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

FORM 10-K

[X] Annual Report under Section 13 or 15(d) of the Securities Exchange Act of 1934
For the fiscal year ended December 31, 2017

or

[ ] Transitional Report under Section 13 or 15(d) of the Securities Exchange Act of 1934

Commission File Number: 333-184948

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

Delaware	**45-1539785**
(State or other jurisdiction of incorporation)	(IRS Employer Identification No.)

7380 Coca Cola Drive, Suite 106,
Hanover, Maryland 21076
(Address of principal executive offices)

(443) 776-3133
(Registrant's telephone number, including area code)

N/A
(Former name, former address and former fiscal year, if changed since last report)

Securities registered under Section 12(b) of the Act: None

Securities registered under Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer as defined in Rule 405 of the Securities Act
Yes [ ] No [X]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act.
Yes [X] No [ ]

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days.
Yes [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Date File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files)
Yes [X] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

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

Large accelerated filer	[ ]	Accelerated filer	[ ]
Non-accelerated filer	[ ] (Do not check if a smaller reporting company)	Smaller reporting company	[X]
Emerging growth company	[X]		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [X]

Indicate by check mark whether the registrant is a shell company (as defined by Rule 12b-2 of the Act). Yes [ ] No [X]

As of June 30, 2017, the last business day of the registrants most recently completed second fiscal quarter, the aggregate value of the registrant's common stock (excluding shares held by affiliates), based upon the $0.98 price at which such common stock was last sold on June 30, 2017, was approximately $1.0 million.

As of April 13, 2018, we have 35,272,626 shares of common stock outstanding and no shares of preferred stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Not applicable.

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Part I

Item 1. Business.

On October 2, 2017 Heatwurx, Inc., "(Heatwurx") and Processa Therapeutics, LLC ("Processa"), a Delaware limited liability company and a wholly-owned subsidiary of Heatwurx, entered into an Asset Purchase Agreement (the "Acquisition Agreement") with Promet Therapeutics, LLC, a Delaware limited liability company ("Promet") pursuant to which, at the effective time on October 4, 2017, Heatwurx acquired all of the assets of Promet, in exchange for issuing to Promet approximately 222,217,000 shares (approximately 31,745,000 shares following our reverse stock split) of the common stock of Heatwurx. Following the closing, Heatwurx changed its name to Processa Pharmaceuticals, Inc. As used in this Form 10-K, unless the context suggests otherwise, "we," "us," "our," "the Company" or "Processa" refer to Processa Pharmaceuticals, Inc., its wholly-owned subsidiaries and the acquired assets from Promet.

Following the acquisition, we have abandoned our prior business plan and we are now pursuing Promet's historical business and proposed business, with a focus on developing drugs to treat patients that have a high unmet medical need.

Overview

Processa is an emerging pharmaceutical company focused on the clinical 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. Within this group of pharmaceutical products, we currently are developing one product for two indications (i.e., the use of a drug to treat a particular disease) and searching for additional products for our portfolio.

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, even if it be anecdotal, such that the patient's survival and/or quality of life might improve,
(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 within 2-4 years to completion of a pivotal study for the submission of a new drug application ("NDA") to the U.S. Food and Drug Administration ("FDA") or to license the drug to a potential strategic partner just prior to a more expensive and time consuming pivotal study.

Processa's lead product, PCS-499 (previously known as CTP-499), is an oral tablet that is an analog of an active metabolite of an already approved drug. The advantage of PCS-499 is that it potentially may work in many conditions because it has multiple pharmacological targets that it affects that are important in the treatment of these conditions. The compound has previously been shown to be safe and tolerable with a trend toward efficacy in diabetic nephropathy. Based on the pharmacological activity, Processa has identified other unmet medical need conditions where the use of PCS-499 may result in clinical efficacy. These include Necrobiosis Lipoidica (NL) and Radiation-Induced Fibrosis (RIF) in head and neck cancer patients. NL is a chronic, disfiguring condition for which most patients do not have any treatment options. It develops more commonly in women than in men on the lower extremities, and ulceration can occur in approximately 30% of NL patients, which may lead to more severe complications, such as deep tissue infections and osteonecrosis that can threaten life of the limb. The Processa development team has already met with the FDA on the NL condition and has developed a strategy for moving the program for NL forward starting with a Phase 2 clinical trial in NL patients in late 2018. The Processa team will meet with the FDA to further define the program for use of PCS-499 for the RIF condition in the next few months. CTP-499 had previously been investigated for a different indication in Phase 2 studies before we exercised an option to license CTP-499 from CoNCERT Pharmaceuticals in March 2018. Based on the diverse pharmacological activity of CTP-499, the Processa team has defined a strategy to develop this product in two indications where physicians and patients seek significant medical help. CTP-499 will be investigated for the treatment of two conditions that occur as a result of multiple pathophysiological changes, necrobiosis lipoidica and the adverse effects associated with radiation therapy in the treatment of head and neck cancer. Besides the diverse pharmacological properties of CTP-499 targeting many of the physiological changes that occur for these two indications, an analog drug with similar pharmacology, presently approved for a different indication, has been successfully used in some patients for the treatment of these indications but cannot be used in many patients because it has dose limiting side effects, not allowing for higher doses to be administered to obtain adequate efficacy. The CTP-499 dose limiting side effects appear to occur at a much higher dose based on the existing clinical and pre-clinical data for CTP-499, allowing physicians to potentially increase the dose to effectively treat significantly more patients with these two conditions. These two indications do not have any FDA-approved treatments, have the potential to seriously affect a patient's day-to-day quality of life and have projected maximum annual gross sales of $750 million to $2 billion worldwide. Our team had a successful pre-IND (Investigating New Drug) meeting with the FDA on necrobiosis lipoidica in October 2017, defining the next steps to move CTP-499 into Phase 2 studies and the path to eventual approval. Our ability to generate meaningful revenue from any products in the United States depends on obtaining FDA authorization. Even if our products are authorized and approved by the FDA, we must still meet the challenges of successful marketing, distribution and consumer acceptance.

To advance its mission, Processa has assembled an experienced and talented management and product development team. The Processa team is experienced in developing drug products through all principal regulatory tiers from Initial New Drug ("IND") enabling studies to NDA submission. The Company's combined scientific, development and regulatory experience has resulted in more than 30 drug approvals by the FDA, over 100 meetings with FDA and involvement with more than 50 drug development programs, including drug products targeted to patients who have an unmet medical need.

In parallel the Processa team is looking to acquire additional drug candidates to help patients who have an unmet medical need. Processa has evaluated over 50 potential assets for acquisition and is presently performing due diligence on a cancer drug and a drug used for a cardiovascular condition that has no approved treatment.

Research and Development, Product Manufacturing, and Clinical Supplies

We currently have no in-house laboratory, drug manufacturing, product manufacturing, or clinical facilities. We rely on third-party contract labs, animal facilities, clinical facilities, and drug manufacturers to make the material used to support the development of our product candidates and to execute the actual studies. However, the study designs and the final evaluation/interpretation of the data are made by Processa with the third-party contractors providing the hands-on services to perform the studies. We purchase the material used in our clinical trial activities from various companies and suppliers.

Customers and Distribution

As we are still in the process of developing our products, we do not currently sell or distribute pharmaceutical products.

Intellectual Property

Our success will depend in large part on our ability 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 patents, once obtained;
- preserve our trade secrets; and
- operate without infringing the patents and proprietary rights of other 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 composition of matter, medical uses, processes for preparation and formulations.

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.

Asset Acquisitions by Licensing Agreements or Company Acquisitions

On March 19, 2018 Promet, Processa and CoNCERT Pharmaceuticals, Inc. ("CoNCERT") executed an Amendment to the Option Licensing Agreement granting an exclusive license, including the right to assign the license, sublicense, develop, manufacture, use and commercialize CTP-499 worldwide. Upon exercising the option to license CTP-499, Promet transferred $8.0 million of its Processa shares, approximately 5.9% of all Processa outstanding shares, to CoNCERT with CoNCERT also being eligible to receive royalties on commercial sales. Promet with CoNCERT's agreement has subsequently assigned the license to Processa after exercising the licensing option

We have also evaluated over 50 potential assets for acquisition and are presently performing due diligence on a cancer drug and a drug used for a cardiovascular condition that has no approved treatment. If one or both of these assets are a good fit for our portfolio, we will try to acquire the asset through in-licensing or acquisition of the Company.

Sales and Marketing

We do not currently have sales or marketing capabilities. In order to commercially market any pharmaceutical product that we successfully advance through preclinical and clinical development and for which we obtain regulatory approval, we must either develop a sales and marketing infrastructure or collaborate with third parties with sales and marketing capabilities. Because of the early stage of our pharmaceutical development programs, we have not yet developed a sales and marketing strategy for any pharmaceutical products that we may successfully develop.

