, that an indemnified party will have the right to retain its own counsel, with the fees and expenses thereof to be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or potential differing interests between such indemnified party and any other party represented by such counsel in such proceeding. The failure to deliver written notice to the indemnifying party within a reasonable time of the commencement of any such action will relieve such indemnifying party of any liability to the indemnified party under this Section 5 to the extent, and only to the extent, prejudicial to its ability to defend such action, but the omission so to deliver written notice to the indemnifying party will not relieve it of any liability that it may have to any indemnified party otherwise than under this Section 5.

5.4 If the indemnification provided for in this Section 5 is held by a court of competent jurisdiction to be unavailable to an indemnified party with respect to any Losses referred to herein, the indemnifying party, in lieu of indemnifying such indemnified party thereunder, will to the extent permitted by applicable Law contribute to the amount paid or payable by such indemnified party as a result of such Loss in such proportion as is appropriate to reflect the relative fault of the indemnifying party, on the one hand, and of the indemnified party, on the other, in connection with the Violation(s) or Yuhan Violation(s), as applicable, that resulted in such Loss, as well as any other relevant equitable considerations. The relative fault of the indemnifying party and of the indemnified party will be determined by a court of law by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission to state a material fact relates to information supplied by the indemnifying party or by the indemnified party and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission; provided, however, that the obligations of Yuhan hereunder shall be limited to an amount equal to the net proceeds it receives in such Registration; and provided, further, that no Person guilty of fraudulent misrepresentation within the meaning of Section 11(f) of the Securities Act, shall be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation.

5.5 The obligations of the Company and Yuhan under this Section 5 will survive termination of this Agreement and the expiration or withdrawal of the Shelf Registration Statement. No indemnifying party, in the defense of any such claim or litigation, will, except with the consent of each indemnified party, consent to entry of any judgment or enter into any settlement which does not include as an unconditional term thereof the giving by the claimant or plaintiff to such indemnified party of a release from all liability in respect to such claim or litigation.

**Exhibit 10.13**

**LICENSE AGREEMENT**

**BY AND BETWEEN**

**PROCESSA PHARMACEUTICALS, INC.**

**AND**

**ELION ONCOLOGY, INC**

**DATED AS OF AUGUST 23, 2020**

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**LICENSE AGREEMENT**

**THIS LICENSE AGREEMENT** is entered into as of this 23 day of August, 2020 (the "Effective Date"), by and between Processa Pharmaceuticals, Inc. a corporation organized under the laws of Delaware, having a business address at 7380 Coca Cola Drive, Suite 106, Hanover, MD 21076 ("Processa"), and Elion Oncology, Inc. a corporation organized under the laws of Maryland whose principal place of business is at 4800 Hampden Lane, Bethesda, MD 20814 ("Elion").

WHEREAS, Elion has developed or obtained rights to Elion Know-How, Elion Patent Rights and the Elion Compound (each as defined below); and

WHEREAS, Processa desires to obtain a license of the Elion Patent Rights and the Elion Know-How to Develop and Commercialize Compounds and Products (each as defined below), under the terms and conditions set forth herein, and Elion desires to grant such a license;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, the Parties agree as follows:

## ARTICLE I
## DEFINITIONS

The following terms, whether used in the singular or plural, shall have the following meanings:

1.1 "Affiliate". Affiliate means any Person directly or indirectly controlled by, controlling or under common control with, a Party, but only for so long as such control shall continue. For purposes of this definition, "control" (including, with correlative meanings, "controlled by", "controlling" and "under common control with") means, with respect to a Person, possession, direct or indirect, of (a) the power to direct or cause direction of the management and policies of such Person (whether through ownership of securities or partnership or other ownership interests, by contract or otherwise), or (b) at least 50% of the voting securities (whether directly or pursuant to any vested and exercisable option, warrant or other similar arrangement) or other comparable equity interests. For clarity, neither of the Parties shall be deemed to be an "Affiliate" of the other.

1.2 "Bankruptcy Code". Bankruptcy Code means Title 11 of the U.S. Code, as amended from time to time.

1.3 "Business Day". Business Day means a day that is not a Saturday, Sunday or a day on which banking institutions in New York City, New York are authorized by Law to remain closed.

1.4 "Calendar Quarter". Calendar Quarter means each of the periods ending on March 31, June 30, September 30, and December 31 of any Calendar Year; provided, however, that the first Calendar Quarter shall begin on the Effective Date and end on the last day of the calendar quarter during which the Effective Date occurs; provided, that, the final Calendar Quarter shall end on the last day of the Term.

1.5 "Calendar Year". Calendar Year means each calendar year during the Term; provided, however, that the first Calendar Year shall begin on the Effective Date and end on December 31 of the calendar year during which the Effective Date occurs; provided, that, the final Calendar Year shall end on the last day of the Term.

1.6 "Combination Product". Combination Product means (a) any pharmaceutical product that is a single formulation consisting of a Compound and one or more other active compounds or active ingredients, which other active compounds or active ingredients are not Compounds ("Other API") or (b) any combination of a Compound sold together with any separately formulated Other API for a single invoiced price.

1.7 "Commercialization" or "Commercialize". Commercialization or Commercialize means activities directed to obtaining pricing and reimbursement approvals, marketing, promoting, Manufacturing commercial supplies of, distributing, importing, offering for sale, or selling a product.

1.8 "Commercially Reasonable Efforts". Commercially Reasonable Efforts means, with respect to an objective, the reasonable, diligent, good faith efforts of a Party (including the efforts of its Affiliates and Sublicensees) to accomplish such objective that a biopharmaceutical company of comparable size and resources would normally use to accomplish a similar objective under similar circumstances, and, specifically with respect to obligations hereunder relating to a Compound or Product, the carrying out of such obligations with those efforts and resources that a biopharmaceutical company of comparable size and resources would use were it Developing, Manufacturing or Commercializing its own pharmaceutical products that are at a similar stage of development or product life cycle and of similar market potential as the Compound or Product, taking into account actual and potential issues of safety, efficacy or stability, product profile (including product modality, category and mechanism of action), stage of development or life cycle status, product labeling or anticipated labeling, the present and future market potential, past performance of the Compound or Product, actual and projected Development, Regulatory Approval, pricing and reimbursement approval, Manufacturing and Commercialization costs, existing or projected pricing, sales, reimbursement and financial return, medical and clinical considerations, present and future regulatory environment, any issues regarding the ability to Manufacture the Compound or Product, the likelihood and timing of obtaining Regulatory Approvals and pricing and reimbursement approvals, proprietary position, strength and duration of patent protection and anticipated exclusivity, competitive Third Party products at the time and the likely competitive environment at the time of projected entry into the market and thereafter, and any other relevant scientific, technical, operational and commercial factors, all as measured by the facts and circumstances at the time such efforts are due. Commercially Reasonable Efforts will be determined on a country-by-country and indication-by-indication basis for the Compound or Product, and the level of effort is expected to change over time, reflecting changes in the status and value of the Compound or Product and the market conditions and country(ies) involved.

1.9 "Compound". Compound means Eniluracil together with all analogs, derivatives, metabolites, stereoisomers, polymorphs, formulations, mixtures or compositions thereof, and any existing or future improved or modified versions of the foregoing developed by or on behalf of Processa, its Affiliates or Sublicensees (or their respective Affiliates or assignees).

1.10 "Clinical Trial" shall mean any study in which human subjects are dosed with a drug, whether approved or investigational, including any Phase 1, 2, 3 or 4 clinical study.

1.11 "Condition Precedent Period". Condition Precedent Period means the period of time beginning on the Effective Date and ending on October 30, 2020.

1.12 "Control" or "Controlled". Control or Controlled means, with respect to any tangible property or intellectual property right or other intangible property, the possession (whether by ownership or license (other than by grant of a license to one Party by the other Party pursuant to this Agreement or by grant of a license or sublicense to a Sublicensee by Processa pursuant to a license or sublicense agreement)) by a Person of the ability to grant to another Person access to such tangible property or access to or a license or sublicense to such intellectual property right or other intangible property, as provided herein without violating the terms of any agreement with any other Person. Notwithstanding the foregoing, for the purpose of defining whether intellectual property, Patent Rights, Know-How or Confidential Information is Controlled by a Party, if such intellectual property, Patent Rights, Know-How or Confidential Information is first acquired, licensed or otherwise made available to such Party after the Effective Date and if the use, practice or exploitation thereof by or on behalf of the other Party, its Affiliates or sublicensees would require the first Party to pay any amounts to the Third Party from which the first Party acquired, licensed or otherwise obtained such intellectual property, Patents, Know-How or Confidential Information ("Additional Amounts"), such intellectual property, Patent Rights, Know-How or Confidential Information shall be deemed to be Controlled by the first Party only if the other Party agrees to pay (if necessary) and does in fact pay all Additional Amounts with respect to such other Party's use of or license to such intellectual property, Patent Rights, Know-How or Confidential Information to the extent specified in this Agreement.

1.13 "Cover", "Covering" or "Covered". Cover, Covering or Covered means, with respect to a compound, product, technology, process or method that, in the absence of ownership of or a license granted under a Patent Right, the manufacture, use, offer for sale, sale or importation of such compound or product or the practice of such technology, process or method would infringe such Patent Right (or, in the case of a Patent Right that has not yet issued, would infringe such Patent Right if it were to issue).

1.14 "Development" or "Develop". Development or Develop means pre-clinical, non-clinical and clinical drug research, discovery and development activities, including IND-enabling toxicology and other IND-enabling pre-clinical development efforts, stability testing, process development, compound property optimization, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, clinical pharmacology, Manufacturing supplies of compounds and products for pre-clinical, non-clinical and clinical use, clinical studies (including pre- and post-approval studies and investigator sponsored clinical studies), regulatory affairs, and Regulatory Approval and clinical study regulatory activities (excluding regulatory activities directed to obtaining pricing and reimbursement approvals).

1.15 "Elion Intellectual Property". Elion Intellectual Property means the Elion Know-How and the Elion Patent Rights.

1.16 "Elion Know-How". Elion Know-How means all Know-How that is Controlled by Elion or any of its Affiliates as of the Effective Date or thereafter during the Term (other than any Know-How included in Joint Intellectual Property) that is necessary or useful to Develop, Manufacture or Commercialize any Compound or Product; provided, however, that, if Elion is acquired by a Third Party, "Elion Know-How" shall exclude any Know-How that (a) is Controlled by such Third Party or the Affiliates of such Third Party (other than Elion and the Persons that were Elion's Affiliates immediately prior to the closing of such acquisition transaction (such Affiliates, " Elion Pre-Existing Affiliates")) ("Elion Excluded Affiliates") and (b) was not Controlled by Elion or any of the Elion Pre-Existing Affiliates immediately prior to the closing of such acquisition transaction; provided further that, if, after the closing of such acquisition, any such Elion Excluded Affiliate Develops or Commercializes any Compound or Product or otherwise performs any activities or obtains any rights with respect to any Compound or Product, such Affiliate will cease to be an Elion Excluded Affiliate and applicable Know-How that is Controlled by such Affiliate shall be included in Elion Know-How.

1.17 "Elion Patent Rights". Elion Patent Rights means all Patent Rights in the Territory that are Controlled by Elion or any of its Affiliates as of the Effective Date or thereafter during the Term (other than Joint Patent Rights) that Cover any Compound or Product. The Elion Patent Rights existing as of the Effective Date are set forth on Schedule 1.16; provided, however, that, if Elion is acquired by a Third Party, "Elion Patent Rights" shall exclude any Patent Rights that (a) are Controlled by such Third Party or the Affiliates of such Third Party (other than Elion and Elion Pre-Existing Affiliates) and (b) were not Controlled by Elion or any of the Elion Pre-Existing Affiliates immediately prior to the closing of such acquisition transaction; provided further that, if, after the closing of such acquisition, any such Elion Excluded Affiliate Develops or Commercializes any Compound or Product or otherwise performs any activities or obtains any rights with respect to any Compound or Product, such Affiliate will cease to be an Elion Excluded Affiliate and applicable Patent Rights that are Controlled by such Affiliate shall be included in Elion Patent Rights.

1.18 "EMA". EMA means the European Medicines Agency and any successor agency.

1.19 "FDA". FDA means the U.S. Food and Drug Administration and any successor agency.

1.20 "Field". Field means all medical uses.

1.21 "First Commercial Sale". First Commercial Sale means, with respect to a Product in a country, the first sale of such Product in such country by Processa, any of its Affiliates or any Sublicensee to the first unrelated Third Party (unless any such entity is an end-user of the Product) in such country for use or consumption of such Product in such country after receipt of the first Regulatory Approval for such Product in such country. Sales for purposes of testing the Product and sample purposes shall not be deemed a First Commercial Sale. For clarity, First Commercial Sale will be determined on a Product-by-Product and country-by-country basis, as applicable.

1.22 "Governmental Authority". Governmental Authority means any national, federal, state or local government, or political subdivision thereof, or any multinational organization or authority or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body.

1.23 "IND". IND means an investigational new drug application filed with the FDA with respect to a Compound or Product, or an equivalent application filed with the Regulatory Authority of a country or regulatory jurisdiction in the Territory other than the U.S., and all amendments and supplements thereto.

1.24 "Joint Intellectual Property". Joint Intellectual Property means the Joint Inventions and Joint Patent Rights.

1.25 "Know-How". Know-How means all unpatented technical information, trade secrets, formulae, standards, knowledge, directions, instructions, test protocols, procedures and results, studies, analyses, raw material sources, data, manufacturing data, and any other confidential or proprietary interest in information.

1.26 "Law" or "Laws". Law or Laws means all laws, statutes, rules, regulations, orders, judgments, or ordinances of any Governmental Authority.

1.27 "Losses". Losses means any and all (a) claims, losses, liabilities, damages, fines, royalties, governmental penalties or punitive damages, deficiencies, interest, awards, judgments, and settlement amounts (including special, indirect, incidental, and consequential damages, lost profits, and Third Party punitive and multiple damages), and (b) in connection with all of the items referred to in clause (a) above, any and all costs and expenses (including reasonable counsel fees and all other expenses reasonably incurred in investigating, preparing or defending any litigation or proceeding, commenced or threatened).

1.28 "Major Market". Major Market means each of the United States, Canada, France, Germany, Italy, Spain, the United Kingdom, the People's Republic of China (including Hong Kong, Taiwan and Macau), Republic of Korea, Australia, New Zealand and Japan.

1.29 "Manufacture" or "Manufacturing". Manufacture or Manufacturing means activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and storage of a product.

1.30 "MHLW". MHLW means the Japanese Ministry of Health, Labour and Welfare, and any successor agency.

1.31 "NDA". NDA means a New Drug Application, as defined in the Act, filed with the FDA with respect to a Compound or Product, or an equivalent application filed with the Regulatory Authority of a country in the Territory other than the U.S., and all amendments and supplements thereto.

