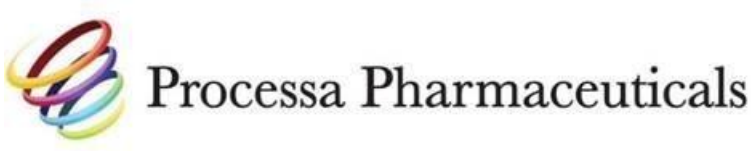
Filed Pursuant to Rule 424(b)(4)
Registration No. 333-235511



4,800,000 Shares of Common Stock

This is a firm commitment public offering of 4,800,000 shares of our common stock at a public offering price of $4.00 per share.

Prior to this offering, there has been a limited public market for our common stock on the OTCQB® Market, or OTCQB. On September 28, 2020, the last reported sale price of our common stock as reported on the OTCQB was $10.98 per share. Our common stock has been approved for listing on the Nasdaq Capital Market, or Nasdaq, under the symbol "PCSA" contingent on the completion of this offering. Our common stock will commence trading on Nasdaq on October 2, 2020. There can be no assurance that a trading market will develop for our shares of common stock on Nasdaq. The final offering price of $4.00 per share was determined between us and the underwriters at the time of pricing.

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	$ 4.00	$ 19,200,000
Underwriting discounts and commissions[(1)]	$ 0.32	$ 1,536,000
Proceeds, before expenses, to us	$ 3.68	$ 17,664,000

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

Certain of our officers, directors and existing stockholders have agreed to purchase an aggregate of 37,250 shares in this offering on the same terms as those offered to the public. The underwriters will receive the same underwriting discounts and commissions on any shares purchased by these officers, directors and stockholders as they will on any other shares sold to the public in this offering.

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 October 6, 2020.

Joint Bookrunning Managers

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

Co-Manager

National Securities Corporation

Prospectus dated October 1, 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 ≥ 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 195,562 shares of common stock (based on interest accrued through June 30, 2020) at a conversion price of $3.60 per share, which, pursuant to the LOC Agreement, is a 10% discount on the public offering price of $4.00 per share.

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). Per the Yuhan License Agreement, we will issue an additional 250,000 shares to Yuhan based on the public offering price of $4.00 per share.

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	4,800,000 shares of common stock.
Common Stock to be Outstanding After this Offering*	10,315,447 shares of common stock.
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.
Nasdaq Capital Market Symbol	Our common stock has been approved for listing on Nasdaq under the symbol "PCSA" contingent on the completion of this offering and it will commence trading on Nasdaq on October 2, 2020.

* 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;

- 238,740 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 interest accrued through June 30, 2020 and a conversion price of $3.60 per share, which, pursuant to the 2019 Senior Note Agreement, is a 10% discount on the public offering price of $4.00 per share.

- 1,142,916 shares of common stock to be issued to stockholders who purchased common stock units in our 2018 Private Placement Transactions, based on the public offering price of $4.00 per share, as a result of full ratchet anti-dilution provisions;

- 195,562 shares of common stock issuable upon the conversion of the $700,000 principal amount outstanding under the LOC Agreement with DKBK and related accrued interest expected to occur simultaneously with the closing of this offering, based on interest accrued through June 30, 2020 and a conversion price of $3.60 per share, which, pursuant to the LOC Agreement, is a 10% discount on the public offering price of $4.00 per share;

- 625,000 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 the public offering price of $4.00 per share;

- 500,000 shares of common stock issued to Yuhan in connection with the Yuhan License Agreement, based on the public offering price of $4.00 per share; and

- 825,000 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 the public offering price of $4.00 per share.

* Unless otherwise indicated, all information in this prospectus gives effect to the Reverse Split.

Certain of our officers, directors and existing stockholders have agreed to purchase an aggregate of 37,250 shares in this offering on the same terms as those offered to the public. The underwriters will receive the same underwriting discounts and commissions on any shares purchased by these officers, directors and stockholders as they will on any other shares sold to the public in this offering.