Competition

The biotechnology and pharmaceutical industries are extremely competitive. Our potential competitors in the field are many in number and include major pharmaceutical and specialized biotechnology companies. Many of our potential competitors have significantly more financial, technical and other resources than we do, which may give them a competitive advantage. In addition, they may have substantially more experience in effecting strategic combinations, in-licensing technology, developing drugs, obtaining regulatory approvals and manufacturing and marketing products. We cannot give any assurances that we can compete effectively with these other biotechnology and pharmaceutical companies. Our potential competitors in these markets may succeed in developing products that could render our products and those of our collaborators obsolete or non-competitive. In addition, many of our competitors have significantly greater experience than we do in the fields in which we compete.

Government Regulation

Pharmaceutical Regulation

If we market any pharmaceutical products in the United States, they will be subject to extensive government regulation. Likewise, if we seek to market and distribute any such products abroad, they would also be subject to extensive foreign government regulation.

In the United States, the FDA regulates pharmaceutical products. FDA regulations govern the testing, manufacturing, advertising, promotion, labeling, sale and distribution of pharmaceutical products, and generally require a rigorous process for the approval of new drugs.

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our future drugs. Whether or not we obtain FDA approval for a drug, we must obtain approval of a drug by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the drug in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or mutual recognition procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The mutual recognition procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state generally must decide whether to recognize approval.

The definition of "rare or orphan disease" differs between the US and other foreign countries, and as such may impact the development program, the regulatory approval process, the exclusivity marketing periods, sales and marketing and the pricing. Since many of the products being developed will be used in rare diseases the differences in the regulations between the US and other foreign countries may add complexity to the development program, the clinical studies, regulatory approval and costing for the product.

Regulation in the United States

The FDA testing and approval process requires substantial time, effort and money. We cannot assure you that any of our products will ever obtain approval. The FDA approval process for new drugs includes, without limitation:

- preclinical studies;
- submission of an Investigational New Drug application, or IND, for clinical trials;
- adequate and well-controlled human clinical trials to establish safety and efficacy of the product;
- review of a New Drug Application, or NDA; and
- inspection of the facilities used in the manufacturing of the drug to assess compliance with the FDA's current Good Manufacturing Practices, or cGMP, regulations.

Preclinical studies include laboratory evaluation of the product, as well as animal studies to assess the potential safety and effectiveness of the product. Most of these studies must be performed according to good laboratory practices, a system of management controls for laboratories and research organizations to ensure the consistency and reliability of results. The results of the preclinical studies, existing clinical and/or human use data (if applicable) together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which we are required to file before we can commence any clinical trials for our product candidates in the United States. Clinical trials may begin 30 days after an IND is received, unless the FDA raises concerns or questions about the conduct of the clinical trials. If concerns or questions are raised, an IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. We cannot assure you that submission of any additional IND for any of our preclinical product candidates will result in authorization to commence clinical trials.

Clinical trials involve the administration of the product candidate that is the subject of the trial to volunteers or patients under the supervision of a qualified principal investigator. Each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at each institution at which the study will be conducted. The IRB will consider, among other things, ethical factors, safety of human subjects and the possible liability of the institution arising from the conduct of the proposed clinical trial. Also, clinical trials must be performed according to good clinical practices, which are enumerated in FDA regulations and guidance documents.

Clinical trials typically are conducted in sequential phases: Phases 1, 2 and 3. The phases may overlap. The FDA may require that we suspend clinical trials at any time on various grounds, including if the FDA makes a finding that the subjects participating in the trial are being exposed to an unacceptable health risk.

In Phase 1 clinical trials, a drug is usually tested on patients to determine safety, any adverse effects, proper dosage, absorption, metabolism, distribution, excretion and other drug effects.

In Phase 2 clinical trials, a drug is usually tested on a limited number of subjects to preliminarily evaluate the efficacy of the drug for specific, targeted indications, determine dosage tolerance and optimal dosage, and identify possible adverse effects and safety risks.

In Phase 3 clinical trials, a drug is usually tested on a larger number of subjects in an expanded patient population and at multiple clinical sites.

We cannot assure you that any of our current or future clinical trials will result in approval to market our products.

An NDA must include comprehensive and complete descriptions of the preclinical testing, clinical trials and the chemical, manufacturing and control requirements of a drug that enable the FDA to determine the drug's safety and efficacy. A NDA must be submitted, filed and approved by the FDA before any product that we may successfully develop can be marketed commercially in the United States.

The facilities, procedures and operations for any of our contract manufacturers must be determined to be adequate by the FDA before product approval. Manufacturing facilities are subject to inspections by the FDA for compliance with cGMP, licensing specifications and other FDA regulations before and after a NDA has been approved. Foreign manufacturing facilities are also subject to periodic FDA inspections or inspections by foreign regulatory authorities. Among other things, the FDA may withhold approval of NDAs or other product applications if deficiencies are found at the facility. Vendors that may supply us with finished products or components used to manufacture, package and label products are also subject to similar regulations and periodic inspections.

In addition, the FDA imposes a number of complex regulatory requirements on entities that advertise and promote pharmaceuticals, including, but not limited to, standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities, and promotional activities involving the Internet.

Failure to comply with FDA and other governmental regulations can result in fines, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA's review of NDAs, injunctions and criminal prosecution. Any of these actions could have a material adverse effect on us.

Foreign Regulation

Since we plan to market our products in foreign countries, we may also be subject to a wide variety of foreign regulations governing the development, manufacture and marketing of our products. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to marketing the product in those countries. The approval process varies, and the time needed to secure approval in any region such as the European Union or in a country with an independent review procedure may be longer or shorter than that required for FDA approval. We cannot assure you that clinical trials conducted in one country will be accepted by other countries or that an approval in one country or region will result in approval elsewhere.

Additional Regulation

Third-Party Reimbursement

In the United States, physicians, hospitals and other healthcare providers that purchase pharmaceutical products generally rely on third-party payors, principally private health insurance plans, Medicare and, to a lesser extent, Medicaid, to reimburse all or part of the cost of the product and procedure for which the product is being used. Even if a product is approved for marketing by the FDA, there is no assurance that third-party payors will cover the cost of the product and related medical procedures. If they do not, end-users of the drug would not be eligible for any reimbursement of the cost, and our ability to successfully market any such drug would be materially and adversely impacted.

Reimbursement systems in international markets vary significantly by country and, within some countries, by region. Reimbursement approvals must be obtained on a country-by-country basis. In many foreign markets, including markets in which we hope to sell our products, the pricing of prescription pharmaceuticals is subject to government pricing control. In these markets, once marketing approval is received, pricing negotiations could take significant additional time. As in the United States, the lack of satisfactory reimbursement or inadequate government pricing of any of our products would limit their widespread use and lower potential product revenues.

Fraud and Abuse Laws

Federal and state anti-kickback and anti-fraud and abuse laws, as well as the federal Civil False Claims Act may apply to certain drug and device research and marketing practices. The Civil False Claims Act prohibits knowingly presenting or causing to be presented a false, fictitious or fraudulent claim for payment to the United States. Actions under the Civil False Claims Act may be brought by the Attorney General or by a private individual acting as an informer or whistleblower in the name of the government. Violations of the Civil False Claims Act can result in significant monetary penalties. The federal government is using the Civil False Claims Act, and the threat of significant liability, in its investigations of healthcare providers, suppliers and drug and device manufacturers throughout the country for a wide variety of drug and device marketing and research practices and has obtained multi-million-dollar settlements. The federal government may continue to devote substantial resources toward investigating healthcare providers', suppliers' and drug and device manufacturers' compliance with the Civil False Claims Act and other fraud and abuse laws. We may have to expend significant financial resources and management attention if we ever become the focus of such an investigation, even if we are not guilty of any wrong doings.

HIPAA

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, requires the use of standard transactions, privacy and security standards and other administrative simplification provisions, by covered entities which include many healthcare providers, health plans and healthcare clearinghouses. HIPAA instructs the Secretary of the Department of Health and Human Services to promulgate regulations implementing these standards in the United States.

Other Laws

We are also subject to other federal, state and local laws of general applicability, such as laws regulating working conditions, and various federal, state and local environmental protection laws and regulations, including those governing the discharge of material into the environment.

Employees

As of December 31, 2017, we had 13 employees. None of our employees is subject to a collective bargaining agreement or represented by a labor or trade union, and we believe that our relations with our employees is good. We believe that we have been successful in attracting skilled and experienced personnel, but competition for personnel is intense and there can be no assurance that we will be able to attract and retain the individuals needed.