1.32 "Net Sales". Net Sales means the gross amounts billed or invoiced by Processa, or any of its Affiliates or Sublicensees or assignees, to any Third Party with respect to sales of Products in the Territory, calculated in the same manner as reported in such Person's audited financial statements, less the following:

(a) Volume, cash or trade discounts, credits or allowances, including discounts in the form of inventory management fees paid to wholesalers and distributors all to the extent such discounts are included in the invoices and actually granted;

(b) Credits, refunds or allowances granted upon returns, rejections or recalls and for retroactive price reductions or billing errors;

(c) Freight, postage, shipping and insurance costs incurred in transporting the applicable Products to the extent that such items are applicable to such sale and are separately itemized and invoiced and actually paid as evidenced by invoices, receipts or other appropriate documents;

(d) Amounts paid (including rebates and chargeback payments or credits or other equivalents thereof) to formularies, government or government agency programs, trade customers, managed health care organizations and pharmacy benefit managers (or equivalents thereof) to obtain listing or purchase of the applicable Products not to exceed 25% of the originally billed or invoiced amount;

(e) Bad debts, uncollectible amounts, and collection costs relating to the sale of Products that are actually written offprovided that, if the debt is thereafter paid, the corresponding amount shall be added to the Net Sales of the period during which it is paid; and

(f) To the extent not reimbursed by a third party, taxes, tariffs, duties or other governmental charges (other than income taxes) levied on, absorbed, or otherwise imposed on the sales, transportation, delivery, use, exportation, or importation of the applicable Products.

Sales of Products between Processa and its Affiliates or Sublicensees for resale shall be excluded from the computation of Net Sales, provided that the subsequent resale of such Products to a Third Party are included in the computation of Net Sales. Disposal or use of Products at or below cost for regulatory, development or charitable purposes, such as clinical trials, compassionate use, named patient use, or indigent patient programs, shall not be deemed a sale hereunder.

With respect to any sale of any Product in a given country for any substantive consideration other than monetary consideration on arm's length terms (which has the effect of reducing the invoiced amount below what it would have been in the absence of such non-monetary consideration), for purposes of calculating the Net Sales under this Agreement, such Product shall be deemed to be sold exclusively for cash at the average Net Sales price charged to Third Parties for cash sales in such country during the applicable reporting period (or if there were only *de minimis* cash sales in such country, at the fair market value as determined in good faith based on pricing in comparable markets).

For purposes of calculating Net Sales for Combination Products in each applicable country:

(a) If a Product is sold in any country as part of a Combination Product involving a co-formulation or co-packaging of the Compound with an Other API for which Processa has not acquired (whether by acquisition or licensing) all of the exclusive rights to commercialize such Other API in such country, then the Net Sales for such Combination Product in such country used to determine Net Sales Milestone Payments, Net Sales Royalties, and any other use of Net Sales in this Agreement will be equal to the positive difference (if any) between (x) Net Sales of such Combination Product calculated as above (with the deductions set forth in Section1.32 (a) – (f)) minus (y) all of the direct costs incurred by Process to obtain, combine and manufacture the Other API into the Combination Product in such country or to obtain, combine and manufacture the other pharmaceutical product which includes the Other API into the Combination Product in such country.

(b) If a Product is sold in any country as part of a Combination Product involving a co-formulation or co-packaging of the Compound with an Other API for which (i) Processa has acquired (whether by acquisition or licensing) all of the exclusive rights to commercialize such Other API in such country and (ii) such Other API has demonstrated through pre-clinical and/or clinical studies an effect on cancer, then the Net Sales for such Combination Product in such country used to determine Net Sales Milestone Payments, Net Sales Royalties, and any other use of Net Sales in this Agreement will be equal to 35% of the positive difference (if any) between (x) Net Sales of such Combination Product calculated as above (with the deductions set forth in Section1.32 (a) – (f)) minus (y) all of the direct costs incurred by Processa (including for clarity all royalties, milestones and other payments ) to obtain, combine and manufacture the Other API in the Combination Product in such country or to obtain, combine and manufacture the other pharmaceutical product which includes the Other API into the Combination Product in such country.

(c) If a Product is sold in any country as part of a Combination Product involving a co-formulation or co-packaging of the Compound with an Other API for which (i) Processa has acquired (whether by acquisition or licensing) all of the exclusive rights to commercialize such Other API in such country and (ii) such Other API has demonstrated through pre-clinical and/or clinical studies no effect on cancer, then the Net Sales for such Combination Product in such country used to determine Net Sales Milestone Payments, Net Sales Royalties, and any other use of Net Sales in this Agreement will be equal to 50% of the positive difference (if any) between (x) Net Sales of such Combination Product calculated as above (with the deductions set forth in Section1.32 (a) – (f)) minus (y) all of the direct costs incurred by Process (including for clarity all royalties, milestones and other payments ) to obtain, combine, and manufacture the Other API in the Combination Product in such country or to obtain, combine and manufacture the other pharmaceutical product which includes the Other API into the Combination Product in such country.

1.33 "Party". Party means either Elion or Processa; "Parties" means both Elion and Processa.

1.34 "Patent Rights". Patent Rights means all patent applications, patents, certificates of invention, applications for certificates of invention and priority patent filings, including any continuations, continuations-in-part, renewals, requests for continued examination and divisions of any such patents and patent applications, any patents or certificates of invention issuing from any of the foregoing, any extensions, reissues, reexaminations, substitutions, confirmations, registrations, revalidations, revisions, additions or supplementary patent certificates thereto, and all foreign counterparts thereof.

1.35 "Payments". Payments means royalties and other amounts payable by Processa to Elion pursuant to this Agreement.

1.36 "Person". Person means any natural person or any corporation, company, partnership, joint venture, firm, Governmental Authority, or other entity, including a Party. .

1.37 "Phase 1B". Phase 1B means the clinical study to be conducted pursuant to Protocol ELC101-20 entitled a "Phase 1b Dose-escalation Study of the Safety and Pharmacokinetics of Fixed-dose Eniluracil with Escalating Doses of Capecitabine Administered Orally in Patients with Advanced, Refractory Gastrointestinal (GI) Tract Tumors with Dose Confirmation at the Recommended Phase 2 Dose (RP2D)," as approved by the FDA pursuant to IND for the Product or, after prior notification and discussion with Elion when commercially practicable, any FDA accepted modification of the Protocol that would still classify it as a Phase 1B or Phase 2 study. As used herein, "Dose Confirmation" shall mean any dose confirmation in the Phase 1B or any dose confirmation that facilitates a Phase 2.

1.38 "Phase 2". Phase 2 means a human clinical trial of a product in any country that would satisfy the requirements of U.S. 21 C.F.R. Part 312.21(b) and is intended to explore a variety of doses, dose response, and duration of effect, and to generate evidence of clinical safety and effectiveness for a particular indication or indications in a target patient population, or a similar clinical study prescribed by the relevant Regulatory Authorities in a country other than the United States.

1.39 "Phase 3". Phase 3 means a human clinical trial of a product in any country that would satisfy the requirements of 21 C.F.R. §312.21(c), as amended (or the non-United States equivalent thereof) and is intended to (a) establish that the product is safe and efficacious for its intended use, (b) define contraindications, warnings, precautions and adverse reactions that are associated with the product in the dosage range to be prescribed, and (c) support Regulatory Approval for such product.

1.40 "Phase 4". Phase 4 means a human clinical trial of a product which is (a) conducted to satisfy a requirement of a Regulatory Authority in order to maintain a Regulatory Approval or (b) conducted voluntarily after Regulatory Approval of the product has been obtained from an appropriate Regulatory Authority for enhancing marketing or scientific knowledge of an approved indication.

1.41 "Pivotal Clinical Trial" shall mean (a) a Phase 3 Clinical Trial that is intended by Company or its Affiliates or Sublicensees to be submitted (together with any other registration trials that are prospectively planned when such Phase 3 Clinical Trial is Initiated) for Regulatory Approval in the U.S. or the EU, or (b) any other Clinical Trial that is intended by Company or its Affiliates or Sublicensees to establish that a Product is safe and efficacious for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with such pharmaceutical product in the dosage range to be prescribed, which Clinical Trial is a registration trial intended by Company or its Affiliates or Sublicensees to be sufficient for filing an application for a Regulatory Approval for such product in the U.S. or another country or some or all of an extra-national territory, solely as evidenced by the acceptance for filing for a Regulatory Approval for such Product after completion of such Clinical Trial.

1.42 "Processa Intellectual Property" means, collectively, Processa Know-How and Processa Patent Rights.

1.43 "Processa Know-How". Processa Know-How means all Know-How Controlled as of the Effective Date or thereafter during the Term by Processa or any of its Affiliates (other than any Know-How included in Joint Intellectual Property) that is used by Processa or any of its Affiliates in the Development, Manufacture or Commercialization of any Compound or Product; provided, however, that, if Processa is acquired by a Third Party, "Processa Know-How" shall exclude any Know-How that (a) is Controlled by such Third Party or the Affiliates of such Third Party (other than Processa and the Persons that were Processa's Affiliates immediately prior to the closing of such acquisition transaction (such Affiliates, "Processa Pre-Existing Affiliates")) ("Processa Excluded Affiliates") and (b) was not Controlled by Processa or any of the Processa Pre-Existing Affiliates immediately prior to the closing of such acquisition transaction; provided further that, if, after the closing of such acquisition, any such Processa Excluded Affiliate Develops or Commercializes any Compound or Product or otherwise performs any activities or obtains any rights with respect to any Compound or Product, such Affiliate will cease to be a Processa Excluded Affiliate and applicable Know-How that is Controlled by such Affiliate shall be included in Processa Know-How.

1.44 "Processa Patent Rights". Processa Patent Rights means all Patent Rights in the Territory Controlled as of the Effective Date or thereafter during the Term by Processa or any of its Affiliates (other than Joint Patent Rights) that Cover any Compound or Product and are used by Processa or any of its Affiliates in the Development, Manufacture or Commercialization of any Compound or Product; provided, however, that, if Processa is acquired by a Third Party, "Processa Patent Rights" shall exclude any Patent Rights that (a) are Controlled by such Third Party or the Affiliates of such Third Party (other than Processa and Processa Pre-Existing Affiliates) and (b) were not Controlled by Processa or any of the Processa Pre-Existing Affiliates immediately prior to the closing of such acquisition transaction; provided further that, if, after the closing of such acquisition, any such Processa Excluded Affiliate Develops or Commercializes any Compound or Product or otherwise performs any activities or obtains any rights with respect to any Compound or Product, such Affiliate will cease to be a Processa Excluded Affiliate and applicable Patent Rights that are Controlled by such Affiliate shall be included in Processa Patent Rights.

1.45 "Product". Product means any pharmaceutical preparation containing one or more Compounds as its only active ingredient(s) or a Combination Product with the active ingredient. For the avoidance of doubt, nothing in this Agreement grants to Processa any right or license under any Patent Rights or Know-How Controlled by Elion with respect to any Other API.

1.46 "Regulatory Approval". Regulatory Approval means an approval by the applicable Regulatory Authority of an NDA and any other approval, license, registration, permit, notification or authorizations (or waiver) of the applicable Regulatory Authority, which is necessary for the manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale, or other commercialization of pharmaceutical products in a given country or regulatory jurisdiction, other than any pricing or reimbursement approval.

1.47 "Regulatory Authority". Regulatory Authority means any Governmental Authority with responsibility for granting licenses or approvals necessary for the development, manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale or other commercialization of pharmaceutical products in a country or regulatory jurisdiction, including but limited to the FDA, EMA or MHLW.

1.48 "Regulatory Exclusivity". Regulatory Exclusivity means exclusive marketing rights or data protection or other exclusivity rights conferred by any Regulatory Authority with respect to a Product in a country or regulatory jurisdiction within the Territory, other than a Patent Right, including orphan drug exclusivity, pediatric exclusivity and rights conferred in the U.S. under the Hatch-Waxman Act.

1.49 "Satisfactory Public Offering". Satisfactory Public Offering means the firm commitment underwritten public offering of shares of common stock of Processa, par value $0.0001 per share (the "Common Stockk" pursuant to a Registration Statement on Form S-1 filed and declared effective by the SEC, as more specifically described and satisfying all of the conditions in Sections 2.

1.50 "Satisfactory Public Offering Securities". Satisfactory Public Offering Securities means shares of Common Stock issued to investors in the Satisfactory Public Offering.

1.51 "Senior Executive". Senior Executive means, with respect to Elion, the CEO of Elion, or his or her designee, and, with respect to Processa, the CEO of Processa, or his or her designee. "Senior Executives" means the applicable officers of Elion and Processa.

1.52 "Sublicensee". Sublicensee means a Third Party that has been granted a sublicense under the rights granted to Processa pursuant to Section 2.2 of this Agreement, beyond the mere right to purchase Compound or Product from Processa or its Affiliates.

1.53 "Territory". Territory means all countries of the world.

1.54 "Third Party". Third Party means any Person other than Elion or Processa or any of their respective Affiliates.

1.55 "U.S.". U.S. means the United States of America, including its territories and possessions.

1.56 "Valid Claim". Valid Claim means any claim of (a) an issued and unexpired patent within the Elion Patent Rights that has not been revoked or held unenforceable or invalid by a final decision of a court or other Governmental Authority of competent jurisdiction, or that has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise; or (b) a patent application within the Elion Patent Rights; provided that such a claim within a patent application has not been canceled, withdrawn, or abandoned or been pending for more than seven (7) years from the date of its first priority filing in the applicable country. For clarity, a claim of a patent that, pursuant to clause (b), had ceased to be a Valid Claim before it issued but that subsequently issues and is otherwise described by clause (a), shall again be considered to be a Valid Claim once it issues until it is no longer considered a Valid Claim in accordance with clause (a).

1.57 Additional Definitions. Each of the following definitions is set forth in the Section of this Agreement indicated below:

| **Definition:** | **Section:** |
|---|---|
| Abandoned Patents | Section 7.2(a) |
| Agents | Section 8.1 |
| Commercialization Plan | Section 4.2 |
| Condition Precedent | Section 2.1(a) |
| Condition Precedent Satisfaction Date | Section 2.1(a) |
| Confidential Information | Section 8.2 |
| Courts | Section 12.1 |
| Demand Registration | Section 6.2 |
| Effective Date | Preamble |
| Elion | Preamble |
| Elion Excluded Affiliates | Section 1.15 |
| Elion Parties | Section 10.1 |
| Elion Pre-Existing Affiliates | Section 1.15 |
| Elion Sole Inventions | Section 7.1(a) |
| First Tranche Shares | Section 6.1 |
| Indemnified Party | Section 10.3(a) |
| Indemnifying Party | Section 10.3(a) |
| Infringement Claim | Section 7.3(a) |
| Joint Inventions | Section 7.1(b) |
| Joint Patent Rights | Section 7.2(b) |
| Late Payment Notice | Section 6.15 |
| Litigation Conditions | Section 10.3(a) |
| MRS | Section 6.4 |
| Offering Price | Section 2.1(a) |
| Paragraph IV Claim | Section 7.8(a) |
| Periodic Report | Section 6.10 |
| Product Liability Claim | Section 10.1(b) |
| Processa | Preamble |
| Processa Excluded Affiliates | Section 1.42 |
| Processa Parties | Section 10.2 |
| Processa Pre-Existing Affiliates | Section 1.42 |
| Processa Sole Inventions | Section 7.1(a) |
| Royalty Term | Section 6.8(b) |
| Second Tranche Shares | Section 6.1 |
| Sole Inventions | Section 7.1(a) |
| Sublicensee Intellectual Property | Section 2.2(b) |
| Sublicense Materials | Section 2.2(b) |
| Taxes | Section 6.12 |
| Term | Section 11.1 |
| Third Party Claims | Section 10.1 |
| Third Party Patent Licenses | Section 6.8(c) |

1.58 Captions; Certain Conventions; Construction. All headings and captions herein are for convenience only and shall not be interpreted as having any substantive meaning. The Schedules to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. Unless otherwise expressly provided herein or the context of this Agreement otherwise requires:

(a) words of any gender include each other gender;

(b) words such as "herein", "hereof" and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear;

(c) words using the singular shall include the plural, and vice versa;

(d) the words "include," "includes" and "including" shall be deemed to be followed by the phrase "but not limited to", "without limitation", "inter alia" or words of similar import;

(e) the word "or" shall be deemed to include the word "and" (*i.e.*, shall mean "and/or")

(f) references to "Article," "Section," "subsection", "paragraph", "clause" or other subdivision, or to a Schedule, without reference to a document, are to the specified provision or Schedule of this Agreement; and

(g) references to "$" or "dollars" shall be references to U.S. Dollars.