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	$ 17,599,154
Total Assets	10,011,456	10,111,456	27,157,956
Working Capital (Deficit) [3]	(1,321,086)	(717,063)	16,329,437
2019 Senior convertible debt [4]	859,102	859,102	859,102
Line of Credit Payable	504,023	-	-
Total Liabilities [5]	3,418,436	2,914,413	2,914,413
Total Stockholders' Equity	6,593,020	7,197,043	24,243,543

(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 the public offering price of $4.00 per share: (i) the issuance of 1,142,916 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 conversion of the $700,000 (inclusive of the $200,000 draw on July 21, 2020) principal amount outstanding under the LOC Agreement with DKBK and related accrued interest expected to occur simultaneously with the closing of this offering into 195,562 shares of common stock (based on interest accrued through June 30, 2020); (iii) the issuance of 625,000 shares of common stock to Aposense; (iv) the issuance of 500,000 shares of common stock to Yuhan; and (v) the issuance of 825,000 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 8,803,925.

(2) Gives effect to the Pro Forma Adjustments and the issuance of 4,800,000 shares of common stock in this offering and the receipt of $17.0 million in net proceeds. The number of outstanding shares on a pro forma as adjusted basis would be 13,603,925.

(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 28.2% of our outstanding capital stock. 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 $17.0 million from the sale of the shares of our common stock in this offering, based on the public offering price of $4.00 per share and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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 third quarter 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

Our common stock has been approved for listing on the Nasdaq Capital Market, or Nasdaq, under the symbol "PCSA" contingent on the completion of this offering and it will commence trading on Nasdaq on October 2, 2020. Our common stock was previously 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.

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 the public offering price of $4.00 per share.
- on a pro forma basis, as adjusted to give further effect to the issuance by us of 4,800,000 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	$ 17,599,154
2019 Senior Convertible Notes and accrued interest	859,102	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; 8,803,925 shares issued and outstanding, pro forma and 13,603,925 shares issued and outstanding pro forma, as adjusted[(1)]	552	882	1,362
Additional paid-in capital	19,182,228	27,685,921	44,731,941
Accumulated equity	(12,589,760)	(20,489,760)	(20,489,760)
Total stockholders' equity	6,593,020	7,197,043	24,243,543
Total capitalization	$ 7,956,145	$ 8,056,145	$ 25,102,645

(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
- 238,740 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 $3.60 per share, which, pursuant to the 2019 Senior Note Agreement, is a 10% discount on the public offering price of $4.00 per share.

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 the public offering price of $4.00 per share and is calculated based on an aggregate of 8,803,925 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 4,800,000 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 the public offering price of $4.00 per share, and is calculated based on an aggregate of 13,603,925 shares of our common stock outstanding.

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

Public offering price per share		$ 4.00
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	0.16	
Pro forma net tangible book value as of June 30, 2020, before giving effect to the offering	(0.08)	
Increase in net tangible book value per share from new investors participating in this offering	1.28	
Pro forma, as adjusted net tangible book value per share after this offering		1.20
Dilution in net tangible book value per share to new investors participating in this offering		2.80

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 4,800,000 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.

- 238,740 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 $3.60 per share, which, pursuant to the 2019 Senior Note Agreement, is a 10% discount on the public offering price of $4.00 per share.

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 the third quarter of 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 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). Per the Yuhan License Agreement, we will issue an additional 250,000 shares based on the public offering price of $4.00 per share in this offering. 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 825,000 shares of our common stock, based on the public offering price of $4.00 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 625,000 shares of common stock determined by dividing $2.5 million by the public offering price of $4.00 per share. 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 served on the Board of Directors and as 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.

DKBK has informed us that they will convert the $700,000 principal amount outstanding under the LOC Agreement with DKBK and related accrued interest simultaneously with the closing of this offering into 195,562 shares of common stock, based on interest accrued through June 30, 2020 and a conversion price of $3.60 per share, which, pursuant to the LOC Agreement, is a 10% discount on the public offering price of $4.00 per share.

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.

Participation in this Offering

Certain of our officers, directors and existing stockholders have agreed to purchase an aggregate of 37,250 shares in this offering on the same terms as those offered to the public. The underwriters will receive the same underwriting discounts and commissions on any shares purchased by these officers, directors and stockholders as they will on any other shares sold to the public in this offering.

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 and, with respect to shares beneficially owned after this offering, gives effect to the Pro Forma Adjustments. 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.

Certain of our officers, directors and existing stockholders have agreed to purchase an aggregate of 37,250 shares in this offering on the same terms as those offered to the public. The underwriters will receive the same underwriting discounts and commissions on any shares purchased by these officers, directors and stockholders as they will on any other shares sold to the public in this offering. The below ownership percentages do not reflect the purchase of shares of common stock in this offering by these officers, directors or stockholders.