Status as an Emerging Growth Company

We are an "emerging growth company" as that term is defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (i.e., those that have not had a registration statement declared effective under the Securities Act of 1933, as amended (the "Securities Act"), or do not have a class of securities registered under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) are required to comply with such new or revised financial accounting standards.

The JOBS Act also provides that an emerging growth company can elect to opt out of the extended transition period provided by Section 102(b)(1) of the JOBS Act and comply with the requirements that apply to nonemerging growth companies, but any such election to opt out is irrevocable. We may still take advantage of all of the other provisions of the JOBS Act, which include, but are not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, the reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and the exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. Forward-looking statements give our current expectations or forecasts of future events. You can identify these statements by the fact that they do not relate strictly to historical or current facts. You can find many (but not all) of these statements by looking for words such as "approximates," "believes," "hopes," "expects," "anticipates," "estimates," "projects," "intends," "plans," "would," "should," "could," "may" or other similar expressions in this report on Form 10-K. These statements may be found under the sections of this report on Form 10-K captioned "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business" included in this report on Form 10-K, as well as in this report on Form10-K generally. In particular, these include statements relating to future actions, prospective products, applications, customers, technologies, future performance or results of anticipated products, expenses, and financial results. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from our historical experience and our present expectations or projections. Factors that could cause actual results to differ from those discussed in the forward-looking statements include, but are not limited to:

- our limited operating history, limited cash and history of losses;
- our ability to achieve profitability;
- our ability to secure required FDA or other governmental approvals for our product candidates and the breadth of the indication sought;
- the impact of competitive or alternative products, technologies and pricing;
- whether we are successful in developing and commercializing our technology, including through licensing;
- the adequacy of protections afforded to us and/or our licensor by the anticipated patents that we own or license and the cost to us of maintaining, enforcing and defending those patents;
- our and our licensor's ability to protect non-patented intellectual property rights;
- our exposure to and ability to defend third-party claims and challenges to our and our licensor's anticipated patents and other intellectual property rights;
- our ability to obtain adequate financing to fund our business operations in the future;
- our ability to continue as a going concern; and
- other factors discussed in the "Risk Factors" section of this report.

The forward-looking statements are based upon management's beliefs and assumptions and are made as of the date of this report on Form 10-K. We undertake no obligation to publicly update or revise any forward-looking statements included in this report on Form 10-K or to update the reasons why actual results could differ from those contained in such statements, whether as a result of new information, future events or otherwise, except to the extent required by federal securities laws. Actual future results may vary materially as a result of various factors, including, without limitation, the risks outlined under the section of this report on Form 10-K captioned "Risk Factors" and matters described in this report on Form 10-K generally. In light of these risks and uncertainties, we cannot assure you that the forward-looking statements contained in this report on Form 10-K will in fact occur. You should not place undue reliance on these forward-looking statements.

Item 1A. Risk Factors

We are subject to various risks that may materially harm our business, prospects, financial condition and results of operations. An investment in our common stock is speculative and involves a high degree of risk. In evaluating an investment in of our shares of our common stock, you should carefully consider the risks described below, together with the other information included in this Form 10-K.

If any of the events described in the following risk factors actually occurs, or if additional risks and uncertainties that are not presently known to us or that we currently deem immaterial later materialize, then our business, prospects, results of operations and financial condition could be materially adversely affected. In that event, the trading price of our common stock could decline, and you may lose part or all of your investment in our shares. The risks discussed below include forward-looking statements, and our actual results may differ substantially from those discussed in these forward-looking statements. See "Special Note Regarding Forward-Looking Statements."

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.

Promet Therapeutics, LLC whose assets were acquired by Processa had an accumulated deficit of $3.253 million incurred since its inception on August 31, 2015 through the date of acquisition on October 4, 2017. Subsequent to the date of acquisition, the accumulated deficit increased to $3.859 million at December 31, 2017. The Company will incur additional losses as we continue our research and development activities, seek regulatory approvals for our product candidates and engage in clinical trials. 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 will require additional financing to continue as a going concern.

Absent additional funding, we believe that our present cash and cash equivalents will be sufficient to fund our operations through the end of the year. The development of our new business model will require substantial additional capital in the future to further our development and license in 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.

Our ability to obtain additional financing will be subject to a number of 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 do not have any credit facilities as a source of future funds, and there can be no assurance that we will be able to raise sufficient additional capital on acceptable terms, or at all. 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 financing, if obtained, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, could increase our expenses and require that our assets secure such debt. Moreover, any debt we incur must be repaid regardless of our operating results. If we choose to pursue additional indications and/or geographies for our product candidates, in-license additional development assets, or otherwise expand more rapidly than we presently anticipate, we may also need to raise additional capital sooner than expected.

As a result, substantial doubt exists about the Company's ability to continue as a going concern within one year after the date the financial statements are available to be issued. The consolidated financial statements included herein 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 the Company be unable to continue as a going concern based on the outcome of the uncertainties described above.

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.

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 a 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. In the United States, the FDA generally requires the completion of clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before an NDA is approved. Regulatory authorities in other jurisdictions impose similar requirements. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are eventually approved for commercialization. If our development efforts for our product candidates, including regulatory approval, are not successful for their planned indications, or if adequate demand for our product candidates is not generated, our business will be materially adversely affected.

We cannot guarantee that regulators will agree with our assessment of the results of the clinical trials we intend to conduct in the future or that such trials will be successful. The FDA, EMA and other regulators have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional clinical trials, or pre-clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of our product candidates.

We have no 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 the Company, conducting research and developing our core technologies, and identifying and optimizing our lead product clinical candidates. 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 no corporate experience conducting clinical trials in any jurisdiction and have not had previous experience commercializing product candidates or submitting an investigational new drug application or any Application to the FDA or similar submissions to initiate clinical trials or obtain marketing authorization to foreign regulatory authorities. We cannot be certain that planned clinical trials will begin or be completed on time, if at all, that our planned development programs 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.

In order to obtain marketing approval for any of our product candidates, we must demonstrate the safety and efficacy of the product candidate for the relevant clinical indication or indications through preclinical studies and clinical trials as well as additional supporting data. If our product candidates are associated with undesirable side effects in preclinical studies or clinical trials or have characteristics that are unexpected, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

Although CoNCERT Pharmaceuticals had dosed our drug product in healthy human volunteers and diabetic nephropathy patients, we have not yet initiated any clinical trials or dosed any of our product candidates in the targeted population of patients. 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.

If significant adverse events or other side effects are observed in any of our future clinical trials, 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 or other applicable regulatory authorities, or an Institutional Review Board ("IRB") 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 applicable therapeutic and vaccine 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. For example, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for any of our product candidates, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve any of our product candidates with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that indication.

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 regulations, or 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, or current Good Manufacturing Practices regulations, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents.

The FDA has the authority to require a risk evaluation and mitigation strategy, or REMS, as part of an NDA or after approval, which may impose further requirements or restrictions on the distribution or use or marketing of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria or requiring patient testing, monitoring and/or enrollment in a registry. Any of these requirements or restrictions on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of our product candidates. Moreover, product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of our product candidates.

With respect to sales and marketing activities by us or any future partner, advertising and promotional materials must comply with FDA rules in addition to other applicable federal, state and local laws in the United States and similar legal requirements in other countries. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific/educational grant programs. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

In addition, if any of our product candidates are approved for a particular indication, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for our product candidates, physicians may nevertheless legally prescribe our products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. 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 sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed.

If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, problems with the facility where the product is manufactured, or we or our manufacturers fail to comply with applicable regulatory requirements, we may be subject to various administrative or judicial sanctions, such as issuance of warning letters, withdrawal of the product from the market, injections or the imposition of civil or criminal penalties or monetary fines, suspension of any ongoing new clinical trials or suspension or withdrawal of regulatory approval.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase our product liability exposure.

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 approved, 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 the Processa 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 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.

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 for manufacture of 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.

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.

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. There can be no assurance that we will receive orphan drug designation for any of our 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 or 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 breakthrough therapy designation or any other 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 a breakthrough therapy designation or access to any other 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 and 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 are 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. Increasingly, third-party payors attempt to contain health care costs in ways that are likely to impact our development of products including:

- failing to approve or challenging the prices charged for health care products;
- introducing reimportation schemes from lower priced jurisdictions;
- limiting both coverage and the amount of reimbursement for new therapeutic products;
- denying or limiting coverage for products that are approved by the regulatory agencies but are considered to be experimental or investigational by third-party payors; and
- refusing to provide coverage when an approved product is used in a way that has not received regulatory marketing approval.

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 control 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 own 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 rights to develop and commercialize the product candidates we license are subject to the validity of the owner's intellectual property rights. Enforcement of our licensed patents or defense or any claims asserting the 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 develop and commercialize our product candidates.