This Agreement shall be construed as if the Parties drafted it jointly.

## ARTICLE II
## GRANTS OF RIGHTS

2.1 Condition Precedent.

(a) The grant of license rights is conditioned upon Prosessa's closing of a Satisfactory Public Offering by October 30, 2020 pursuant to which (i) Processa has raised in excess of $15,000,000 in gross proceeds from the sale of shares of its Common Stock pursuant to a firm commitment underwriting registered on a Registration Statement on Form S-1 filed and declared effective by the SEC (such price per share set forth in the applicable Registration Statement on Form S-1 which has been declared effective, the "Offering Price"), and (ii) Processa has listed its Common Stock for trading on the Nasdaq Capital Markets (collectively, the "Condition Precedent") during the Condition Precedent Period. The date on which Processa and Elion satisfy the Condition Precedent, if any, shall be the "Condition Precedent Satisfaction Date."

(b) Expiration of the Agreement. If, for any reason (including a failure to meet the conditions in Sections 2.1 prior to the end of the Condition Precedent Period) the Condition Precedent is not fully satisfied within the Condition Precedent Period, then this Agreement shall terminate in accordance with Section 11.2.

2.2 Licenses.

(a) License. Subject to the terms of this Agreement, upon Processa's satisfaction of the Condition Precedent pursuant to Section 2.1, Elion shall, and hereby does, grant to Processa an exclusive (even as to Elion and its Affiliates), royalty-bearing right and license, including the right to sublicense in accordance with Section 2.2(b), under the Elion Intellectual Property and Elion's interest in the Joint Intellectual Property, to Develop, Manufacture, use and Commercialize, including filing for, obtaining and maintaining Regulatory Approval for, Products in the Field in the Territory.

(b) Sublicenses. From and after the Condition Precedent Satisfaction Date, Processa shall have the right to grant sublicenses under the licenses to Elion Intellectual Property and Elion's interest in the Joint Intellectual Property granted to Processa under Section 2.2(a) to its Affiliates and to Third Parties subject to Elion's prior written approval; provided, however, that any such sublicense shall be subject to all applicable terms and conditions of this Agreement. Each agreement with each Sublicensee must include grants of rights to Processa sufficient to enable Processa to grant substantially the rights set forth in Sections 11.8(b) through 11.8(f) with respect to (i) all Know-How and Patent Rights (including all applicable pre-clinical and clinical data, including pharmacology and biology data; Manufacturing documents and materials; and Manufacturing technologies) Controlled by such Sublicensee during the Term and used by such Sublicensee in the Development, Manufacture or Commercialization of any Compound or Product (collectively, "Sublicensee Intellectual Property"); (ii) all filings with Regulatory Authorities in the Territory relating to Compounds and Products and Regulatory Approvals relating to Compounds and Products held by such Sublicensee, including related correspondence with Regulatory Authorities; (iii) all Manufacturing agreements to which such Sublicensee is a party that are related to Compounds or Products; (iv) all of such Sublicensee's inventory of Compounds and Products existing as of the applicable date; and (v) all trademarks owned by such Sublicensee and used solely in connection with the Products, along with all associated goodwill ((i) – (v), collectively, "Sublicense Materials").

2.3 Rights Retained by the Parties. Any rights of Elion or Processa, as the case may be, not expressly granted to the other Party under the provisions of this Agreement shall be retained by such Party.

2.4 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement, including the licenses granted under Section 2.1, 2.2 or 11.8(e) to Patent Rights and Know-How (including any data included in the Know-How), are and will otherwise be deemed to be for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined in Section 101(35A) of the Bankruptcy Code. Each Party will retain and may fully exercise all of its respective rights and elections under the Bankruptcy Code. The Parties agree that each Party, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code or any other provisions of applicable Law outside the United States that provide similar protection for "intellectual property."

2.5 Transfer of Elion Material and Know-How. During the period beginning on the Condition Precedent Satisfaction Date and ending on the date that is thirty (30) days after the Condition Precedent Satisfaction Date, Elion shall transition Elion Know-How to Processa and provide Processa with reasonable amounts of consultation regarding the transferred Elion Know-How. In addition, Elion, will transfer all material to Processa related to Eniluracil including but not limited to i) documents including communications, reports, white papers and supporting material, lab or study notes, manufacturing documents, and similar material, ii) drug substance, iii) drug product, iv) know-how related to the development of Eniluracil, and v) regulatory approvals or clearances or submissions, such as transferring the Eniluracil IND to Processa.

## ARTICLE III
## DEVELOPMENT

3.1 General. From and after the Condition Precedent Satisfaction Date, and subject to the terms of this Agreement, including the requirements of ARTICLE V, Processa (together with its Affiliates or Sublicensees) shall control and be solely responsible for the Development of and regulatory activities with respect to Compounds and Products in the Field in the Territory, including all costs and expenses relating thereto; provided, however, that, prior to the Condition Precedent Satisfaction Date, Elion will reasonably cooperate with Processa, as Processa may reasonably request and at Processa's expense, to enable Processa to interact with FDA in order to discuss the Development of and regulatory activities with respect to Compounds and Products for the indications Processa desires to pursue with respect to such Compounds and Products. If Processa requests Elion's cooperation as described above, the Parties shall mutually agree in advance on a budget therefor, and Processa shall reimburse Elion for any expenses incurred by Elion under this Section 3.1 within thirty (30) days after receiving an invoice therefor.

3.2 Exchange of Information Regarding Development. At least once each Calendar Year, beginning on the Effective Date and ending on the date on which Processa obtains the first Regulatory Approval for a Product in a Major Market, Processa shall provide Elion with a reasonably detailed report describing Processa's Development activities and the summary results thereof with respect to all Compounds and Products.

## ARTICLE IV
## COMMERCIALIZATION

4.1 General. From and after the Condition Precedent Satisfaction Date, and subject to the terms of this Agreement, including the requirements of ARTICLE V, Processa (together with its Affiliates or Sublicensees) shall control and be solely responsible for the Commercialization of Products in the Field in the Territory, including all costs and expenses relating thereto.

4.2 Commercialization Plans. During the Royalty Term with respect to each Product, at least thirty (30) days prior to the commencement of each Calendar Year, Processa shall provide Elion, for information purposes only, a summary of the planned Commercialization activities to be conducted by or on behalf of Processa and its Affiliates and Sublicensees with respect to such Product in each country in the Territory during such Calendar Year (each such plan, a "Commercialization Plan").

## ARTICLE V
## DILIGENCE

5.1 Commercially Reasonable Efforts. From and after the Condition Precedent Satisfaction Date during the Term, Processa shall, directly or through its Affiliates or Sublicensees, use Commercially Reasonable Efforts to Develop and obtain Regulatory Approval for one (1) Product in the Field in the U.S. Without limiting or derogating from the foregoing, Processa, by itself or through its Affiliates or Sublicensees, shall meet each of the following milestones within the respective time periods set forth herein:

(a) Dosing of a first patient in a Phase 1B trial for the Product within 12 months from the Condition Precedent Satisfaction Date; and

(b) Dosing of a first patient in a Phase 2 or Phase 3 trial for the Product within 48 months from the Condition Precedent Satisfaction Date.

5.2 Termination for Failure to Meet Diligence Obligations. If, at any time during the Term, Processa fails to timely achieve any of the foregoing milestones, or if Elion reasonably believes that Processa (itself and through its Affiliates and Sublicensees or assignees) has not complied with its obligations under Section 5.1, Elion shall provide written notice to Processa specifying the nature of such reasonable belief, and Elion may terminate this Agreement pursuant to Section 11.5.

**ARTICLE VI**
**FINANCIAL PROVISIONS**

6.1 Equity and Cash Upon Satisfying Condition Precedent. In partial consideration for the rights granted to Processa hereunder, if the Condition Precedent pursuant to Section 2.1 is satisfied, Processa: (a) shall pay to Elion, as Elion shall direct, $100,000 in immediately available funds within five (5) Business Days following the Condition Precedent Satisfaction Date; (b) shall issue to Elion (which may include its designees who are Affiliates of Elion ), for no additional consideration, 100,000 shares of Common Stock within twenty (20) Business Days following the Condition Precedent Satisfaction Date (the "First Tranche Shares") and (c) subject to the proviso to this sentence, shall for no additional consideration issue 400,000 shares of Common Stock (the "Second Tranche Shares") directly to a grantor trust at Elion's sole cost (the "Trust"), which shares shall be held by the trustee of such trust in a brokerage account held by Merrill Lynch or a similar brokerage firm if possible, pursuant to a grantor trust arrangement that is consistent with the principles of IRS Rev. Proc. 92-64 and IRS Notice 2000-56; provided that (x) the trustee of the grantor trust shall be required to release the Second Tranche Shares from the grantor trust to Elion (or its designees who are Affiliates of Elion) on January 15, 2021, and (y) in the case that the Offering Price is less than $8.34, then the number of Second Tranche Shares shall be increased (and therefore Processa shall cause additional Second Tranche Shares to be issued to and held by such grantor trust) to equal the sum of 100,000 shares plus the quotient obtained by dividing $2,500,000 by the Offering Price. *By way of example, if the Offering Price equals $5 per share, then the number of Second Tranche Shares issued by Processa and held by the grantor trust would equal 600,000 (which is the sum of 100,000 plus 500,000).* The First Tranche Shares and Second Tranche Shares will contain a restrictive legend that restricts the sale, transfer, or disposition of these shares ("Lock-up") as follows: 50% of the shares of Common Stock shall subject to the Lock-up for six months following the Effective Date; 25% of the shares of Common Stock shall be subject to the Lock-up for nine months following the Effective Date and the remaining 25% of the shares of Common Stock shall be subject to the Lock-up for one year following the Effective Date. In addition, the shares of Common Stock received by Elion shall contain a customary restrictive legend that specifies that such shares of Common Stock have not been registered with the Securities and Exchange Commission ("SEC") until such time as Processa shall receive a satisfactory opinion of legal counsel (which may be Processa's legal counsel) that specifies that such restrictive legend is no longer required by law; it being understood and agreed that Processa shall reimburse Elion for the reasonable costs associated with such opinion if not delivered by Processa's legal counsel.

6.2 Demand Registration. Notwithstanding the foregoing, unless a resale exemption from registration is available to Elion for the shares proposed to be transferred (such as Rule 144 of the Securities Act of 1933, as amended) pursuant to Section 6.1, at any time following the date that is one hundred and eighty (180) days following the Effective Date, Elion may request that the shares of Common Stock issued to it pursuant to this Article VI be registered for resale with the SEC from time to time by Processa (without an underwriter or placement agent) (the "Demand Registration"). Upon receipt of a Demand Registration, Processa shall use commercially reasonable efforts to register such shares for resale by Elion and shall use its commercially reasonable efforts to and keep such registration statement effective for at least 12 months (or such shorter period as will terminate when all the shares covered by the registration statement have been sold or withdrawn).

6.3 Cessation of Demand Registration. The Demand Registration right shall cease and no longer be applicable once the shares issued to Elion issued under Section 6.1 are sold or may be sold without volume limitation restrictions under Rule 144 of the Securities Act of 1933, as amended, provided, however, that if a director, officer, employee or agent of Elion should become a member of Processa's Board of Directors or employed as an Officer in Processa after the Effective Date, the Demand Registration right shall cease and no longer be applicable once the shares issued to Elion under Section 6.1 are sold or may be sold under Rule 144 of the Securities Act of 1933, as amended, in compliance with the requirements for sales by Affiliates (as defined under Rule 144). Processa agrees that the rights granted to Elion under this Article VI shall be assignable to the assignees of the shares of Common Stock of Processa who are designated by Elion and who are Affiliates of Elion provided that the Rule 144 holding period with respect to such shares is not extended as a result of such transfer (in which case, the Demand Registration right shall immediately cease with respect to such shares).

6.4 Development and Regulatory Milestone Payments. The development and regulatory milestone payments shall be provided to Elion in 2 forms: Milestone Restricted Shares which shall be identical to the shares of Common Stock which constitute the Satisfactory Public Offering Securities ("MRSs") or cash. The MRSs shall be issued within five (5) Business Days following satisfaction of the applicable Milestone Event and shall be subject to a six month Lock-up following the date of satisfaction of such applicable Milestone Event. All MRSs shall contain a customary restrictive legend that specifies that such shares of Common Stock have not been registered with the SEC until such time as Processa shall receive a satisfactory opinion of legal counsel (which may be Processa's legal counsel) that specifies that such restrictive legend is no longer required by law; it being understood and agreed that Processa shall reimburse Elion for the reasonable costs associated with such opinion if not delivered by Processa's legal counsel. Each milestone cash payment owed by Processa to Elion pursuant to this Section 6.4 shall be payable by Processa within thirty (30) days following the first achievement of the corresponding milestone event. For the avoidance of doubt each milestone payment, whether it be MRSs or cash, is only payable once, regardless of the number of times such milestone may be achieved by Processa, its Affiliates, and Sublicensees. For purposes of this Section 6.4, if the Initiation of a clinical trial of a Licensed Product satisfies more than one of the clinical milestone events below (*e.g.*, if the first clinical trial of a Licensed Product is a Pivotal Trial), then the milestone payments corresponding to both of such clinical milestone events shall be made simultaneously upon the dosing of the first patient of such clinical trial. In addition, if a given milestone event is achieved by a Licensed Product without one or more preceding milestone events having been achieved by such Licensed Product, then the milestone payments corresponding to such skipped milestone events shall be made simultaneously upon achievement of such milestone event by such Licensed Product.

| Milestone Event | Milestone Payment ($) |
|---|---|
| 1. 1st Year Anniversary of Effective Date | 100,000 MRSs |
| 2. 2nd Year Anniversary of Effective Date | 100,000 MRSs |
| 3. 1st Patient in Dose Confirmation Study | 100,000 MRSs |
| 3. NDA Submission | 300,000 MRSs |
| 4. 1st FDA Approval in US | $5,000,000 |
| 5. 2nd FDA Approval in US | $3,000,000 |
| 6. 1st Regulatory Approval Outside US | $2,000,000 |
| 7. 2nd Regulatory Approval Outside US | $2,000,000 |

6.5 Anti-Dilution from Reverse Split and Other Adjustments. Processa hereby agrees that if the Common Stock (including the First Tranche Shares and Second Tranche Shares) and MRSs issuable pursuant to this Article VI (or any securities to which such shares are converted or otherwise exchanged into as a result of any merger, consolidation or other comparable business reorganization) are the subject of any reverse stock split, stock dividend or other comparable adjustment, then Processa covenants and agrees to cause and otherwise ensure that the Common Stock (including the First Tranche Shares and Second Tranche Shares) and MRSs (and any conversion securities or other consideration) will be proportionately adjusted accordingly to achieve a result as if no such reverse stock split, stock dividend or other comparable adjustment occurred.