	Shares beneficially owned prior to this offering		Shares beneficially owned after this offering[13][14]	
	Shares	Percent	Shares	Percent
Name and address of beneficial owner [1]				
Officers and Directors				
David Young [2], [9]	1,348,557	24.2%	1,692,581	12.1%
Sian Bigora [3]	500,677	9.1%	532,852	3.9%
Patrick Lin [7]	345,448	6.3%	383,381	2.8%
Wendy Guy [4]	318,402	5.8%	352,010	2.6%
Virgil Thompson [8]	88,108	1.6%	91,965	*
Justin Yorke [5]	446,946	7.9%	640,103	4.6%
Geraldine Pannu	-	*	3,268	*
James Stanker [12]	52,282	*	78,728	*
Total for all Officers and Directors	3,100,420	55.7%	3,774,888	26.0%
More than 5% Stockholders:				
CorLyst, LLC [6], [9], [11]	1,095,649	19.8%	1,144,171	8.4%
Young-Plaisance Revoc. Trust [9], [10]	482,030	8.7%	579,248	4.2%
CoNCERT Pharmaceuticals, Inc.	298,615	5.4%	298,615	2.2%

* 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) 195,562 shares of common stock beneficially owned by David Young as a result of the conversion of the LOC Agreement with DKBK; (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 Yorke and Geraldine Pannu on August 5, 2020 pursuant to our 2019 Omnibus Incentive Plan, which shares vest upon the completion of this offering; and (iii) the vesting of 5,198 shares of common stock issuable pursuant to options held directly by each of David Young, Sian Bigora, Patrick Lin, Wendy Guy and James Stanker; and 589 shares of common stock issuable pursuant to options held directly by each of Virgil Thompson and Justin Yorke.

(14) 335,694 (of the total 1,142,916) shares of common stock to be issued to those who purchased common stock units in our 2018 Private Placement Transactions, based on the public offering price of $4.00 per share, as a result of full ratchet anti-dilution provisions, allocated in the above table as follows:

- CorLyst: 48,522 (further allocated as follows: David Young related entities – 14,324, Sian Bigora – 5,729; Wendy Guy – 7,162; the Young-Plaisance Revoc. Trust – 18,921; and other unrelated stockholders – 2,386 (included under David Young as the managing partner));
- David Young: 8,088;
- Young-Plaisance Trust: 78,297;
- Patrick Lin: 11,487; and
- Funds managed by Justin Yorke: 189,300.

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 related accrued interest of the $805,000 2019 Senior Notes are converted upon the closing of this offering, we would issue 238,740 shares of common stock, based on interest accrued through June 30, 2020 and a conversion price of $3.60 per share, which, pursuant to the 2019 Senior Note Agreement, is a 10% discount on the public offering price of $4.00 per share.

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 195,562 shares of common stock based on interest accrued through June 30, 2020 and a conversion price of $3.60 per share, which represents a 10% discount on the public offering price of $4.00 per share of our common stock.

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 initial 250,000 shares of common stock 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 136,040 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 initial 250,000 shares of common stock 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	2,400,000
Benchmark Company, LLC	1,680,000
National Securities Corporation	720,000
Total	4,800,000

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.

Certain of our officers, directors and existing stockholders have agreed to purchase an aggregate of 37,250 shares in this offering on the same terms as those offered to the public. The underwriters will receive the same underwriting discounts and commissions on any shares purchased by these officers, directors and stockholders as they will on any other shares sold to the public in this offering.

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 of $0.192 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.

	Per Share	Total
Public offering price	$ 4.00	$ 19,200,000
Underwriting discounts and commissions to be paid by us	$ 0.32	$ 1,536,000
Proceeds, before expenses, to us	$ 3.68	$ 17,664,000

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately $618,000, 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.

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

Our common stock has been approved for listing on Nasdaq under the symbol “PCSA” contingent on the completion of this offering and it will commence trading on Nasdaq on October 2, 2020.

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. The underwriters must close out any short position by purchasing shares in the open market. A 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

Processa Pharmaceuticals, Inc.

4,800,000 Shares of Common Stock

PROSPECTUS

Joint Bookrunning Managers

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

Co-Manager

National Securities Corporation

October 1, 2020