In addition, 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. Certain of our licenses contained in our agreements with CoNCERT Pharmaceuticals contain 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. Our rights under the licenses are subject to our continued compliance with the terms of the license, including the payment of royalties due under the license. Termination 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.

It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights.

Our commercial success will depend, in part, on obtaining and maintaining patent protection for our technologies, products and processes, successfully defending these patents against third-party challenges and successfully enforcing 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 intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowable or enforceable in our patents. The existing patent and patent applications relating to our product candidates and related technologies 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, because legal means afford only limited protection and may not adequately protect our rights, permit us to gain or keep our competitive advantage, or provide us with 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 filed by us, or that we 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 have rights. If we cannot maintain the confidentiality of our proprietary technology and other confidential information, our ability to receive patent protection and our ability to protect valuable information owned by us may be imperiled. Enforcing a claim that a third-party entity illegally obtained and is using any of our 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 protection or trade secret protection for our product candidates or our technologies, third parties could use our proprietary information, 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 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 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 proprietary 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 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 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 therapeutic 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 core leadership team and a total of 15-20 full-time or part-time employees or consultants. In particular, we plan to add 1 main consultant to the development team and other consultants as needed, we also plan to add a CFO and finance/accounting staff. 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.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face a potential 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 of our product candidates or any other future product. For example, we may be sued if any product we develop, including any of our product candidates, or any materials that we use in our products allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. In the US, claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any of our product candidates or any future products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- substantial costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- the inability to commercialize some or all of our product candidates; and
- a decline in the value of our stock.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We intend to obtain product liability insurance covering our clinical trials. However, such insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms, or at all. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

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

We are in the relatively early stage 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 suffer negative publicity concerning the safety of our products in development, our sales may be harmed and we may be forced to withdraw such products.

If concerns should arise about the safety of any of our products that are being developed or marketed, regardless of whether or not such concerns have a basis in generally accepted science or peer-reviewed scientific research, such concerns could adversely affect the further development or market for these products. Similarly, negative publicity could result in an increased number of product liability claims, whether or not these claims are supported by applicable law or covered by insurance.

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.

To induce valuable personnel to remain at our Company, in addition to salary and cash incentives, we expect that we will provide stock options, restricted stock units or other equity securities that vest over time upon approval of a plan by the Board of Directors. 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.

Future capital raises may dilute our existing stockholders' ownership and/or have other adverse effects on our operations.

If we raise additional capital by issuing equity securities, our existing stockholders' percentage ownership will be reduced, and these stockholders may experience substantial dilution. We may also issue equity securities that provide for 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 market 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;
- 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;
- changes in estimates or recommendations by securities analysts, if any, who cover our Common Stock;
- future sales of our Common Stock;
- period-to-period fluctuations in our financial results;
- publicity or announcements regarding regulatory developments relating to our products;
- period-to-period fluctuations in our financial results, including our cash and cash equivalents balance, operating expenses, cash burn rate or revenue levels;
- Common Stock sales in the public market by one or more of our larger stockholders, officers or directors;
- our filing for protection under federal bankruptcy laws; or
- a negative outcome in any litigation or potential legal proceeding.

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. 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.

Our Common Stock is currently traded in the OTC Pink Marketplace and is subject to additional trading restrictions as a "penny stock," which could adversely affect the liquidity and price of such stock. If our Common Stock remains subject to the SEC's penny stock rules, broker-dealers may experience difficulty in completing customer transactions and trading activity in our securities may be adversely affected.

Our Common Stock currently trades in the OTC Pink Marketplace. The OTCQB, the OTC Bulletin Board and Pink Sheets are viewed by most investors as a less desirable, and less liquid, marketplace. As a result, an investor may find it more difficult to purchase, dispose of or obtain accurate quotations as to the value of our Common Stock.

Because our Common Stock is not listed on any national securities exchange, such shares will also be subject to the regulations regarding trading in "penny stocks," which are those securities trading for less than $5.00 per share, and that are not otherwise exempted from the definition of a penny stock under other exemptions provided for in the applicable regulations. The following is a list of the general restrictions on the sale of penny stocks:

Before the sale of penny stock by a broker-dealer to a new purchaser, the broker-dealer must determine whether the purchaser is suitable to invest in penny stocks. To make that determination, a broker-dealer must obtain, from a prospective investor, information regarding the purchaser's financial condition and investment experience and objectives. Subsequently, the broker-dealer must deliver to the purchaser a written statement setting forth the basis of the suitability finding and obtain the purchaser's signature on such statement.

A broker-dealer must obtain from the purchaser an agreement to purchase the securities. This agreement must be obtained for every purchase until the purchaser becomes an "established customer." The Securities Exchange Act of 1934 (the "Exchange Act"), requires that before effecting any transaction in any penny stock, a broker-dealer must provide the purchaser with a "risk disclosure document" that contains, among other things, a description of the penny stock market and how it functions, and the risks associated with such investment. These disclosure rules are applicable to both purchases and sales by investors.

A dealer that sells penny stock must send to the purchaser, within 10 days after the end of each calendar month, a written account statement including prescribed information relating to the security.

These requirements can severely limit the liquidity of securities in the secondary market because fewer brokers or dealers are likely to be willing to undertake these compliance activities. As a result of our Common Stock not being listed on a national securities exchange and the rules and restrictions regarding penny stock transactions, an investor's ability to sell to a third party and our ability to raise additional capital may be limited. We make no guarantee that market-makers will make a market in our Common Stock, or that any market for our Common Stock will continue.

Our principal stockholders have significant influence over us, they may have significant influence over actions requiring stockholder approval, and your interests as a stockholder may conflict with the interests of those persons.

Based on the number of outstanding shares of our Common Stock held by our stockholders as of December 31, 2017, our directors, executive officers and their respective affiliates beneficially owned or controlled over 90% of our outstanding shares of Common Stock and Promet, our largest stockholder, directly owned approximately 90% of the outstanding shares of our Common Stock. In March 2018, Promet transferred approximately 2,090,000 or 6.58% of Promet's Common Stock to CoNCERT Pharmaceuticals in exchange for modifying the option and licensing agreement between Promet and CoNCERT Pharmaceuticals. Dr. Young by virtue of his position as a Managing Member of Promet, may be deemed under federal securities laws to be the beneficial owner of those shares. As a result, those stockholders have the ability to exert a significant degree of influence with respect to the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. The interests of these persons may not always coincide with our interests or the interests of our other stockholders. This concentration of ownership could harm the market price of our Common Stock by (i) delaying, deferring or preventing a change in corporate control, (ii) impeding a merger, consolidation, takeover or other business combination involving us, or (iii) discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us. The significant concentration of stock ownership may adversely affect the trading price of our Common Stock due to investors' perception that conflicts of interest may exist or arise.

Our Common Stock is highly illiquid and the public market for the Common Stock may be minimal.

There is currently very little public trading for our Common Stock, and trading may not significantly increase in the foreseeable future.

The lack of an active market impairs an investors' ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable. The lack of an active market may also reduce the fair market value of investors' shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire additional intellectual property assets by using our shares as consideration.

There may be limitations on the effectiveness of our internal controls, and a failure of our control systems to prevent error or fraud may materially harm our company.

Proper systems of internal controls over financial accounting and disclosure are critical to the operation of a public company. As we are a start-up company, we may be unable to effectively establish such systems. This would leave us without the ability to reliably assimilate and compile financial information about our company and significantly impair our ability to prevent error and detect fraud, all of which would have a negative impact on our company from many perspectives.

Moreover, we do not expect that disclosure controls or internal control over financial reporting, even if established, will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected.

See Item 9A - Controls and Procedures – Material Weaknesses and Related Remediation Initiatives for a discussion of two material weaknesses relating to a lack of accounting staff to implement effective financial reporting and disclosure controls and a cybersecurity breach that resulted in a fraud loss where the probability of recovery of the loss is remote. While we are taking steps to prevent these control weaknesses from reoccurring, we cannot provide assurance that we will be successful. We are in the early stages of operations and fund raising so we currently lack the financial resources necessary to implement an effective internal control system to prevent and/or detect and correct material misstatements due to fraud or error. 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.

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 the value of our Company.

We have never and do not anticipate paying any cash dividends to our stockholders in the foreseeable future. Consequently, investors must rely on sales of their Common Stock or underlying common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments. There is no guarantee that the valuation of our Company will appreciate in value or even maintain the valuation at which our stockholders have purchased their shares.

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 Company, whether voluntary or involuntary, the proceeds and/or assets of our company remaining after giving effect to such transaction, and the payment of all of our debts, including Senior Convertible Notes, 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 to the holders of Common Stock or Common Stock any amounts, upon such a liquidation, dissolution or winding-up of our Company. In this event, you could lose some or all of your investment.