6.6 Development and Commercialization Costs. For clarity, following the Effective Date, Processa shall be solely responsible for all costs it incurs in Developing and Commercializing Compounds and Products, including all Manufacturing costs.

6.7 Sales Milestone Payments. Processa shall pay Elion the one-time, non-refundable, non-creditable sales milestone payments set forth in the table below within thirty (30) days after the end of the first Calendar Quarter during which the Worldwide Annual Net Sales first reach the values indicated below. For clarity, the milestone payment reached will apply once and only once when the milestone is first achieved (and more than one payment may occur in each Calendar Year). Thereafter, the milestone will no longer apply.

| Worldwide Annual Net Sales | Amount |
|---|---|
| $50M | $2,000,000 |
| $100M | $4,000,000 |
| $250M | $10,000,000 |
| $500M | $20,000,000 |
| $1 Billion | $40,000,000 |

6.8 Product Royalties.

(a) Royalty Rate. Processa shall pay to Elion royalties, on a Product-by-Product and country-by-country basis, equal to 9% of Net Sales of Products in the Territory during each Calendar Quarter during the applicable Royalty Term for the aggregate Worldwide Annual Net Sales in the Territory, subject to adjustment as provided in this Section 6.8. Upon the expiration of the Royalty Term with respect to each Product in each country, Processa shall have a fully-paid up irrevocable license with respect to such Product in such country. Notwithstanding anything to the contrary contained herein, in no event shall the royalty reductions described in this Section 6.8, alone or together, reduce the royalties payable to Elion below 4.5% of Net Sales for a Product in a country in any given Calendar Quarter; it being understood and agreed that Processa may carry over and apply any such royalty reductions, which are incurred or accrued in a Calendar Quarter and are not deducted in such Calendar Quarter due to the limitation set forth above in this 6.8(a), to any subsequent Calendar Quarter(s) and shall continue applying such reduction on a Calendar Quarter basis thereafter until fully deducted, in all cases subject to the limitation set forth in this sentence.

(b) Royalty Term and Adjustments. Processa's royalty obligations to Elion under this Section 6.8 shall commence on a country-by-country and Product-by-Product basis on the Effective Date and shall expire on a country-by-country basis and Product-by-Product basis on the latest of (i) expiration or invalidation of the last Valid Claim Covering such Product in such country and (ii) the tenth ($10^{th}$) anniversary of the date of the First Commercial Sale by Processa or any of its Affiliates or Sublicensees to a non-Sublicensee Third Party of such Product in such country and (iii) the expiration of the last Regulatory Exclusivity relating to such Product in such country (the "Royalty Term"); provided that, during any period within the Royalty Term remaining after the expiration of all Valid Claims Covering such Product in such country and all Regulatory Exclusivity as to such Product in such country, the royalties payable as to such Product in such country under this Section 6.8 shall be reduced to 4.5% of Net Sales for such Product in such country pursuant to Section 6.8.

(c) Third Party Payments. If, in the opinion of patent counsel mutually acceptable to both Processa and Elion, in order to Develop, Manufacture, use or Commercialize a Product in the Field in a country of the Territory without infringing any third party intellectual property rights relating to the Elion Intellectual Property, Processa or its Affiliate or Sublicensee is obligated to obtain a license or comparable grant of rights (*e.g.*, a covenant not to sue) under any Patent Rights from a Third Party ("Third Party Patent Licenses") and pay a royalty under such Third Party Patent License with respect to such Product in such country, then, subject to Section 6.8, forty percent (40%) of such royalties actually paid by Processa, its Affiliates or Sublicensees shall be creditable against royalties payable to Elion hereunder with respect to such Product in such country; provided that, if Processa is obligated to enter into any Third Party Patent License, Processa shall use Commercially Reasonable Efforts to minimize the royalties owed by Processa under such Third Party Patent License.

6.9 Sublicense. Subject to the examples provided below, if (a) Processa sub-licenses all rights to the Product in any country in the Territory to a Third Party, Elion shall receive thirty-three percent (33%) of any Sublicense Consideration including Development and Regulatory Milestones (Section 6.4 and 6.5), Sales Milestones (Section 6.7) and Product Royalties (Section 6.8); and (b) notwithstanding the foregoing, in the event that Processa receives Sublicense Consideration on account of a specific Product, then in such case Processa shall be required to pay Elion thirty-three percent (33%) of all Sublicense Consideration within thirty (30) days of receipt, but shall not be required to pay Development and Regulatory Milestone Payment (Section 6.4 and 6.5) or Sales Milestone Payment (Section 6.7) or Product Royalties (Section 6.8) on account of such specific Product in addition to the Sublicense Payments. To clarify, three example scenarios are presented:

Example 1: If Processa Develops the Product and receives Regulatory Approval in multiple countries in the Territory and licenses out the commercial sales to Sublicensee in these multiple countries in the Territory such that Processa no longer retains any rights to commercialize the Product in these multiple countries in the Territory, then the financial terms of this ARTICLE VI would then be the following: Sections 6.4 - 6.5 would apply, Sections 6.7 - 6.8 would no longer apply, and this Section 6.9 would apply such that Processa shall pay Elion thirty-three percent (33%) of all Sublicense Consideration.

Example 2: If Processa Develops and Commercializes the Product in US while Sublicensing the Product for Development and Commercialization in other territories, then the financial terms of ARTICLE VI would then be the following: Sections 6.4 - 6.5 would apply, Sections 6.7 - 6.8 would only apply to the countries in the Territory in which Processa Commercializes the Product, and this Section 6.9 would apply such that Processa shall pay Elion thirty-three percent (33%) of all Sublicense Consideration.

Example 3: If Processa sublicenses the Product prior to Phase 3 trial prior to any Regulatory Approval of the Product and Sublicensee completes Development, obtains Regulatory Approval, and Commercializes the Product, then the financial terms of ARTICLE VI would then be the following: for Sections 6.4 – 6.5 Processa would pay for milestones that it has completed, the remaining milestones of Section 6.4 – 6.5 not completed by Processa would no longer apply, Sections 6.7 – 6.8 would not apply, and this Section 6.9 would apply such that Processa shall pay Elion thirty-three percent (33%) of all Sublicense Consideration.

"Sublicense Considerations" shall mean any payments or other consideration that Processa or its Affiliates receive as a direct result of the grant of a sublicense or an option to obtain such sublicense, including without limitation license fees, license option fees, milestone payments, license maintenance fees and equity and other securities (including earnouts and contingent value rights and other comparable deferred payment mechanisms), provided that in the event that Processa or its Affiliates receive non-monetary consideration in connection with a sublicense, Sublicense Considerations shall be calculated based on the fair market value of such consideration or transaction, assuming an arm's length transaction made in the ordinary course of business. Notwithstanding the foregoing, "Sublicense Considerations" shall not include: (a) Net Sales or (b) amounts expressly dedicated to, and actually expended upon to reimburse Processa and its Affiliates, following any such sublicense, for, the Development of Products, up to the actual costs incurred by Processa and its Affiliates for such activities. Processa shall pay Elion the sublicense fee within thirty (30) days after the receipt of the Sublicense Consideration.

6.10 Reports; Payments. Within thirty (30) days after the end of each Calendar Quarter commencing from the earlier of (a) the First Commercial Sale of a Product; or (b) the grant of a sublicense or receipt of Sublicense Consideration, Processa shall furnish Elion with a quarterly report ("Periodic Report") detailing, at a minimum, the following information for the applicable Calendar Quarter, each listed by Product and by country of sale: (i) the total number of units of Product sold by Company, its Affiliates and Sublicensees for which royalties are owned to Elion hereunder, including a breakdown of the number and type of Products sold, (ii) gross amounts received for all such sales, (iii) deductions by type taken from Net Sales as specified herein, (iv) Net Sales, (v) Royalties and milestone payments owed to Elion, listed by category, (vi) Sublicense Consideration received during the preceding Calendar Quarter and sublicense fees due to Elion, (vii) the currency in which the sales were made, including the computations for any applicable currency conversions, (viii) invoice dates and all other data enabling the royalties and sublicense fees payable to be calculated accurately and (ix) a detailed summary of progress against each development and commercial milestone, and an estimate of the timing of the achievement of the next development and commercial milestone. Once the events set forth in sub-section (a) or (b), above, have occurred, Periodic Reports shall be provided to Elion whether or not royalties, milestone payments or sublicense fees are payable for a particular Calendar Quarter. In addition to the foregoing, upon Elion's reasonable request, Processa will provide to Elion such other information as may be reasonably requested by Elion, and will otherwise cooperate with Elion as reasonably necessary, to enable Elion to verify Processa's compliance with the payment and related obligations under this Agreement, including verification of the calculation of amounts due to Elion under this Agreement and of all financial information provided or required to be provided in the Periodic Reports. Concurrently with each such report, Processa shall pay to Elion all amounts payable by it under Sections 6.4, 6.7, 6.8 and 6.9.

6.11 Books and Records; Audit Rights. Processa shall keep complete and accurate records of the underlying revenue and expense data relating to the calculations of Net Sales and payments required by 6.4, 6.7, 6.8 and 6.9. Elion shall have the right, once annually at its own expense, to have an independent, certified public accounting firm, selected by Elion and reasonably acceptable to Processa, review any such records of Processa in the location(s) where such records are maintained by Processa upon reasonable notice (which shall be no less than fourteen (14) days prior notice) and during regular business hours and under obligations of strict confidence, for the sole purpose of verifying the basis and accuracy of payments made under 6.4, 6.7, 6.8 and 6.9 within the thirty-six (36) month period preceding the date of the request for review. The report of such accounting firm shall be limited to a certificate stating whether any report made or payment submitted by Processa during such period is accurate or inaccurate and the actual amounts of Net Sales, milestone payments, Sublicense Consideration and royalties due, for such period. Processa shall receive a copy of each such report concurrently with receipt by Elion. Should such inspection lead to the discovery of a discrepancy to Elion's detriment, Processa shall pay within five (5) Business Days after its receipt from the accounting firm of the certificate the amount of the discrepancy plus interest calculated in accordance with Section 6.15. Elion shall pay the full cost of the review unless the underpayment of royalties is greater than five percent (5%) of the amount due for any applicable Calendar Year, in which case Processa shall pay the reasonable cost charged by such accounting firm for such review. Any overpayment by Processa revealed by an examination shall be fully creditable against future Payments.

6.12 Tax Matters. All payments to be made to Elion by Processa hereunder shall be reduced by or on account of any taxes, levies, imposts, duties, charges, value added taxes ("VAT"), assessments or fees (collectively, "Taxes") that are required by any applicable Law (with due regard to any relief to which Elion may be entitled) that Taxes be deducted and withheld from any payment made to Elion by Processa under this Agreement. If any such applicable Law requires (with due regard to any relief to which Elion may be entitled) that Taxes be deducted and withheld from any payment made to Elion by Processa under this Agreement, Processa shall (a) deduct those Taxes, together with any interest and penalties properly assessed thereon, from such payment or from any other payment owed by Processa hereunder; (b) transmit the amounts so deducted to the proper Governmental Authority; (c) send evidence of the requirement together with proof of due transmission of the amounts described in clause (b) to Elion promptly following such payment; and (d) remit to Elion the net amount of such payment remaining after the payment of such Taxes. In determining whether to deduct any amount hereunder and prior to making such deduction, Processa shall contact Elion and reasonably consider the documentation supplied by Elion, and of other facts known to Processa, supporting a reduction in any Tax otherwise required to be deducted, or a credit therefor or refund thereof. Processa will reasonably cooperate with Elion in respect of Tax matters relating to payments made by Processa to Elion under this Agreement and any disputes with a Governmental Authority regarding such matters (at Elion's sole cost and expense), including without limitation: (y) complying with reasonable requests from Elion to change the form, place or other circumstances of payments to be made to Elion by Processa under this Agreement so as to reduce the incidence of Taxes on such payments or recover any Taxes imposed on such payments (any such recovery to be for the benefit of Elion); and (z) in connection with any official or unofficial audit or contest relating to such payments. Notwithstanding anything in this Agreement to the contrary, if any failure to comply with applicable Laws or filing or record retention requirements by a Party leads to the imposition of withholding Tax liability or VAT on the other Party that would not have been imposed in the absence of such action or in an increase in such liability above the liability that would have been imposed in the absence of such action, then (i) the sum payable by that Party (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that the other Party receives a sum equal to the sum which it would have received had no such action occurred, and (ii) otherwise, the sum payable by that Party (in respect of which such deduction or withholding is required to be made) shall be made to the other Party after deduction of the amount required to be so deducted or withheld, which deducted or withheld amount shall be remitted in accordance with applicable Law.

6.13 Payment Method and Currency Conversion All Payments shall be made in U.S. dollars in immediately available funds via either a bank wire transfer, an ACH (automated clearing house) mechanism, or any other means of electronic funds transfer, at Processa's election, to Elion's bank account, or to such other bank account as Elion shall designate in a notice at least ten (10) days before the payment is due. For the purposes of determining the amount of any royalties or other payments due for the relevant Calendar Quarter under this Agreement, the amount of Net Sales in any foreign currency shall be converted into U.S. dollars in accordance with the prevailing rates of exchange for the relevant month for converting such first currency into such other currency used by Processa's (or its Sublicensee's) internal accounting systems, which are independently audited on an annual basis. Upon request by Elion, Processa shall disclose the bases for the rates of exchange used for purposes of assuring that such rates reflect prevailing rates of exchange.

6.14 Blocked Payments. If by reason of applicable Laws in any country in the Territory, it becomes impossible or illegal for Processa or its Affiliates or Sublicensees to transfer, or have transferred on its behalf royalties or other payments to Elion or to Processa or its Affiliates or Sublicensees, Processa shall promptly notify Elion of the conditions preventing such transfer. To the extent any payments to Elion cannot be transferred pursuant to the preceding sentence, such amounts shall be deposited in local currency in the relevant country to the credit of Elion in a recognized banking institution designated by Elion or, if none is designated by Elion within a period of thirty (30) days, in a recognized banking institution selected by Processa or its Affiliate or Sublicensee, as the case may be, and identified in a notice given to Elion. If so deposited in a foreign country, Processa shall provide, or cause its Affiliate or Sublicensee to provide, reasonable cooperation to Elion so as to allow Elion to assume control over such deposit as promptly as practicable.

6.15 Late Payments. If a Party shall fail to make a timely payment pursuant to the terms of this Agreement, the other Party shall provide written notice of such failure to the non-paying Party (a "Late Payment Notice"), and interest shall accrue on the past due amount starting on the date of the Late Payment Notice at an annual rate equal to the "prime rate", as reported by The Wall Street Journal, plus five percent (5%).

**ARTICLE VII**
**INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION AND RELATED MATTERS**

7.1 Ownership of Inventions.

(a) Sole Inventions. Each Party shall exclusively own all inventions relating to any Compound or Product or its manufacture or use made solely by such Party, its employees, agents, and consultants ("Sole Inventions"). Sole Inventions made solely by Processa, its employees, agents and consultants are referred to herein as "Processa Sole Inventions". Sole Inventions made solely by Elion, its employees, agents and consultants are referred to herein as "Elion Sole Inventions". For clarity, products Covered by Processa Sole Inventions shall be deemed Products for the purpose of this Agreement.