Item 1B. Unresolved Staff Comments

None

Item 2. Properties.

Our principal executive offices are located at 7380 Coca Cola Drive, Suite 106, Hanover, MD 21076, and our telephone number is (443) 776-3133. Our website address is www.Processapharmaceuticals.com.

In October 2016, we leased approximately 6500 square feet of office space in Hanover, Maryland. The term of the lease is three years. The rent for the remaining months of the lease term expiring September 30, 2019 is approximately $6,919 per month for 2018 and $7,749 for 2019. There are no options to extend the lease term. Total rent expense was $105,594 and $50,997 for the years ended December 31, 2017 and 2016 respectively. Rent expense for 2017 includes accrued rent liability of $13,284 and common area maintenance and real estate tax reimbursements of $22,929.

Item 3. Legal Proceedings.

From time to time we may be involved in claims arising in the ordinary course of business. To our knowledge, no material legal proceedings, governmental actions, investigations or claims are currently pending against us or involve us that, in the opinion of our management could reasonably be expected to have a material adverse effect on our business and financial condition.

Item 4. Mine Safety Disclosures.

None.

Part II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and issuer Purchases of Equity Securities.

Our authorized capital stock consists of 350,000,000 shares of Common Stock, $0.0001 value per share, and 10,000,000 shares of preferred stock, $0.0001 par value per share. As of April 13, 2018, we have 35,272,626 shares of common stock outstanding and no shares of preferred stock outstanding.

Our common stock is quoted on the OTCQB under the symbol "PCSA". We have one class of common stock. As of April 13, 2018, there were approximately 143 registered holders of record of our common stock.

The following table sets forth the high and low sales price of our common stock on the OTCQB during the periods listed below (as adjusted for a 1-7 reverse stock split on December 11, 2017):

Quarter Ended	High	Low
December 31, 2017	$ 5.11	$ 0.48
September 30, 2017	$ 4.69	$ 0.98
June 30, 2017	$ 0.98	$ 0.98
March 31, 2017	$ 1.75	$ 0.98
December 31, 2016	$ 2.31	$ 1.12
September 30, 2016	$ 2.31	$ 1.12
June 30, 2016	$ 2.31	$ 1.12
March 31, 2016	$ 2.80	$ 1.05

Dividend Policy

We have not previously declared or paid any dividends on our common stock. The payment of dividends on our common stock in the future will depend on our profitability at the time, cash available for those dividends, and such other factors as our board of directors may consider appropriate. We do not anticipate paying dividends on our common stock in the foreseeable future.

Securities Authorized for Issuance under Equity Compensation Plans

The Heatwurx Board of Directors and stockholders approved the Amended and Restated Heatwurx, Inc. 2011 Equity Incentive Plan (the "Plan") in October 2012. All prior awards made under the Plan were cancelled and are available for future issuances.

Eligibility. Employees, non-employee directors, advisors, and consultants of the Company and its affiliates are eligible to receive grants under the Plan.

Shares Available. 257,143 shares are reserved for issuance under the Plan after the one for seven reverse-split. There are currently no outstanding awards under the Plan. If unexercised options expire or are terminated, the underlying shares will again become available for grants under the Plan.

Grants under the Plan. The Plan provides for the grant of options to purchase shares of common stock of the Company. Options may be incentive stock options, designed to satisfy the requirements of Section 422 of the U.S. Internal Revenue Code, or non-statutory stock options, which do not meet those requirements.

Incentive stock options may only be granted to employees of the Company and its affiliates. Non-statutory stock options may be granted to employees, nonemployee directors, advisors, and consultants of Company and its affiliates.

Outstanding Options. As of December 31, 2017, and the date hereof, there were no outstanding option grants under the Plan.

Administration of the Plan. The Plan provides that it will be administered by the Board or a Committee designated by the Board. Our Board of Directors will administer the Plan until such time as the Board appoints a Compensation Committee. The Board or the Compensation Committee once appointed will have complete discretion to:

- determine who should receive an option;
- determine the type, the number shares, vesting requirements and other terms and conditions of options;
- interpret the Plan and options granted under the Plan; and
- make all other decisions relating to the operation and administration of the Plan and the options granted under the Plan.

Terms of Options. The exercise price for non-statutory and incentive stock options granted under the equity compensation plan may not be less than 100% of the fair market value of the common stock on the option grant date or 110% in the case of incentive stock options granted to employees who own stock representing more than 10% of the voting power of all classes of common stock of the Company and its parent and subsidiaries ("10%-Stockholders"). The Board of Directors, until a Compensation Committee has been appointed, has the authority to establish the vesting, including the terms under which vesting may be accelerated, and other terms and conditions of the options granted. Options can have a term of no more than ten years from the grant date except for incentive stock options granted to 10%-stockholders which can have a term of no more than five years from the grant date.

The Plan authorizes the Board of Directors or the Compensation Committee once appointed to provide for accelerated vesting of options upon a "Change in Control", as defined in the Plan. A Change in Control includes:

- any Person (as such term is used in Sections 13(b) and 14(b) of the 1934 Act) is or becomes the beneficial owner ("Beneficial Owner") (as defined in Rule 13d-3 promulgated under the 1934 Act), directly or indirectly, of securities representing fifty percent (50%) or more of the combined voting power of the Company's securities that are then outstanding; provided, however, that an initial public offering shall not constitute a Change in Control for purposes of the Plan;
- a merger or consolidation after which the Company's then current stockholders own less than 50% of the surviving corporation; or
- a sale of all or substantially all of the Company's assets.

Amendment and Termination. The Board of Directors may amend or terminate the Plan and outstanding options at any time without the consent of option holders provided that such action does not adversely affect outstanding options. Amendments are subject to stockholder approval to the extent required by applicable laws and regulations. Unless terminated sooner, the Plan will automatically terminate on April 15, 2021, the tenth anniversary of April 15, 2011, the date the Plan was adopted by our Board of Directors and approved by our Stockholders.

The table below provides information as to the number of options outstanding and their weighted average exercise price at December 31, 2017.

	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	—	$ N/A	257,143
Equity compensation plans not approved by security holders	—	N/A	-
Total	—		257,143(1)

(1) Consists of shares available for issuance under the Plan.

Recent Sales of Unregistered Securities

On October 4, 2017 certain entities affiliated with current shareholders purchased $1.25 million of our senior secured convertible notes ("Senior Notes") in a bridge financing undertaken by us to support our operations. On November 21, 2017, additional third party accredited investors contributed $1.33 million in financing proceeds. The Senior Notes were issues solely to investors who are "accredited investors" within the meaning of Rule 501(a) of Regulation D in reliance on the exemptions from registration under Regulation D and Securities Act Section 4(2).

Repurchases of Equity Securities

We repurchased no shares of our common stock during the fourth quarter of 2017.

Item 6. Selected Financial Data

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis should be read together with our financial statements and the related notes appearing elsewhere in this report. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements" for a discussion of the uncertainties, risks and assumptions associated with these statements. Actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth under "Risk Factors" and elsewhere in this Annual Report on Form 10-K.

Background

On October 2, 2017 Heatwurx, Inc., "(Heatwurx") and Processa Therapeutics, LLC ("Processa"), a Delaware limited liability company and a wholly-owned subsidiary of Heatwurx entered into an Asset Purchase Agreement (the "Acquisition Agreement") with Promet Therapeutics, LLC, a Delaware limited liability company ("Promet") pursuant to which, at the effective time on October 4, 2017, Heatwurx acquired all of the assets of Promet, in exchange for issuing to Promet approximately 222,217,000 shares of the common stock of Heatwurx (approximately 31,745,000 shares following our reverse stock split). Following the closing, Heatwurx changed its name to Process Pharmaceuticals, Inc. As used in this Form 10-K, unless the context suggests otherwise, "we," "us," "our," "the Company" or "Processa" refer to Processa Pharmaceuticals, Inc., its wholly-owned subsidiaries and the acquired assets from Promet.

Following the acquisition, we have abandoned our prior business plan and we are now pursuing Promet's historical business and proposed business, with a focus on developing drugs to treat patients that have a high unmet medical need. Prior to the acquisition, Heatwurx had nominal net liabilities and operations. It was considered a nonoperating public shell corporation. Therefore, because Promet is considered the accounting acquirer (and legal wholly-owned subsidiary of Heatwurx) and Heatwurx is considered the accounting acquiree (and legal acquirer), we have presented Promet's information as that of the Company, including operations prior to the closing of the Acquisition Agreement.

Overview of the Company

Processa is an emerging pharmaceutical company focused on the clinical 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. Within this group of pharmaceutical products, we currently are developing one product for two indications (i.e., the use of a drug to treat a particular disease) and searching for additional products for our portfolio.

Going Concern and Management's Plan

The Company's consolidated financial statements are prepared using U.S. GAAP and are based on the assumption that the Company will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. The Company faces certain risks and uncertainties that are present in many emerging growth companies 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 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.

The Company has relied exclusively on private placements with a small group of accredited investors to finance its business and operations. We do not have any credit facilities as a source of future funds. The Company has had no revenue since inception on August 31, 2015. The Company does not currently have any revenue under contract nor does it have any immediate sales prospects. As of December 31, 2017, the Company had an accumulated deficit of approximately $3.859 million incurred since inception. For the year ended December 31, 2017, the Company incurred a net loss from continuing operations of approximately $1.856 million and used approximately $1.655 million in net cash from operating activities from continuing operations. The Company had total cash and cash equivalents of approximately $2.847 million as of December 31, 2017. We have raised proceeds of $2.58 million from the Senior Convertible Notes issued through December 31, 2017. No additional Senior Convertible Notes have been issued through the date this report was available to be issued. On March 19, 2018, we modified the Option and License Agreement with CoNCERT Pharmaceuticals, Inc. ("CoNCERT") (see Notes 10 and 14 in the consolidated financial statements in Item 8 of Form 10-K) effective January 2018, which enabled us to exercise our option to license the CoNCERT patent rights and know-how to develop and commercialize compounds (CTP-499 and each metabolite thereof) and products, as defined in the agreement. Although we have other drugs being positioned into our pipeline, the loss of our rights to CTP-499 would have materially and adversely affected our planned growth and business plan. 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.

We are in the process of raising additional funds by potentially selling additional Senior Convertible Notes, convertible loans or other securities. No assurance can be given that we will be successful in raising adequate funds needed. 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.

Uncertainty concerning our ability to continue as a going concern may hinder our ability to obtain future financing, as well as adversely affect our collaborative drug development relationships. Continued operations and our ability to continue as a going concern are dependent on our ability to obtain additional funding in the near future and thereafter, and no assurances can be given that such funding will be available at all or will be available in sufficient amounts 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 yielding funds, we will rapidly exhaust our resources and will 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 the 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 the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are available to be issued. The consolidated financial statements included in Item 8 of Form 10-K 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 the Company be unable to continue as a going concern based on the outcome of these uncertainties described above.

Recent Developments

Our first FDA meeting with the FDA was held on October 18, 2017. This was a pre-IND meeting to review the proposed development program of PCS-499 (formerly known as CTP-499) for the treatment of Necrobiosis Lipoidica with special emphasis on the clinical program. The IND for this indication is expected to be submitted to the FDA in Q3 2018, and the Phase 2 study will commence in Q4 2018.

On or about November 21, 2017, Processa received proceeds from the second tranche of a Senior Convertible Note for $1,330,000 (convertible to shares of Processa Pharmaceuticals, Inc.). This first tranche was for $1,250,000 from prior Heatwurx and Promet shareholders.

In January 2018 we incurred losses of approximately $144,000 due to fraud from a cybersecurity breach. While we are taking steps to prevent such event from reoccurring, we cannot provide assurance that similar issues will not reoccur. Failure of our internal control systems to prevent error or fraud could materially adversely impact us.

On March 21, 2018, Processa announced that it has been assigned the license for the clinical stage compound CTP-499 and plans to develop the drug in multiple unmet medical need conditions.

On March 19, 2018 Promet, Processa and CoNCERT Pharmaceuticals, Inc. ("CoNCERT") executed an Amendment to the Option Licensing Agreement granting an exclusive license, including the right to assign the license, sublicense, develop, manufacture, use and commercialize CTP-499 worldwide. Upon exercising the option to license CTP-499, Promet transferred $8.0 million of its Processa shares, approximately 5.9% of all Processa outstanding shares, to CoNCERT with CoNCERT also being eligible to receive royalties on commercial sales. Promet with CoNCERT's agreement has subsequently assigned the license to Processa after exercising the licensing option.

Promet, Processa and CoNCERT entered into this Agreement to permit Processa to exercise the Option exchange for 2,090,301 shares of Processa's common stock upon the terms and subject to the conditions stated in this Agreement.

On June 26, 2017, Processa terminated the development and licensing agreement with Drexel for the cyclic peptide. Processa was investigating the effects of the cyclic peptide for a rare orphan condition known as Krabbe Disease. Certain pharmacological targets were proposed to be an important factor in the development of any efficacious treatment for this condition. Based on preliminary data available for the peptide, it appeared that the cyclic peptide might be a feasible option for use in the condition. Unfortunately, as the peptide was further evaluated, there were inconsistent results related to the pharmacological effects as well as issues with manufacturing a viable formulation for clinical studies. Although other conditions were considered for the development of the peptide, the long-term program was determined not to meet the requirements for Processa to continue with development of the peptide. As such, the development and licensing agreement was terminated. The costs incurred under this agreement were substantially completed at December 31, 2016. Insignificant costs were incurred in 2017 to finalize and terminate the agreement.

Processa also has evaluated over 50 potential assets for acquisition and are presently performing due diligence on a cancer drug and a drug used for a cardiovascular condition that has no approved treatment. If one or both of these assets are a good fit for our portfolio, we will try to acquire the asset through in-licensing or acquisition of the Company as long as the acquisition makes good business sense.

Critical Accounting Policies and Use of Estimates

The discussion and analysis of our financial condition and results of operations are based on our audited consolidated financial statements which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis. We base our estimates on historical experience and on other assumptions that we believe 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 (see also Note 1, 2 and 3 to our consolidated financial statements included in Item 8 of this Annual Report on Form 10-K).

Going Concern. As noted above in Going Concern and Management's Plan, 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 the consolidated financial statements included in Item 8 of the Form 10-K 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 the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are available to be issued. The 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 the Company be unable to continue as a going concern based on the outcome of these uncertainties described above.

Reverse Acquisition. The asset acquisition of Promet by Heatwurx has been accounted for 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*. Under this method of accounting, Heatwurx, a nonoperating public shell corporation with nominal net liabilities, acquired all the assets of Promet, a private operating entity, through issuance of 90 percent of the issued and outstanding common stock of Heatwurx immediately after the asset acquisition. As a result of the change in control, Promet comprises the ongoing operations and assets of the combined entity and Promet senior management comprises the senior management of the Company and Promet is considered the accounting acquirer. Heatwurx has been treated as the "acquired" company for financial reporting purposes. The transaction is considered to be a capital transaction in substance. Accordingly, for accounting purposes, it is assumed that Promet issued shares to Heatwurx at fair value for Heatwurx's net liabilities assumed by Promet at closing of the reverse acquisition. The fair value of the net liabilities assumed from Heatwurx, net of the par value of the assumed shares issued to Heatwurx is recognized as a reduction of additional paid-in capital.

As a result of the above, the operations prior to the asset purchase transaction are those of Promet. The assets and liabilities of Promet are recognized and measured at the historical carrying amounts. The accumulated deficit and other equity balances of Promet have been carried forward and adjusted to reflect the legal shares and par value of Heatwurx with the difference allocated to additional paid-in capital. Additional paid-in capital is also reduced by the fair value over the historical cost of the net liabilities assumed from Heatwurx, since the transaction is accounted for as a capital transaction, not a business combination.

Earnings per share ("EPS") is calculated using the equity structure of Processa Pharmaceuticals, Inc., including the equity interests issued to Promet. Prior to the reverse acquisition, EPS is based on Promet's net income and weighted average common shares outstanding that were received in the asset purchase transaction. Subsequent to the reverse acquisition, EPS is based on the actual number of common shares of Processa Pharmaceuticals, Inc. outstanding during that period.

The Company completed a reverse split or a one-for-seven exchange of its shares. As a result, the consolidated financial statements have been retrospectively adjusted to reflect the one-for-seven reverse split. See Note 2 and Note 3 of the consolidated financial statements included at Item 8 of the Form 10-K for more information.

At the closing of the asset purchase transaction on October 4, 2017, Heatwurx issued Promet 31,745,242 shares of the Company's common stock or approximately 90% of the 35,272,626 total common shares issued and outstanding adjusted for the reverse split. As the accounting acquirer, Promet had assets of $1,168,609 and members' equity of $1,017,342. Members' equity consisted of members' interest of $4,270,000 and accumulated deficit of $3,252,658. Promet acquired the fair value of net liabilities assumed from Heatwurx at acquisition of $37,750 consisting of $6,280 of cash and $44,030 of accounts payable and accrued expenses. The transaction was accounted for as a capital transaction. As a result, the fair value of the net liabilities assumed from Heatwurx of $37,750, net of the par value of the assumed shares issued to Heatwurx of $38,102 is recognized as a reduction of additional paid-in capital. Promet's members' interest was allocated to common stock at par value for $3,175 with the balance of $4,266,825 allocated to additional paid in capital. The loss from operations was $1,249,887 from January 1, 2017 through the acquisition date of October 4, 2017 and $606,428 from the acquisition date through December 31, 2017.