(b) Joint Inventions. The Parties shall jointly own all inventions relating to any Compound or Product or its manufacture or use made jointly by employees, agents and consultants of Processa, on the one hand, and employees, agents and consultants of Elion, on the other hand, on the basis of each Party having an undivided interest in the whole ("Joint Inventions"). Joint Inventions may only be used in accordance with and subject to the terms and conditions of this Agreement.

(c) Inventorship. For purposes of determining whether an invention is a Processa Sole Invention, an Elion Sole Invention or a Joint Invention, questions of inventorship shall be resolved in accordance with United States patent Laws.

7.2 Prosecution and Maintenance of Patent Rights.

(a) Prosecution of Elion Patent Rights. With respect to Elion Patent Rights, Elion and Processa shall cooperate in good faith in connection with the continued prosecution and maintenance by Elion of such Elion Patent Rights. If Processa satisfies the Condition Precedent pursuant to Section 2.1, the out-of-pocket costs and expenses incurred by Elion after the Condition Precedent Satisfaction Date to obtain, prosecute and maintain Elion Patent Rights shall be borne one hundred percent (100%) by Processa. Elion shall notify Processa at least ninety (90) days prior to the deadline for entering into national phase with respect to any PCT application included in Elion Patent Rights. No later than sixty (60) days prior to entry into national phase, Processa shall provide Elion with a list of any countries in which Processa would like Elion to file. Elion shall file international patent applications, or designate for national filing and file, in all countries requested by Processa. Elion shall promptly deliver to Processa copies of all official correspondence with the applicable patent and trademark offices in the Territory relating to the Elion Patent Rights and, after the Condition Precedent Satisfaction Date shall promptly provide Processa drafts of all proposed material filings and correspondence to any patent authority with respect to the Elion Patent Rights for Processa's review and comment prior to the submission of such proposed filings and correspondences. Elion shall keep Processa informed of the status of all pending patent applications that pertain to any Compound or Product. Elion, its agents and attorneys shall not unreasonably decline to implement or incorporate any comments of Processa regarding any aspect of such patent prosecutions. Elion shall not abandon any Elion Patent Rights (the "Abandoned Patents") without at least ninety (90) days' prior notice to Processa. If Elion decides to abandon any Elion Patent Rights, Processa shall have the option to continue to prosecute and maintain the Abandoned Patents in Elion's name.

(b) Prosecution of Joint Patent Rights. Processa shall be responsible for obtaining, prosecuting, and/or maintaining patents and patent applications, in any countries in the Territory, Covering Joint Inventions ("Joint Patent Rights"). The out-of-pocket costs and expenses incurred to obtain, prosecute and maintain Joint Patent Rights shall be borne one-hundred percent (100%) by Processa. Processa shall keep Elion informed of the status of all pending Joint Patent Rights. Processa, its agents and attorneys shall not unreasonably decline to implement or incorporate any comments of Elion regarding any aspect of such patent prosecutions. Processa shall not abandon any Joint Patent Right without at least ninety (90) days' prior notice to Elion. If Processa decides to abandon any Joint Patent Right, Elion shall have the option to continue to prosecute and maintain such Joint Patent Right jointly in both Parties' names, at Elion's sole expense.

(c) Prosecution of Processa Patent Rights. Processa has the sole right, but not the responsibility, to obtain, prosecute, and/or maintain the Processa Patent Rights. Processa shall keep Elion informed of the status of all pending Processa Patent Rights. Processa, its agents and attorneys shall not unreasonably decline to implement or incorporate any comments of Elion regarding any aspect of such patent prosecutions. Processa shall not abandon any Processa Patent Right without at least ninety (90) days' prior notice to Elion. If Processa decides to abandon any Processa Patent Right, Elion shall have the option to continue to prosecute and maintain such Processa Patent Right jointly in both Parties' names, at Elion's sole expense.

(d) Cooperation. Each Party agrees to cooperate fully in the preparation, filing, prosecution, and maintenance of Elion Patent Rights, Joint Patent Rights, and Processa Patent Rights, pursuant to this Section 7.2 and in the obtaining and maintenance of any patent term extensions, supplementary protection certificates, pediatric extensions, and their equivalent with respect thereto. Such cooperation includes: (i) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, so as enable the other Party to apply for and to prosecute patent applications in any country as permitted by this Section 7.2; and (ii) promptly informing the other Party of any matters coming to such Party's attention that may affect the preparation, filing, prosecution, or maintenance of any such patent applications.

7.3 Third Party Infringement.

(a) Notice. Each Party shall promptly report in writing to the other Party during the Term any known or suspected (i) infringement of any of the Elion Patent Rights, Processa Patent Rights or Joint Patent Rights, or (ii) unauthorized use or misappropriation of any of the Elion Know-How, Processa Sole Invention or Joint Inventions, in the case of either clause (i) or clause (ii), that would reasonably be expected to adversely impact the (A) Development, Manufacture, use or Commercialization of a Compound or Product in the Field in the Territory, or (B) the valid scope of the rights licensed to Processa under ARTICLE II (an " Infringement Claim"), of which such Party becomes aware, and shall provide the other Party with all available evidence supporting such Infringement Claim.

(b) Initial Right to Enforce. Subject to Section 7.3(c), Processa (itself or through its Affiliate or Sublicensee) shall have the first right, but not the obligation, to initiate a suit, or take other appropriate action that it believes is reasonably required to protect (*i.e.*, prevent or abate actual or threatened infringement or misappropriation of) or otherwise enforce the Processa Intellectual Property, Elion Intellectual Property and Joint Intellectual Property with respect to an Infringement Claim; provided, however, that Processa shall (i) consult with Elion in good faith with respect to any claim that any Elion Patent Right, Processa Patent Right or Joint Patent Right is invalid or unenforceable and (ii) implement any reasonable comment from Elion regarding any aspect of defending against any such claim described in clause (i). Any such suit by Processa shall be brought either in the name of Elion or its Affiliate, the name of Processa or its Affiliate, or the names of Processa, Elion and their respective Affiliates, as may be required by the Law of the forum. For this purpose, Elion shall execute such legal papers and cooperate in the prosecution of such suit, including providing full access to documents, information and witnesses as reasonably requested by Processa in connection with such suit, as may be reasonably requested by Processa; provided that Processa shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by Elion in connection with such cooperation. For clarity, as between Elion and Processa, (A) Elion shall have the sole right, but not the obligation, to protect Elion Intellectual Property against any suspected misappropriation or infringement that does not constitute an Infringement Claim and (B) the Parties shall jointly determine by mutual agreement whether and how to protect Joint Intellectual Property against any suspected misappropriation or infringement that does not constitute an Infringement Claim, and the provisions of this ARTICLE VII shall not apply with respect thereto.

(c) Step-In Right. If Processa does not initiate a suit or take other appropriate action that it has the initial right to initiate or take with respect to an Infringement Claim pursuant to Section 7.3(b), then Elion may, in its discretion, provide Processa with notice of Elion's intent to initiate a suit or take other appropriate action. If Elion provides such notice and Processa does not initiate a suit or take such other appropriate action within thirty (30) days after receipt of such notice from Elion, then Elion shall have the right to initiate a suit or take other appropriate action that it believes is reasonably required to protect the Processa Intellectual Property, Elion Intellectual Property and Joint Intellectual Property. Any suit by Elion shall be either in the name of Elion or its Affiliate, the name of Processa or its Affiliate, or the names of Processa, Elion, and their respective Affiliates, as may be required by the Law of the forum. For this purpose, Processa shall execute such legal papers and cooperate in the prosecution of such suit, including providing full access to documents, information and witnesses as reasonably requested by Elion in connection with such suit, as may be reasonably requested by Elion; provided that Elion shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by Processa in connection with such cooperation.

(d) Conduct of Certain Actions; Costs. The Party initiating suit or taking other action with respect to an Infringement Claim shall have the sole and exclusive right to select counsel for, and otherwise control, any suit or action initiated by it pursuant to Section 7.3(b) or 7.3(c). The initiating Party shall assume and pay all of its own out-of-pocket costs incurred in connection with any litigation or proceedings initiated by it pursuant to Sections 7.3(b) and 7.3(c), including the fees and expenses of the counsel selected by it. The other Party shall have the right to participate, but not control, and be represented in, any such suit by its own counsel at its own expense.

(e) Recoveries. Except as otherwise agreed by the Parties as part of a cost-sharing arrangement, any damages, settlements, accounts of profits, or other financial compensation recovered from a Third Party by the Party that assumes control over enforcing any Infringement Claim shall be allocated between the Parties as follows:

(i) first, to reimburse the Parties' actual out-of-pocket expenses (including reasonable counsel fees and expenses) incurred in pursuing such Infringement Claim; and

(ii) second, if Processa controlled the defense of the Infringement Claim any remaining amount shall be shared by the Parties, with Processa retaining 75% of such remaining amount and Elion retaining 25% of such remaining amount. If Elion controlled the defense of the Infringement Claim any remaining amount following reimbursement of expenses under clause (i) shall be retained by Elion.

7.4 Patent Invalidity Claim. Each of the Parties shall promptly notify the other in the event of any legal or administrative action by any Third Party against an Elion Patent Right, Processa Patent Right or Joint Patent Right of which it becomes aware, including any nullity, revocation, reexamination or compulsory license proceeding. Elion shall have the first right, but not the obligation, to defend against any such action involving an Elion Patent Right, and the costs of any such defense shall be at Elion's expense; provided, however, that, in the case of any *inter partes* review or similar post-grant matter before the Patent Trial and Appeal Board or similar administrative body that is based on the same subject matter as any claim or counterclaim in any Infringement Claim or Paragraph IV Claim, Processa shall have the first right, but not the obligation, to defend against any such action involving an Elion Patent Right, and the costs of any such defense shall be at Processa's expense. Processa shall have the first right, but not the obligation, to defend against any such action involving a Processa Patent Right or Joint Patent Right, and the costs of any such defense shall be at Processa's expense. If the Party that has the first right to defend against any such action involving such Elion Patent Right, Processa Patent Right or Joint Patent Right does not do so, then the other Party shall have the right, but not the obligation, to defend such action and any such defense shall be at such other Party's expense. Upon request of the Party that defends against any such action involving an Elion Patent Rights, Processa Patent Right or Joint Patent Right, the other Party agrees to join in any such action and to cooperate reasonably with the defending Party, including providing full access to documents, information and witnesses as reasonably requested by the defending Party in connection with such action, provided that the defending Party shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by the other Party in connection with such cooperation.

7.5 Claimed Infringement. Each of the Parties shall promptly notify the other in the event a Party becomes aware that the practice by either Party of the Elion Patent Rights infringes, or is suspected or alleged to infringe, the intellectual property rights of any Third Party in the Territory, and shall promptly provide the other Party with any notice it receives or has received from a Third Party related to such suspected, alleged or actual infringement.

7.6 Patent Term Extensions. Processa shall have the exclusive right and obligation to seek patent term extensions or supplemental patent protection, including supplementary protection certificates, in each country in the Territory in relation to the Products at Processa's expense. Elion and Processa shall cooperate in connection with all such activities, and Processa, its agents and attorneys will give due consideration to all timely suggestions and comments of Elion regarding any such activities; provided that all final decisions shall be made by Processa.

7.7 Patent Marking. Processa shall comply with the patent marking statutes in each country in the Territory in which any Product is sold by Processa, its Affiliates, or its Sublicensees.

7.8 Certification under Drug Price Competition and Patent Restoration Act.

(a) Notice. If a Party becomes aware of any certification filed pursuant to 21 U.S.C. § 355(b)(2)(A) or 355(j)(2)(A)(vii)(IV) or its successor provisions, or any similar provision in any country in the Territory other than the U.S., claiming that any Elion Patent Rights, Processa Patent Rights or Joint Patent Rights are invalid or otherwise unenforceable, or that infringement will not arise from the manufacture, use, import or sale of a product by a Third Party (a "Paragraph IV Claim"), such Party shall promptly notify the other Party in writing within five (5) Business Days after its receipt thereof.

(b) Control of Response; Recoveries. Processa shall have the first right, but not the obligation, to initiate and control patent infringement litigation for any Paragraph IV Claim; provided, however, that Processa shall (i) consult with Elion in good faith with respect to any claim that any Elion Patent Right, Processa Patent Right or Joint Patent Right is invalid or unenforceable and (ii) implement any comment from Elion regarding any aspect of defending against any such claim. Any suit by Processa shall be brought either in the name of Elion or its Affiliate, the name of Processa or its Affiliate, or the names of Processa, Elion, and their respective Affiliates, as may be required by the Law of the forum. For this purpose, Elion shall execute such legal papers and cooperate in the prosecution of such suit, including providing full access to documents, information and witnesses, as may be reasonably requested by Processa; provided that Processa shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by Elion in connection with such cooperation. If Processa elects not to assume control over litigating any Paragraph IV Claim, Processa shall notify Elion as soon as practicable but in any event not later than ten (10) days before the first action required to litigate such Paragraph IV Claim so that Elion may, but shall not be required to, assume sole control over litigating such Paragraph IV Claim using counsel of its own choice. Any suit by Elion shall be either in the name of Elion or its Affiliate, the name of Processa or its Affiliate, or the names of Processa, Elion, and their respective Affiliates, as may be required by the Law of the forum. For this purpose, Processa shall execute such legal papers and cooperate in the prosecution of such suit, including providing full access to documents, information and witnesses, as may be reasonably requested by Elion; provided that Elion shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by Processa in connection with such cooperation. Any compensation recovered as a result of such litigation shall be allocated as set forth in Section 7.3(e) above.

7.9 Privileged Communications. In furtherance of this Agreement, it is expected that Processa and Elion will, from time to time, disclose to one another privileged communications with counsel, including opinions, memoranda, letters, and other written, electronic and verbal communications. Such disclosures are made with the understanding that they shall remain confidential, that they will not be deemed to waive any applicable attorney-client or attorney work product or other privilege and that they are made in connection with the shared community of legal interests existing between Elion and Processa, including the community of legal interests in avoiding infringement of any valid, enforceable patents of Third Parties and maintaining the validity of Elion Patent Rights, Processa Patent Rights and Joint Patent Rights.

7.10 Settlement. Neither Party shall unilaterally enter into any settlement or compromise of any suit, action or proceeding under this ARTICLE VII that would in any manner alter, diminish, or be in derogation of the other Party's rights under this Agreement without the prior written consent of such other Party, which shall not be unreasonably withheld.