Stock-Based Compensation: The Company accounts 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 term of the options will be based on the contractual term of the options as determined by the Board of Directors when the 2011 Equity Incentive Plan is amended or terminated and approved by the stockholders to the extent required by applicable laws and regulations. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. The Company estimates forfeitures at the time of grant and makes revisions, if necessary, at each reporting period if actual forfeitures differ from those estimates. The Company has not estimated future unvested forfeitures since there were no option grants outstanding at December 31, 2017. Upon the issuance of 90% of Heatwurx's common stock to Promet on October 4, 2017, there was a Change in Control event, as defined in the Plan. As of September 30, 2017, prior to the Change in Control event, all 269,500 unexercised options and all 40,000-unexercised performance options outstanding at December 31, 2016 were cancelled and are available for issuance.

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

We record equity instruments at their fair value on the measurement date by utilizing the Black-Scholes option-pricing model. Stock Compensation for all share-based payments, is recognized as an expense over the requisite service period.

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. In order to estimate the volatility rate at each issuance date, given that the Company has not established a historical volatility rate as it has minimal trading volume since Processa began trading on October 4, 2017, management will review volatility rates for a number of companies with similar biopharmaceutical operations to arrive at an estimated volatility rate for each option grant. The term of the options will be based on the contractual term of the options as determined by the Board of Directors when the 2011 Equity Incentive Plan is amended or terminated and approved by the stockholders to the extent required by applicable laws and regulations. The risk-free interest rate is determined utilizing the treasury rate with a maturity equal to the estimated term of the option grant. Finally, management will make assumptions regarding a forfeiture rate once the 2011 Equity Incentive Plan is amended or terminated by the Board of Directors and approved by the stockholders to the extent required by applicable laws and regulations.

The Plan approved by the Heatwurx Board of Directors and stockholders in October 2012 has 257,143 shares of common stock after the reverse-split reserved for issuance under the Plan. The Plan is being reviewed by the Board of Directors and may be amended or terminated. Amendments are subject to stockholder approval to the extent required by applicable laws and regulations. Unless terminated sooner, the Plan will automatically terminate on April 15, 2021. There are currently no outstanding option grants under the Plan. If unexercised options expire or are terminated, the underlying shares will again become available for grants under the Plan.

During the year ended December 31, 2016, there were no options or performance options granted or exercised and 321,667 unexercised options with a weighted average exercise price of $1.69 were cancelled. At December 31, 2016, there were 269,500 unexercised options with a weighted average exercise price of $1.88 and a weighted average remaining life of 2.04 years and 40,000 unexercised performance options with a weighted average exercise price of $2.00. Upon the issuance of 90% of Heatwurx's common stock to Promet on October 4, 2017, there was a Change in Control event, as defined in the Plan. As of September 30, 2017, prior to the Change in Control event, all 269,500 unexercised options and all 40,000-unexercised performance options outstanding at December 31, 2016 were cancelled. No stock-based compensation expense was recognized for the years ended December 31, 2017 and 2016.

Warrants. During the year ended December 31, 2016, there were no warrants granted, exercised or cancelled. At December 31, 2016, there were 2,000,304 warrants outstanding with a weighted average exercise price of $2.36 and a weighted average remaining life of 0.63 years. During the nine months ended September 30, 2017, 723,181 warrants with a weighted average exercise price of $2.99 were cancelled a result of non-exercise prior to their exercise date. At September 30, 2017, there were 1,277,123 warrants with a weighted average exercise price of $2.00 and a weighted average remaining life of 0.08 years.

Income Taxes. As a result of the transaction accounted for a reverse acquisition discussed above (also see Note 1 and Note 3 of the consolidated financial statements in Item 8 of Form 10-K), 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. Therefore, no provision or liability for income taxes has been included in these 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 not available to the Company following an ownership change as defined by Internal Revenue Code Section 382. The Heatwurx net deferred tax assets were fully reserved with a valuation allowance.

The Company accounts for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases.

The provision for income taxes includes federal and state income taxes currently payable and deferred taxes resulting from temporary differences between the financial statement and tax basis of assets and liabilities at the enacted tax rates. Changes in deferred income tax assets and liabilities are included as a component of income tax expense. The effect on deferred income tax assets and liabilities attributable to changes in enacted tax rates are charged or credited to income tax expense in the period of enactment. Valuation allowances are recorded to reduce deferred tax assets when it is more-likely-than-not that a tax benefit will not be realized.

With respect to uncertain tax positions, the Company would 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 accrual for interest or penalties on our consolidated balance sheets at December 31, 2017 and 2016. The Company had no unrecognized tax benefits or uncertain tax positions at December 31, 2017 or 2016.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 ("TCJA") was signed into law. In December 2017, the Securities and Exchange Commission 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. For further information, see Note 7 to our consolidated financial statements included in Item 8 of Form 10-K.

We file U.S. federal income and Maryland state tax returns. There are currently no income tax examinations underway for these jurisdictions. However, tax years from and including 2014 remain open for examination by federal and state income tax authorities.

During the year ended December 31, 2017, we incurred operating losses of approximately $606,400. However, we recorded no income tax benefit for the approximately $347,500 ($95,632 net of tax) of general and administrative expenses treated as deferred start-up expenditures for tax purposes and approximately $258,600 ($71,155 net of tax) of tax losses resulting in tax loss carryforwards. The 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. The benefit associated with the net operating loss carry forward 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 net operating losses have not been recorded in the consolidated financial statements. As of December 31, 2016, the Company had no net operating losses for federal and state income tax purposes since Promet's members were taxed separately on their proportionate share of Promet's income, deductions, losses and credits.

Convertible Debt. The $2.58 million of 8% Senior Convertible Notes are discussed in Note 6 to the consolidated financial statements in Item 8 of Form 10-K. Principal and interest under each Senior Note is due on the earlier of (i) the mandatory and automatic conversion of the Senior Note into the next Private Investment in Public Equity ("PIPE") financing we undertake, provided the PIPE financing yields gross proceeds of at least $4 million at a conversion price per share equal to the lower of (a) $72 million pre-money valuation or (b) a 10% discount to the pre-money valuation (Qualified Financing) or (ii) the one-year anniversary of that Senior Note (Maturity Date). The Senior Notes bear interest at 8% per year and are payable in kind (in common stock). At the Maturity Date, the outstanding principal and accrued interest on the Senior Note will be automatically converted into shares of common stock of the Company equal to the lesser of (i) $72 million pre-money valuation or (ii) any adjusted price resulting from the application of down round pricing during the anti-dilution period through December 31, 2018. In such event, the anti-dilution period, as defined, will be extended for a further 12 months. The Senior Notes are secured by a security interest in the assets of the Company and contain negative covenants as defined in the note agreement.

Holders of Senior Notes (a) may elect to receive 110% of principal plus accrued interest in the event there is a change of control prior to conversion of the Senior Notes, (b) are entitled to full ratchet 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, (c) are entitled to certain registration rights for the securities underlying the Senior Notes and (d) have been granted certain preemptive rights pro rata to their respective interests through December 31, 2018. The Senior Notes can be prepaid by the Company at any time following the date of issuance with seven days prior written notice to the note holder.

The Company retained Boustead Securities Ltd. ("Boustead"), a registered broker-dealer, as its exclusive financial adviser and has agreed to pay Boustead (i) six percent (6%) of gross proceeds received by the Company and (ii) warrants to purchase securities in the amount of three percent (3%) of the equity issued or issuable in connection with the Senior Notes bridge financing. These warrants will be issued upon achieving certain financing levels under the PIPE financing. No warrants are issuable, and none have been issued as of December 31, 2017.

No debt was issued and outstanding for 2016.

The Company recognizes debt issuance costs incurred on the Senior Convertible Notes as a reduction of the carrying amount of the Senior Convertible Notes on the face of the consolidated balance sheet. The debt issuance costs are amortized to interest expense using the interest method over the term of the Senior Convertible Notes.

The convertible debt is classified as a liability based on its terms and the guidance in ASC 480,*Distinguishing Liabilities from Equity.* The guidance provides that an unconditional obligation that the issuer must or may settle by issuing a variable number of its equity shares shall be classified as a liability if, at inception, the monetary value of the obligation is based solely or predominately on a fixed monetary amount known at inception.