## ARTICLE VIII
## CONFIDENTIAL INFORMATION

8.1 Treatment of Confidential Information. During the Term and for five (5) years thereafter, each Party shall maintain Confidential Information (as defined in Section 8.2) of the other Party in confidence, and shall not disclose, divulge or otherwise communicate such Confidential Information to others (except for agents, directors, officers, employees, consultants, subcontractors, licensees, sublicensees, partners, Affiliates and advisors who have a need to know such information to perform obligations or exercise rights on behalf of such Party (collectively, "Agents") under obligations of confidentiality no less stringent than those set forth in this ARTICLE VIII) or use it for any purpose other than in connection with the Development, Manufacture, use or Commercialization of Compounds or Products pursuant to this Agreement or otherwise to accomplish the purposes of this Agreement, including exercising its rights or performing its obligations hereunder, and each Party shall exercise Commercially Reasonable Efforts to prevent and restrain the unauthorized disclosure of such Confidential Information by any of its Agents, which efforts shall be at least as diligent as those generally used by such Party in protecting its own confidential and proprietary information, and in any event no less than reasonable efforts. Each Party will be responsible for any breach of this ARTICLE VIII by its Agents. Either receiving Party may disclose Confidential Information of the disclosing Party (a) to Governmental Authorities in order to comply with applicable Laws, respond to inquiries, requests or investigations by Governmental Authorities, including filing, prosecuting or maintaining Patent Rights as permitted by this Agreement; (b) to comply with the regulations or requirements of any stock exchange; (c) to the extent useful to Develop, Manufacture, use or Commercialize any Compound or Product, including making regulatory filings for any Compound or Product, in accordance with this Agreement; (d) to the extent necessary or useful in order to defend or prosecute litigation; and (e) to potential and actual *bona fide* investors, acquirors and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition or collaboration; provided that (x) with respect to any disclosure in accordance with Section 8.1(a), (b) or (d), the receiving Party shall promptly provide prior notice of such disclosure to the disclosing Party and use Commercially Reasonable Efforts to avoid or minimize the degree of such disclosure, (y) with respect to any disclosure in accordance with Section 8.1(a) or (d), the receiving Party will use efforts to secure confidential treatment of such Confidential Information at least as diligent as such Party would use to protect its own confidential information, but in no event less than reasonable efforts, and (z) with respect to any disclosure in accordance with Section 8.1(e), the receiving Party shall obtain the same confidentiality obligations from any Third Parties to which it discloses the Confidential Information of the disclosing Party as it obtains with respect to its own similar types of confidential information, and in any event such obligations shall be no less stringent than those set forth in this ARTICLE VIII.

8.2 Confidential Information. "Confidential Information" means all trade secrets or other proprietary information, including any proprietary data and materials (whether or not patentable or protectable as a trade secret), that is disclosed by a Party to the other Party. Notwithstanding the foregoing, there shall be excluded from the foregoing definition of Confidential Information any of the foregoing that:

(a) either before or after the date of the disclosure to the receiving Party is lawfully disclosed to the receiving Party by a Third Party without any violation of any obligation to the other Party; or

(b) either before or after the date of the disclosure to the receiving Party, becomes published or generally known to the public through no fault or omission on the part of the receiving Party or its Agents; or

(c) is independently developed by or for the receiving Party without reference to or reliance upon the disclosing Party's Confidential Information as demonstrated by contemporaneous written records of the receiving Party.

8.3 Publications. The Parties recognize the desirability of publishing and publicly disclosing the results of clinical trials of pharmaceutical products. Accordingly, subject to coordination through designated representatives of each Party, Processa shall be free to publicly disclose the results of clinical trials involving Compounds or Products, subject to prior review by Elion for issues of patentability and protection of its Confidential Information, in a manner consistent with all Laws applicable to Processa and best industry practices. In addition, if Processa intends to publish articles in scientific or medical journals or to make presentations of the results of clinical trials involving Compounds or Products, Processa shall provide Elion through the designated representatives of each Party at its earliest opportunity with any proposed abstracts, manuscripts or summaries of presentations that cover the results of Development of any Compound or Product. Elion shall respond promptly through its designated representative, and in any event no later than thirty (30) days after receipt of such proposed publication or presentation, or such shorter period as may be required by the publication. If timely requested by Elion, Processa agrees to allow a reasonable period (not to exceed sixty (60) days) to permit filings for patent protection and to otherwise address issues of Confidential Information or related competitive harm to the reasonable satisfaction of Elion. In addition, Processa will consider in good faith any comments furnished by Elion to Processa during such period. Processa shall be responsible to assure that its Affiliates and licensees agree to, and comply with, equivalent undertakings in favor of Elion. Elion and its Affiliates may make any publication or public disclosure of any data concerning the Compounds or Products that existed as of the Effective Date, provided that Elion provides Processa at least thirty (30) days (or such shorter period as may be required by the publication) to review such publication or public disclosure, allows a reasonable period (not to exceed sixty (60) days) to permit filings for patent protection and to otherwise address issues of Confidential Information or related competitive harm to the reasonable satisfaction of Processa, and reasonably considers any timely comments provided by Processa with respect to such publication or public disclosure. Elion shall not, and shall cause each of its Affiliates, licensees, and sublicensees not to, make any other publications or public disclosures regarding the Compounds or Products without Processa's prior written consent. If Processa consents to Elion making such publications, Elion shall provide Processa a reasonable opportunity to comment on any such publications and such comments shall not be unreasonably rejected. All publications involving Compounds or Products shall include appropriate acknowledgement consistent with standard scientific practice of any contributions of each Party to the results being publicly disclosed.

8.4 Press Releases and Other Disclosures. The Parties recognize that each Party may from time to time desire to issue press releases and make other public statements or disclosures regarding the subject matter of this Agreement. In such event, the Party desiring to issue a press release or make a public statement or disclosure shall provide the other Party with a copy of the proposed press release, statement or disclosure for review and approval in advance (except that neither Party shall have any obligation to disclose or approve the disclosure of Confidential Information except to the extent required or permitted pursuant to this ARTICLE VIII). No other public statement or disclosure concerning the existence or terms of this Agreement shall be made, either directly or indirectly, by either Party, without first obtaining the written approval of the other Party. Once any public statement or disclosure has been approved in accordance with this Section 8.4, then either Party may appropriately communicate information contained in such permitted statement or disclosure. Notwithstanding the foregoing provisions of this Section 8.4 this ARTICLE VIII, a Party may (a) disclose the existence and terms of this Agreement where required, as reasonably determined by the disclosing Party, by applicable Law, by applicable stock exchange regulation or by order or other ruling of a competent court and (b) disclose the existence and terms of this Agreement under obligations of confidentiality no less stringent than those set forth in this ARTICLE VIII to agents, advisors, contractors, licensees, sublicensees, and *bona fide* investors, acquirors and other financial or commercial partners, and to potential agents, advisors, contractors, licensees, sublicensees, and *bona fide* investors, acquirors and other financial or commercial partners. To the extent a Party determines in good faith that it is required by applicable Law to publicly file, register or notify this Agreement with a Governmental Authority, including public filings pursuant to securities Laws, it shall provide a proposed redacted form of the Agreement to the other Party a reasonable amount of time prior to filing for the other Party to review such draft and propose changes to such proposed redactions. The Party making such filing, registration or notification shall incorporate any proposed changes timely requested by the other Party, absent a reasonable basis for not making such changes, and shall use Commercially Reasonable Efforts to seek confidential treatment for any terms that the other Party timely requests be kept confidential, to the extent such confidential treatment is reasonably available consistent with applicable Law. Each Party shall be responsible for its own legal and other external costs in connection with any such filing, registration, or notification.

8.5 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that a Party would suffer upon unauthorized disclosure, use, or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages would not be a sufficient remedy for any breach of this ARTICLE VIII. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this ARTICLE VIII.

## ARTICLE IX
## REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 Elion's Representations. Elion hereby represents and warrants as of the Effective Date as follows:

(a) Elion has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder. The execution, delivery, and performance of this Agreement has been duly and validly authorized and approved by all necessary corporate action on the part of Elion. Elion has taken all other action required by Law, its certificate of incorporation or by-laws, or any agreement to which it is a party or by which it or its assets are bound, to authorize such execution, delivery, and performance. Assuming due authorization, execution, and delivery on the part of Processa, this Agreement constitutes a legal, valid, and binding obligation of Elion, enforceable against Elion in accordance with its terms.

(b) The execution and delivery of this Agreement by Elion do not require Elion to obtain any permit, authorization or consent from any Governmental Authority or from any other Person which has not been obtained prior to the Effective Date, and such execution and delivery by Elion will not result in the breach of or give rise to any termination of, rescission, renegotiation or acceleration under or trigger any other rights under any agreement or contract to which Elion may be a party that relates to the Elion Patent Rights or the Elion Know-How.

(c) Schedule 1.16 is a complete and correct list of all Patent Rights owned by Elion as of the Effective Date that Cover any Compound or Product. No Patent Right that covers any Compound or Product has been licensed to Elion.

(d) Elion is the legal and beneficial owner of all the Patent Rights identified onSchedule 1.16, free and clear of any liens, mortgages, security interests or other similar encumbrances. All assignments to Elion of ownership rights relating to such Patent Rights are valid and enforceable. All of the Patent Rights listed identified on Schedule 1.16 that are issued patents are in full force and effect, and all applicable filing, maintenance and other fees required to be paid to a patent office with respect to the Patent Rights listed identified on Schedule 1.16 have been timely paid. Elion has the right to grant the licenses granted by it in this Agreement and has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the Elion Intellectual Property in a manner that conflicts with any rights granted to Processa hereunder.

(e) There is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to Elion's knowledge, threatened against Elion in connection with the Compounds or Products or any Elion Patent Rights, Elion Know-How or against or relating to the transactions contemplated by this Agreement. Elion has not received any written notice from a Third Party that the Development of any Compound or Product conducted by Elion has infringed, or that any Development or Commercialization of any Compound or Product will infringe, any Patent Rights of any Third Party.

(f) No claim or action has been brought or, to Elion's knowledge, threatened by any Third Party alleging that the Elion Patent Rights are invalid or unenforceable, and no Elion Patent Rights are the subject of any litigation, interference, post-grant review, opposition, cancellation or other proceeding challenging the validity or enforceability of the Elion Patent Rights.

(g) Neither Elion nor, to the knowledge of Elion, any of its directors, officers, employees, agents or subcontractors has been convicted of any crime or engaged in any conduct that has resulted in, or would reasonably be expected to result, in debarment by the FDA under 21 U.S.C. § 335a or any similar state or foreign Law.

(h) The shares of Common Stock of Processa that may be issued under this Agreement shall be acquired for investment for Elion's own account (or that of its permitted designee), not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and as of the date hereof, Elion (or, if applicable, its permitted designee) has no present intention of selling, granting any participation or otherwise distributing the shares. Elion, either alone or together with its Affiliates and representatives, has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the shares, and has so evaluated the merits and risks of such investment. Elion (or, if applicable, its permitted designee) is able to bear the economic risk of an investment in the shares and, at the present time, is able to afford a complete loss of such investment. Elion (or, if applicable, its permitted designee) is not acquiring the shares as a result of (a) any advertisement, article, notice or other communication published in any newspaper, magazine or similar media or broadcast over television, radio or the Internet, in each case, relating to Processa, or (b) any seminar or meeting whose attendees, including Elion, have been invited by any general solicitation or general advertising related to Processa.

(i) Elion (or, if applicable, its permitted designee) is as of the date hereof, and as of the date any shares are issued under this Agreement will be, an "accredited investor" as defined in Rule 501 under the Securities Act of 1933, as amended.

(j) Elion (or, if applicable, its permitted designee) acknowledges that it has had the opportunity to review the reports filed by Processa with the SEC and has been afforded, (i) the opportunity to ask such questions as it has deemed necessary of, and to receive answers from, representatives of Processa concerning the terms and conditions of the offering of the shares of Common Stock hereby and the merits and risks of investing in the shares; (ii) access to information about Processa and its financial condition, results of operations, business, properties, management and prospects sufficient to enable it to evaluate its investment; and (iii) the opportunity to obtain such additional information that Processa possesses or can acquire without unreasonable effort or expense that is necessary to make an informed investment decision with respect to the investment.

9.2 Processa's Representations. Processa hereby represents and warrants as of the Effective Date as follows:

(a) Processa has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder. The execution, delivery, and performance of this Agreement has been duly and validly authorized and approved by all necessary corporate action on the part of Processa. Processa has taken all other action required by Law, its certificate of incorporation or by-laws or any agreement to which it is a party or by which it or its assets are bound to authorize such execution, delivery and (subject to obtaining all necessary governmental approvals with respect to the Development, Manufacture, use and Commercialization of Compounds and Products) performance. Assuming due authorization, execution, and delivery on the part of Elion, this Agreement constitutes a legal, valid, and binding obligation of Processa, enforceable against Processa in accordance with its terms.

(b) The execution and delivery of this Agreement by Processa will not violate any U.S. Law or, to Processa's knowledge, any Law of any Governmental Authority outside the U.S.

(c) There is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to the knowledge of Processa, threatened against Processa in connection with or relating to the transactions contemplated by this Agreement.

(d) The execution and delivery of this Agreement do not require Processa to obtain any permit, authorization or consent from any Governmental Authority or from any other Person, and such execution and delivery by Processa will not result in the breach of or give rise to any termination of, rescission, renegotiation or acceleration under or trigger any other rights under any agreement or contract to which Processa may be a party that relates to the Products, Processa Patent Rights or Processa Know-How.

(e) Neither Processa nor, to the knowledge of Processa, any of its directors, officers, employees, agents or subcontractors has been convicted of any crime or engaged in any conduct that has resulted in, or would reasonably be expected to result, in debarment by the FDA under 21 U.S.C. § 335a or any similar state or foreign Law.

9.3 Elion Covenants. Elion covenants and agrees during the Term that, subject to Processa's, its Affiliates' and Sublicensees' performance of their obligations under this Agreement:

(a) Elion shall not grant to any Third Party any rights that would be inconsistent or conflict with Processa's rights hereunder.

(b) Subject to Section 12.7, Elion shall not assign, transfer, convey, or otherwise encumber its right, title, and interest in the Elion Intellectual Property in a manner that conflicts with any rights granted to Processa hereunder.

9.4 Processa Covenant.

(a) Processa shall conduct, and shall use Commercially Reasonable Efforts to cause its contractors and consultants to conduct, all of their activities contemplated under this Agreement in accordance with all applicable Laws of the country in which such activities are conducted, including applicable requirements of "good laboratory practices", "good clinical practices" and "good manufacturing practices", as applicable, as defined by the FDA.

(b) Subject to Section 12.7, Processa shall not assign, transfer, convey, or otherwise encumber its right, title, and interest in the Processa Intellectual Property in a manner that conflicts with any rights granted hereunder to Elion upon termination.

9.5 No Warranty. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED. IN PARTICULAR, BUT WITHOUT LIMITATION, EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY CONCERNING WHETHER ANY OF THE COMPOUNDS OR PRODUCTS ARE FIT FOR ANY PARTICULAR PURPOSE OR SAFE FOR HUMAN CONSUMPTION.

## ARTICLE X
## INDEMNIFICATION

10.1 Indemnification in Favor of Elion. Processa shall indemnify, defend and hold harmless the Elion Parties from and against any and all Losses incurred, suffered or sustained by any of the Elion Parties or to which any of the Elion Parties becomes subject as a result of any Third Party claim, action, suit, proceeding, liability or obligation (which in no event includes any claim by any Processa Party or any Elion Party) (collectively, "Third Party Claims") arising out of, relating to or resulting from:

(a) any misrepresentation or breach of any representation, warranty, covenant or agreement made by Processa in this Agreement; or

(b) the Development Manufacture or Commercialization of Compounds or Products by Processa, its Affiliates or Sublicensees, including all Third Party Claims involving death or bodily injury caused or allegedly caused by the use of such a Compound or Product, and even if such a Compound or Product is altered for use for a purpose not intended (any and all such Third Party Claims "Product Liability Claims"); or

(c) any actual or alleged infringement of any trademark, Patent Right or other intellectual property right, or misappropriation of any trade secret, of any Third Party as a result of the Development, Manufacture or Commercialization of Compounds or Products by Processa, its Affiliates or Sublicensees; or

(d) the gross negligence or willful misconduct of any of the Processa Parties (as hereinafter defined) in connection with Processa's performance of this Agreement.

For purposes of this ARTICLE X, "Elion Parties" means Elion, its Affiliates and their respective agents, directors, officers, licensees, sublicensees and employees.

The indemnification obligations set forth in this Section 10.1 shall not apply to the extent that any Loss is the result of (i) a breach of any representation, warranty, covenant, or agreement made by Elion in this Agreement or (ii) the gross negligence or willful misconduct of any applicable Elion Party.

10.2 Indemnification in Favor of Processa. Elion shall indemnify, defend and hold harmless the Processa Parties from and against any and all Losses incurred, suffered or sustained by any of the Processa Parties or to which any of the Processa Parties becomes subject as a result of any Third Party Claim arising out of, relating to or resulting from:

(a) any misrepresentation or breach of any representation, warranty, covenant or agreement made by Elion in this Agreement; or

(b) the Development, Manufacture or Commercialization of Compounds or Products by Elion, its Affiliates, licensees (excluding Processa) or sublicensees prior to the execution of this Agreement and after any termination of this Agreement, including all Product Liability Claims arising out of any such pre-Agreement, post-termination Development, Manufacture or Commercialization by Elion, its Affiliates, licensees (excluding Processa) or sublicensees; or

(c) any actual or alleged infringement of any trademark, Patent Right or other intellectual property right, or misappropriation of any trade secret, of any Third Party as a result of the Development, Manufacture or Commercialization of Compounds or Products by Elion, its Affiliates, licensees (excluding Processa) or sublicensees prior to the execution of this Agreement and after any termination of this Agreement; or

(d) the gross negligence or willful misconduct of any of the Elion Parties in connection with Elion's performance of this Agreement; or

(e) the formation of the Trust, issuance of the shares of Common Stock to the Trust for the benefit of Elion as provided in Section 6.1 or as a result of the shares of Common Stock being held in such Trust.

For purposes of this ARTICLE X, "Processa Parties" means Processa, its Affiliates and their respective agents, directors, officers, licensees, sublicensees and employees.

The indemnification obligations set forth in this Section 10.2 shall not apply to the extent that any Loss is the result of (i) a breach of any representation, warranty, covenant, or agreement made by Processa in this Agreement, or (ii) the gross negligence or willful misconduct of any applicable Processa Party.

10.3 General Indemnification Procedures.

(a) An Elion Party or Processa Party seeking indemnification pursuant to this ARTICLE X (an "Indemnified Party") shall give prompt notice to the Party from whom such indemnification is sought (the "Indemnifying Party") of the commencement or assertion of any Third Party Claim in respect of which indemnity may be sought hereunder, shall give the Indemnifying Party such information with respect to any indemnified matter as the Indemnifying Party may reasonably request, and shall not make any admission concerning any Third Party Claim, unless such admission is required by applicable Law or legal process, including in response to questions presented in depositions or interrogatories. Any admission made by the Indemnified Party or the failure to give such notice shall relieve the Indemnifying Party of any liability hereunder only to the extent that the ability of the Indemnifying Party to defend such Third Party Claim is prejudiced thereby (and no admission required by applicable Law or legal process shall be deemed to result in prejudice). The Indemnifying Party will have the right, exercisable by notice to the Indemnified Party within ten Business Days after receipt of notice from the Indemnified Party of the commencement of or assertion of any Third Party Claim, to assume direction and control of the defense, litigation, settlement, appeal or other disposition of the Third Party Claim (including the right to settle the claim solely for monetary consideration) with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party; provided that (a) the Indemnifying Party has sufficient financial resources, in the reasonable judgment of the Indemnified Party, to satisfy the amount of any adverse monetary judgment that is sought, (b) the Third Party Claim seeks solely monetary damages and (c) the Indemnifying Party expressly agrees in writing that as between the Indemnifying Party and the Indemnified Party, the Indemnifying Party will be solely obligated to satisfy and discharge the Third Party Claim in full (the conditions set forth in clauses (a), (b) and (c) above are collectively referred to as the "Litigation Conditions"). Within ten Business Days after the Indemnifying Party has given notice to the Indemnified Party of its exercise of its right to defend a Third Party Claim, the Indemnified Party will give notice to the Indemnifying Party of any objection thereto based upon the Litigation Conditions. If the Indemnified Party reasonably so objects, the Indemnified Party will continue to defend the Third Party Claim, at the expense of the Indemnifying Party, until such time as such objection is withdrawn. If no such notice is given, or if any such objection is withdrawn, the Indemnifying Party will be entitled, at its sole cost and expense, to assume direction and control of such defense, with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party. During such time as the Indemnifying Party is controlling the defense of such Third Party Claim, the Indemnified Party will cooperate, and will cause its Affiliates and agents to cooperate upon request of the Indemnifying Party, in the defense or prosecution of the Third Party Claim, including by furnishing such records, information and testimony and attending such conferences, discovery proceedings, hearings, trials or appeals as may reasonably be requested by the Indemnifying Party. In the event that the Indemnifying Party does not satisfy the Litigation Conditions or does not notify the Indemnified Party of the Indemnifying Party's intent to defend any Third Party Claim within ten Business Days after notice thereof, the Indemnified Party may (without further notice to the Indemnifying Party) undertake the defense thereof with counsel of its choice and at the Indemnifying Party's expense (including reasonable, out-of-pocket attorneys' fees and costs and expenses of enforcement or defense). The Indemnifying Party or the Indemnified Party, as the case may be, will have the right to join in (including the right to conduct discovery, interview and examine witnesses and participate in all settlement conferences), but not control, at its own expense, the defense of any Third Party Claim that the other party is defending as provided in this Agreement.

(b) Any Indemnified Party or Indemnifying Party not managing the defense of a Third Party Claim shall have the right to participate in (but not control), at its own expense (subject to the immediately succeeding sentence), the defense. The Indemnifying Party managing the defense shall not be liable for any litigation cost or expense incurred, without its consent, by the Indemnified Party where the action or proceeding is under the control of such Indemnifying Party; provided, however, that, if the Indemnifying Party managing the defense fails to take reasonable steps necessary to defend such Third Party Claim, the Indemnified Party may assume its own defense, and the Indemnifying Party managing the defense will be liable for all reasonable costs or expenses paid or incurred in connection therewith.

(c) The Indemnifying Party shall not, except with the consent of the Indemnified Party, consent to a settlement of, or the entry of any judgment against, an Indemnified Party arising from any Third Party Claim to the extent such settlement or judgment involves equitable or other non-monetary relief from the Indemnified Party. No Party shall, without the prior written consent of the other Party or the Indemnified Party, enter into any compromise or settlement that commits the other Party or the Indemnified Party to take, or to forbear to take, any action.

(d) The Parties shall cooperate in the defense or prosecution of any Third Party Claim and shall furnish such records, information and testimony, and attend such conferences, discovery proceedings, hearings, trials and appeals, as may be reasonably requested in connection therewith; provided, however, that the Indemnifying Party shall reimburse the Indemnified Party for any out-of-pocket expenses actually and reasonably incurred in connection with any such cooperation.

(e) Any indemnification hereunder shall be made net of any insurance proceeds actually recovered by the Indemnified Party from unaffiliated Third Parties; provided, however, that if, following the payment to the Indemnified Party of any amount under this ARTICLE X, such Indemnified Party recovers any such insurance proceeds in respect of the claim for which such indemnification payment was made, the Indemnified Party shall promptly pay an amount equal to the amount of such proceeds (but not exceeding the amount of such net indemnification payment) to the Indemnifying Party.

(f) The Parties agree and acknowledge that the provisions of this ARTICLE X represent the Indemnified Party's exclusive recourse with respect to any Losses for Third Party Claims for which indemnification is provided to the Indemnified Party under this ARTICLE X.

10.4 Insurance. During the Term, if the Condition Precedent is satisfied, and thereafter for so long as a Third Party Claim may be brought for which Processa must indemnify Elion pursuant to Section 10.1, Processa shall obtain and maintain, at its sole cost and expense, product liability insurance in amounts that are reasonable and customary in the pharmaceutical industry, but in no event less than $5 million per occurrence or claim, and $10 million in the aggregate, or a comparable program of self-insurance. Such product liability insurance shall insure against all liability, including product liability and property damage arising out of the Development, use or Commercialization of Compounds and Products by Processa, its Affiliates, or Sublicensees in the Territory. Without limiting the generality of the foregoing, Processa shall maintain comprehensive general liability insurance, including product liability insurance, to cover its activities and, unless its Affiliates and Sublicensees maintain comparable coverage, the activities of its Affiliates and Sublicensees, with respect to Compounds and Products. Processa shall provide satisfactory evidence of adequate insurance coverage to Elion upon the request of Elion prior to the Condition Precedent Satisfaction Date and, upon the written request of Elion, concurrent with any renewal or replacement of such coverage.

## ARTICLE XI
## TERM AND TERMINATION

11.1 Term. The term of this Agreement (the "Term") shall commence on the Effective Date and, unless earlier terminated as provided in this ARTICLE XI, shall continue in full force and effect until the expiration of the last Royalty Term. On a country-by-country and Product-by-Product basis, upon the expiration of the Royalty Term in such country with respect to such Product, Processa shall have a fully paid-up, perpetual, irrevocable license under the Elion Intellectual Property and Elion's interest in the Joint Intellectual Property with respect to such Product in such country.

11.2 Termination for Failure to Satisfy Condition Precedent. If, for any reason (including a failure to meet the conditions in Section 2.1 prior to end of the Condition Precedent Period), the Condition Precedent is not fully satisfied within the Condition Precedent Period, then this Agreement shall automatically terminate in its entirety on the day after the last day of the Condition Precedent Period.

11.3 Termination for Convenience. Processa shall have the right upon sixty (60) days prior written notice to Elion to terminate this Agreement in its entirety for any reason.

11.4 Termination for Cause. In the event of a material breach of this Agreement by a Party, the other Party may give the Party in default notice requiring it to cure such default, which notice shall specify the nature of the breach. If such material breach is not cured within ninety (90) days after receipt of such notice (or within fifteen (15) days in the case of a payment breach), the notifying Party shall be entitled (without prejudice to any other rights conferred on it by this Agreement or under applicable Law) to terminate this Agreement by giving written notice to the defaulting Party. The right of either Party to terminate this Agreement as set forth in this Section 11.4 shall not be affected in any way by its waiver of, or failure to take action with respect to, any previous default.

11.5 Additional Termination by Elion. In the event that Elion has provided written notice to Processa pursuant to Section 5.2, if (a) Processa does not respond to Elion in writing within sixty (60) days of receipt of such notice from Elion and reasonably demonstrate in such response compliance with Processa's obligations under Section 5.1, or (b) Processa has failed to comply with Section 5.1 (a) or Section 5.1(b), Elion shall be entitled (without prejudice to any other rights conferred on it by this Agreement or under applicable Law) to terminate this Agreement with immediate effect by giving written notice to Processa.

11.6 Termination for Insolvency. This Agreement may be terminated by a Party upon written notice to the other Party if (a) the other Party shall make a general assignment for the benefit of its creditors, file a petition in bankruptcy, petition or apply to any tribunal for the appointment of a custodian, receiver or trustee for it or a substantial part of its assets, or shall commence any proceeding under any bankruptcy, reorganization, readjustment of debt, dissolution or liquidation law or statute of any jurisdiction, whether now or hereafter in effect; or (b) if there shall have been filed against the other Party any such *bona fide* petition or application, or any such proceeding shall have been commenced against it, in which an order for relief is entered or that remains undismissed or unstayed for a period of ninety (90) days or more; or (c) if the other Party by any act or omission shall consent to, approve of or acquiesce in any such petition, application or proceeding or order for relief or the appointment of a custodian, receiver or trustee for it or any substantial part of its assets, or shall suffer any such custodianship, receivership or trusteeship to continue undischarged or unstayed for a period of ninety (90) days or more. Termination shall be effective upon the date specified in such notice.

11.7 Termination for Challenge of Elion Patent Rights. If Processa or any of Processa's Affiliates or Sublicensees commences an action in any court or tribunal of competent jurisdiction that challenges, opposes or disputes the validity, enforceability or patentability of any Elion Patent Rights, or any of the claims thereof, or supports or assists any Third Party that commences such an action in any such court or tribunal, Elion shall have the right to terminate this Agreement upon notice to Processa; provided, however, that Elion shall not have a right to terminate if the challenge is brought by a Sublicensee, either directly or indirectly through any Third Party, and Processa or the Affiliate, as the case may be, terminates such Sublicensee's sublicense rights hereunder within thirty (30) days after becoming aware of such challenge.

11.8 Consequences of Termination. If this Agreement (w) terminates automatically pursuant to Section 11.2, (x) is terminated by Elion under Section 11.4, 11.5, 11.6 or 11.7, (y) is terminated by Processa under Section 11.3, or (z) is terminated by Processa under Section 11.4 or 11.6, then the licenses granted to Processa in Section 2.2 and, except as provided in this Section 11.8 and Sections 11.9 and 11.10 (and any Articles and Sections referenced therein), all other rights and obligations of the Parties under this Agreement shall terminate. Upon a termination described in clause (x) (but not clause (w), (y) or (z)) of this Section 11.8, clause (a) shall apply, and, upon a termination described in clause (w), (x) or (y) (but not clause (z)), Processa shall grant, and shall cause any applicable Affiliate to grant, Elion any combination of the following clauses (b) through (f) elected by Elion, provided that (i) upon a termination described in clause (w), only clause (c) and, to the extent that any Processa Intellectual Property, Sublicensee Intellectual Property or Joint Intellectual Property exists as of such termination, clause (e) shall apply, and (ii) Processa shall only be required to grant Elion rights to Sublicensee Materials under the applicable sublicense agreement(s) with Sublicensee(s) to whom Elion has not granted a direct license pursuant to Section l1.8(a):

(a) Sublicenses. Elion hereby grants, effective automatically upon any termination of this Agreement by Elion pursuant to Section 11.4, 11.5, 11.6 or 11.7, a direct license to each then-existing Sublicensee, provided that (i) such Sublicensee is not in breach under the applicable sublicense, (ii) such Sublicensee's failure to comply with the terms of its sublicense or other actions or omissions were not a basis for such termination, and (iii) such Sublicensee continues to satisfy all obligations under this Agreement applicable to such sublicense, including the diligence obligations set forth in ARTICLE V and all payments to Elion required under Section 6, from and after the date that such direct license becomes effective.

(b) Regulatory Matters. Ownership of all filings with Regulatory Authorities in the Territory relating to Compounds and Products and Regulatory Approvals relating to Compounds and Products held Processa or its Affiliates or applicable Sublicensees, including related correspondence with Regulatory Authorities, and Processa shall provide copies thereof to Elion;

(c) Pre-clinical and Clinical Matters. Possession of all pre-clinical and clinical data, including pharmacology and biology data, within the Processa Know-How and applicable Sublicensee Intellectual Property;

(d) Manufacturing Matters. At Elion's option, to be exercised no later than the later of (x) thirty (30) days after the effective date of termination or (y) thirty (30) days after Elion's receipt of the applicable Manufacturing agreements,

(i) use of Commercially Reasonable Efforts by Processa and its Affiliates and applicable Sublicensees to effect the assignment of each Manufacturing agreement specific and exclusive to Compounds or Products to Elion, if such agreement is then in effect and such assignment is permitted under such agreement or by the applicable Third Party; provided that Processa and its applicable Affiliates and applicable Sublicensees shall be released to the extent the applicable Third Party will permit from any obligation arising out of such agreement following such assignment and Elion shall execute such documentation reasonably satisfactory to Processa to effectuate such agreement; provided further that if any such agreement is specific but not exclusive to Compounds or Products, or is not assigned to Elion for any reason, Processa will discuss in good faith with Elion terms upon which Processa and its Affiliates and applicable Sublicensees shall use Commercially Reasonable Efforts to provide Elion with the benefits of such agreement to the extent it relates to Compounds or Products for a limited period of time (not to exceed six (6) months) and upon payment of a reasonably acceptable fee to Processa;

(ii) for a period of up to six (6) months following the effective date of termination, (A) cooperation with Elion in reasonable respects to transfer Manufacturing documents and materials within the Processa Know-How and applicable Sublicensee Intellectual Property that are used (at the time of the termination) by Processa or its Affiliates or applicable Sublicensees exclusively in the Manufacture of Compounds and Products to the extent such Manufacturing documents and materials are not obtained by Elion pursuant to the assignment of agreements pursuant to paragraph (i) above, and (B) cooperation with Elion to provide Elion with reasonable access to and right to use such Manufacturing documents and materials in Processa's or its Affiliates' or applicable Sublicensees' possession or Control to the extent they relate to, but are not used exclusively in, the Manufacture of Compounds and Products, subject to appropriate confidentiality and limitation on use protections applicable to for Manufacturing documents and materials;

(iii) for a period of up to six (6) months following the effective date of termination, (A) cooperation with Elion in reasonable respects to transfer Manufacturing technologies within the Processa Intellectual Property and applicable Sublicensee Intellectual Property that are used (at the time of the termination) by Processa or its Affiliates or applicable Sublicensees exclusively in the Manufacture of Compounds and Products, and (B) cooperation with Elion to provide Elion with reasonable access to and right to use such Manufacturing technologies Controlled by Processa or its Affiliates (other than Processa Excluded Affiliates) or applicable Sublicensees to the extent they relate to, but are not used exclusively in, the Manufacture of Compounds and Products and that Processa or such Affiliates or Sublicensees are permitted to provide such access to Elion; provided that Elion shall reimburse Processa for Processa's reasonable out-of-pocket expenses to provide such requested assistance, to the extent such Manufacturing technologies are not obtained by Elion pursuant to the assignment of agreements pursuant to paragraph (i) above; and

(iv) sale of Processa's or its Affiliates' or applicable Sublicensees' then-existing inventory of Compounds and Products to Elion, at Processa's or its applicable Affiliates' or applicable Sublicensees' cost of Manufacture, but only if the following conditions have been met: (A) such Compounds and Products meet the applicable release specifications; and (B) Processa does not reasonably believe the continued use of such Compounds and Products causes safety concerns;

(e) License Grant. At Elion's option, to be exercised by written notice to Processa no later than thirty (30) days after the effective date of termination, a worldwide license, with the right to sublicense, under the Processa Patent Rights, Processa Know-How, Processa's interest in the Joint Intellectual Property, and applicable Sublicensee Intellectual Property, solely to make, have made, use, sell, offer for sale and import Compounds and Products in the Field that were Developed or Commercialized prior to the effective date of termination, which license would be, at Elion's election, either (i) non-exclusive, fully paid-up, non-royalty-bearing, irrevocable and perpetual or (ii) exclusive and royalty-bearing subject to mutual agreement by Elion and Processa on commercially reasonable terms; provided that, notwithstanding the foregoing, with respect to any Processa Patent Rights or Processa Know-How that Processa acquired from a Third Party (by license or otherwise), or any applicable Sublicensee Intellectual Property that the applicable Sublicensee(s) acquired from a Third Party (by license or otherwise), Processa or the applicable Sublicensee(s) shall only be required to grant to Elion a license to such Processa Patent Rights, Processa Know-How or Sublicensee Intellectual Property to the extent permitted under the applicable agreement with such Third Party, and Elion shall pay Processa or such Sublicensee or such Third Party, as determined by Processa, any payment due to such Third Party relating to the Compounds and Products; provided further that Elion shall execute such documentation reasonably satisfactory to Processa to effectuate such agreement; and if the license granted to Elion is exclusive, Elion shall have the same enforcement rights with respect to any Processa Patent Rights and Patent Rights within the Sublicensee Intellectual Property that exclusively Cover Products that are licensed to Elion pursuant to this Section 11.8(e) as Processa has with respect to Infringement Claims pursuant to Section 7.3 (to the extent that Processa or the applicable Sublicensee(s) have such rights with respect to such Processa Patent Rights or Patent Rights within the Sublicensee Intellectual Property, as applicable), provided that any enforcement of Processa Patent Rights, Joint Patent Rights or Patent Rights within the Sublicensee Intellectual Property that Cover subject matter other than such Products shall be performed by Elion only with the consultation and prior agreement of Processa or the applicable Sublicensee, which such agreement shall not unreasonably withheld, delayed or conditioned.

(f) Assignment of Trademarks. Assign to Elion all of Processa's or its applicable Sublicensees' right, title and interest in any trademark owned by Processa or its Affiliates or applicable Sublicensees and used solely in connection with the Products, along with all associated goodwill.

11.9 Effect of Termination or Expiration; Accrued Rights and Obligations. Termination or expiration of this Agreement for any reason shall not release either Party from any liability that, at the time of such termination or expiration, has already accrued or that is attributable to a period prior to such termination (including payment obligations accrued prior to the effective date of termination or expiration pursuant to ARTICLE VI) nor preclude either Party from pursuing any right or remedy it may have hereunder or at Law or in equity with respect to any breach of this Agreement.

11.10 Survival. The rights and obligations set forth in this Agreement shall extend beyond the Term or termination or expiration of this Agreement only to the extent expressly provided for in this Agreement or to the extent required to give effect to a termination or expiration of this Agreement or the consequences of a termination or expiration of this Agreement as expressly provided for in this Agreement. Without limiting the generality of the foregoing, it is agreed that the provisions of ARTICLE I, Sections 2.3, 2.4, 6.11 (only for thirty-six (36) months after expiration or termination), 6.121, 6.132, 6.143, 6.15, 7.1, 7.9, 8.1, 8.2, 8.5, 9.5, ARTICLE X, and Sections 11.1 (last sentence as to any such license that became perpetual and irrevocable prior to expiration or termination), 11.8, 11.9, 11.10 and ARTICLE XII shall survive expiration or termination of this Agreement for any reason.

## ARTICLE XII
## MISCELLANEOUS

12.1 Governing Law; Jurisdiction. This Agreement shall be governed by and interpreted in accordance with the laws of the State of New York, without regard to its conflicts of laws rules. Each Party (a) irrevocably submits to the exclusive jurisdiction in the state court sitting in New York City, New York (collectively, the " Courts"), for purposes of any action, suit or other proceeding arising out of this Agreement, and (b) agrees not to raise any objection at any time to the laying or maintaining of the venue of any such action, suit or proceeding in any of the Courts, irrevocably waives any claim that such action, suit or other proceeding has been brought in an inconvenient forum and further irrevocably waives the right to object, with respect to such action, suit or other proceeding, that such Court does not have any jurisdiction over such Party. Either Party may serve any process required by such Courts by way of notice under this Agreement. Notwithstanding anything to the contrary in this Section 12.1, each Party shall have the right to institute judicial proceedings against the other Party or anyone acting by, through, or under such other Party, in any court of competent jurisdiction, in order to enforce the instituting Party's rights hereunder through reformation of contract, specific performance, injunction, or similar equitable relief.

12.2 Dispute Resolution. In the event of a dispute arising out of or relating to this Agreement, either Party shall provide written notice of the dispute to the other, in which event the dispute shall be referred to the Senior Executives of each Party, for attempted resolution by good faith negotiations within twenty (20) days after such notice is received. In the event the Senior Executives do not resolve such dispute within the allotted twenty (20) days, either Party may, after the expiration of the twenty (20) day period, seek to resolve the dispute in accordance with Section 12.1.

12.3 Waiver. Waiver by a Party of a breach hereunder by the other Party shall not be construed as a waiver of any succeeding breach of the same or any other provision. No delay or omission by a Party to exercise or avail itself of any right, power, or privilege that it has or may have hereunder shall operate as a waiver of any right, power, or privilege by such Party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.

12.4 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address specified in this Section 12.4 and shall be: (a) delivered personally; (b) sent by registered or certified mail, return receipt requested, postage prepaid; (c) sent via a reputable nationwide overnight courier service; or (d) sent by facsimile or other electronic transmission. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service, or when transmitted with confirmation of receipt, if transmitted by facsimile or other electronic transmission (if such transmission is on a Business Day; otherwise, on the next Business Day following such transmission).

Notices to Processa shall be addressed to:

Processa Pharmaceuticals, Inc.
7380 Coca Cola Drive, Suite 106
Hanover, MD 21076
Attn: Wendy Guy, Chief Administrative Officer
Email: wguy@processapharmaceuticals.com

Notices to Elion shall be addressed to:

Elion Oncology, Inc.
4800 Hampden Lane
Bethesda, MD 20814
Attn: Chief Executive Offer

With a copy to:

Dechert LLP
1900 K Street, NW
Washington, DC 20006
Attn: David E. Schulman

Either Party may change its address by giving notice to the other Party in the manner provided above.

12.5 Entire Agreement. This Agreement (including Schedules) contains the complete understanding of the Parties with respect to the subject matter of this Agreement and supersedes all prior understandings and writings between the Parties relating to such subject matter.

12.6 Severability. If any provision of this Agreement is held unenforceable by a court or tribunal of competent jurisdiction because it is invalid or conflicts with any Law of any relevant jurisdiction, the validity of the remaining provisions shall not be affected. In such event, the Parties shall negotiate a substitute provision that, to the extent possible, accomplishes the original business purpose.

12.7 Assignment. Neither this Agreement nor any right or obligation hereunder may be assigned or otherwise transferred by any Party without the consent of the other Party; provided, however, that any Party may, without such consent, assign this Agreement, in whole or in part: (a) to any of its respective Affiliates,provided that such Affiliate has acknowledged and confirmed in writing that effective as of such assignment, such Affiliate shall be bound by this Agreement to the identical extent applicable to the assigning Party and the assignor confirms to the non-assigning party that it shall remain liable as if no such liability had occurred; or (b) to any successor in interest by way of merger, acquisition or sale of all or substantially all of its business or assets relating to the subject matter of this Agreement, provided that such successor (if the applicable Party is not the surviving entity in such transaction) agrees in writing to be bound by the terms of this Agreement to the identical extent applicable to the assigning Party. Any purported assignment in violation of this Section 12.7 shall be void. Subject to this Section 12.7, any permitted assignee shall assume all obligations of its assignor under this Agreement.

12.8 Counterparts; Exchange by Facsimile. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and that together shall constitute one and the same instrument. Such counterparts may be exchanged by facsimile or PDF (provided that each executed counterpart is transmitted in one complete transmission or electronic mail message). Where there is an exchange of executed counterparts by facsimile or PDF, each Party shall be bound by the Agreement notwithstanding that original copies of the Agreement may not be exchanged immediately. The Parties shall cooperate after execution of the Agreement and exchange by facsimile or PDF to ensure that each Party obtains an original executed copy of this Agreement with reasonable promptness.

12.9 Force Majeure. No Party shall be liable for failure of or delay in performing obligations set forth in this Agreement, and no Party shall be deemed in breach of its obligations, if such failure or delay is due to a natural disaster, explosion, fire, flood, tornadoes, pandemic, quarantine, thunderstorms, earthquake, war, terrorism, riots, embargo, losses or shortages of power, labor stoppage, substance or material shortages, damage to or loss of product in transit not due to a failure by such Party or its Affiliates to exercise reasonable care, events caused by reason of Laws of any Governmental Authority, events caused by acts or omissions of a Third Party not induced or solicited by such Party or its Affiliates, or any other cause reasonably beyond the control of such Party or its Affiliates; provided that such Party uses Commercially Reasonable Efforts to overcome the difficulties created by such force majeure event and to resume performance of its obligations as soon as practicable.

12.10 Third-Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party other than an Elion Party or a Processa Party, as applicable, that is an Indemnified Party under ARTICLE X, and no Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against either Party.

12.11 Relationship of the Parties. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other, except as expressly provided in this Agreement. Neither Party shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said other Party's approval. For all purposes and notwithstanding any other provision of this Agreement to the contrary, the legal relationship under this Agreement of each Party to the other Party shall be that of independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint venturers between the Parties.

12.12 Performance by Affiliates. To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations.

12.13 No Consequential or Punitive Damages. NEITHER PARTY WILL BE LIABLE FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, OR PUNITIVE DAMAGES, INCLUDING LOST PROFITS, ARISING FROM OR RELATING TO THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTHING IN THIS SECTION 12.13 IS INTENDED TO LIMIT OR RESTRICT (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY UNDER THIS AGREEMENT WITH RESPECT TO THIRD PARTY CLAIMS, OR (B) DAMAGES TO WHICH A PARTY MAY BE ENTITLED FOR BREACH OF CONFIDENTIALITY AND LIMITATION ON USE OBLIGATIONS SET FORTH IN THIS AGREEMENT, OR (C) DAMAGES TO WHICH A PARTY MAY BE ENTITLED FOR THE WILLFUL MISCONDUCT, INTENTIONAL BREACH OR FRAUD OF THE OTHER PARTY.

*[Signature page follows]*

IN WITNESS WHEREOF, the Parties have signed this Agreement as of the Effective Date.

**PROCESSA PHARMACEUTICALS, INC.**

By: 
Name: David Young
Title: CEO

**ELION ONCOLOGY, INC.**

By: 
Name: R. Michael Floyd
Title: Chief Executive Officer

Issued:

- U.S. Patent - 8,658,618; Granted 2014: Methods for preventing or reducing neurotoxicity associated with administering DPD inhibitors in combination with 5-FU and 5-FU prodrugs.
- US Patent - 8,318,756; Granted 2012: Methods for administering DPD inhibitors in combination with 5-FU and 5-FU prodrugs.
- Orphan Drug Designation for Eniluracil in Hepatocelluar Carcinomas; Granted in 2005: ADH300004 (ENILURACIL) IN COMBINATION WITH FLUOROPYRIMIDINES FOR THE TREATMENT OF PATIENTS WITH HEPATOCELLULAR CARCINOMA

Filed:

- Formulation patents on formulation of Extended Release Colon Targeted delivery of drugs (May 2018) and ERCT5-FU and Use with Eniluracil (July 2018)

To Be Filed Patents:

- Draftsm pending patents of all other Eniluarcil and DPD related patents.

**Exhibit 21.1**

Subsidiaries of Processa Pharmaceuticals, Inc.

| Subsidiary | State of Incorporation | Percent Ownership |
|---|---|---|
| Processa Therapeutics LLC | Delaware | 100% |

**Exhibit 23.2**

**Consent of Independent Registered Public Accounting Firm**

We hereby consent to the inclusion in this Amendment No. 2 to Registration Statement No. 333-235511 on Form S-1 and the related prospectus of our report dated March 6, 2020, of our audit of the consolidated financial statements of Processa Pharmaceuticals, Inc. as of and for the years ended December 31, 2019 and 2018. We also consent to the reference to our firm under the caption "Experts" in such Registration Statement.

*/s/ BD & Co.*

Owings Mills, MD
September 16, 2020