Additionally, the conversion feature in the convertible debt was evaluated in accordance with ASC Topic 815-15,*Derivatives and Hedging – Embedded Derivatives* and ASC 815-10, *Derivatives and Hedging* to determine whether there is an Embedded Derivative that should be separately recognized and measured in the financial statements. Based on the terms of the convertible debt, the embedded written option would be considered indexed to the issuer's own stock and a separate instrument with the same terms would be classified in stockholders' equity in the statement of financial position, therefore, the written option is not considered a derivative instrument and should not be separated from the host contract.

Further, the mandatory conversion of the debt and accrued interest into common stock encompasses a residual interest in Processa, therefore, the conversion feature would possess principally equity characteristics related to Processa and would be considered clearly and closely related to the host contract. As a result, the conversion feature would not be required to be separately stated

*Research and Development***.** Research and development costs are charged to expense as incurred. These costs include, but are not limited to, employee-related expenses, including salaries, benefits and travel as well as expenses related to contract research arrangements, costs of conducting pre-clinical and clinical trials and materials purchased for research and development activities.

Research and development activities are central to our business model. Product candidates in later clinical development generally have higher development costs than those in earlier stages of development, primarily due to the cost of the clinical trials and manufacturing. As we advance our product candidates, we expect the amount of external research and development will continue to increase for the foreseeable future.

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 clinical research organizations 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 its 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 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.

It is difficult to determine with certainty the duration and completion costs of our current or future preclinical programs and clinical trials of our product candidates, or if, when or to what extent we will generate revenue from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of future clinical and preclinical studies, uncertainties in clinical trial enrollment rate and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate's commercial potential.

Cash and Cash Equivalents. We consider all highly liquid investments with a maturity of three months or less to be cash equivalents. We will be putting cash into certificates of deposit that are purchased through an investment company and are held at multiple banks. The maturities of said certificates of deposit are typically six months or less.

Results of Operations

Our consolidated results of operations for the years ended December 31, 2017 and 2016 are as follows:

	For the years ended December 31,		Change	
	2017	2016	Dollars	Percent
Operating Expenses				
Research and development costs	$ 926,117	$ 1,536,996	$ (610,879)	-39.7%
General and administrative expenses	876,316	384,524	491,792	127.9%
Total operating expenses	1,802,433	1,921,520	(119,087)	-6.2%
Other Income (Expense)				
Interest Expense	(59,063)	-	(59,063)	
Interest Income	5,181	4,454	727	
Total other income (expense)	(53,882)	4,454	(58,336)	
Net Loss	$ 1,856,315	$ 1,917,066	$ (60,751)	-3.2%

Year Ended December 31, 2017 and Year Ended December 31, 2016

*Revenue*s. Processa had no revenues during the years ending December 31, 2017 and 2016, respectively.

Operating Expenses.

Research and Development Expenses. Our research and development costs are expensed as incurred. Research and development expenses primarily consist of (i) licensing of compounds for product testing and development, (ii) program and testing related expenses, (iii) internal research and development staff related payroll, taxes and employee benefits, external consulting and professional fees related to the product testing and development activities of the Company. 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. Research and development expenses were approximately $926,000 and $1,537,000 for the years ended December 31, 2017 and 2016, respectively.

Research and development expenses decreased by approximately $611,000, or 39.7% to $926,000 in 2017 compared to $1,537,000 in 2016. The decrease in research and development expenses relate primarily to the substantial completion of the licensing, program and testing costs incurred under the Drexel agreement in 2016. The contract was officially terminated in June 2017 with insignificant costs incurred during 2017. However, the CoNCERT Pharmaceuticals, Inc. license and option agreement for the replacement compound CTP-499 was not executed until October 2017. As a result, research and development expenses were approximately $747,000 less in 2017 compared to 2016. This decline was partially offset by increased research and development staff related payroll, taxes and employee benefits of approximately $136,000 in 2017 compared to 2016.

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.

We expect research and development expenses to increase as we advance our lead candidates and pipeline product candidates. The funding necessary to bring a drug candidate to market is 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.

General and Administrative Expenses. General and administrative expenses increased by approximately $492,000, or 127.9% to $876,000 in 2017 compared to $384,000 in 2016. The increase in general and administrative expenses relate primarily to professional fees for legal, accounting, advisory and consulting costs of approximately $234,000 related to Company operations and costs of being a public company; increased internal general and administrative staff related payroll, taxes and employee benefits of approximately $214,000 due to growth in Company operations and a full year of expense for 2016 hires; increase in office rent of approximately $55,000 as a result of being the primary obligor on the headquarters lease for a full year in 2017 compared to one-quarter in 2016 and sharing office rent costs with Corlyst, a related party of Promet and a shareholder of Processa, during the balance of 2016; and, one-time costs incurred in 2017 related to the reverse acquisition of Heatwurx by Promet, which closed on October 4, 2017, of approximately $59,000 and the impairment of software costs of approximately $15,000 related to obsolete software costs as a result of the reverse acquisition transaction and change in control of Processa Pharmaceuticals, Inc. These expense increases were partially offset by increased cost reimbursements (payroll, health care and office rent) by Corlyst of approximately $79,000 related to a full year of reimbursements in 2017 compared to one-quarter in 2016 and a net decrease in the other general and administrative expenses.

We expect the general and administrative expenses and consulting costs to increase as we add staff to support the growing research and development activities of the Company and the administration required to operate as a public company.

Other Income (Expense).

Interest Expense. Interest expense was approximately $59,000 and $0 for the years ended December 31, 2017 and 2016, respectively. Interest expense represents accrued interest of approximately $35,700 and the amortization of debt issuance costs of approximately $23,300 on the $2.58 million issuance of 8% Senior Convertible Notes issued on October 4, 2017 ($1,250,000) and November 21, 2017 ($1,330,000). The interest accrues monthly at 8% annually on the principal balance outstanding and is payable in kind through the issuance of common stock of the Company at maturity, which is not later than one-year from the date of issuance of the Senior Convertible Notes. The debt issuance costs are amortized over a one-year period on the effective interest method. The principal balance of the Senior Convertible Notes is also automatically and mandatorily convertible into the common stock of the Company at maturity, except for a change in control event or default. There was no debt in 2016.

Interest Income. Interest income was approximately $5,000 and $4,000 for the years ended December 31, 2017 and 2016, respectively. Interest income represents interest earned on money market funds and certificates of deposit which matured in 2017 and certificates of deposit in 2016.

Financial Condition

Total assets increased by approximately $618,000 at December 31, 2017 compared December 31, 2016. This increase is primarily attributable to the proceeds from issuance of $2.58 million of senior convertible notes reduced by the debt issuance costs of $154,800 which was used to fund the loss from operations of approximately $1.86 million included in the accumulated deficit at December 31, 2017. The senior convertible notes are due within one year of issuance or October and November of 2018. The repayment is through the automatic and mandatory conversion of the principal and fixed interest due into a variable number of common shares based on a valuation of the stock at that date. 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. Absent additional financing, substantial doubt exists about the Company's ability to continue as a going concern as noted under Going Concern above.

Other significant changes in assets include the decrease in a vendor advance payment of approximately $228,000 related to the research and development activities paid in 2016 that was recognized as expense in 2017 with no recurring advance payment in 2017. Additionally, amounts due from Corlyst increased approximately $63,000 based on the timing of billing and collecting the third and fourth quarter administrative service reimbursements for 2017 with no similar receivable due for 2016.

Liabilities, excluding the senior convertible debt, increased approximately $63,500 at December 31, 2017 compared to 2016 related primarily to (i) Heatwurx accounts payable and accrued expenses at acquisition of approximately $44,000 that have not been paid at December 31, 2017 and it is reasonably possible that future payment may not occur for the disputed obligations; (ii) accrued interest of approximately $35,700 on the senior convertible notes that is not due until maturity in October and November 2018, but will be paid through issuance of a variable number of common shares based on a valuation of the stock at that date; and, (iii) accrued rent liability of approximately $13,300 related to the office lease of which $9,963 is noncurrent.

The changes in stockholders' equity consist of the 2017 operating loss in accumulated deficit discussed above and the fair value of the net liabilities assumed from Heatwurx, net of the par value of the assumed shares issued to Heatwurx resulting in a reduction of additional paid-in capital of approximately $38,100.

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 December 31, 2017, we had $2.85 million in cash and cash equivalents compared to $2.09 million in cash and cash equivalents and certificates of deposit as of December 31, 2016 to be used to fund on-going operations. We do not believe we have sufficient cash resources to fund all necessary activities for the completion of the Phase 1 study for CTP-499 and the on-going general and administrative costs of the Company for a period of one year or more from the date the consolidated financial statements were issued. We do not have any credit facilities as a source of future funds, and there can be no assurance that we will be able to raise sufficient additional capital on acceptable terms, or at all. As a result, substantial doubt exists about the Company's ability to continue as a going concern within one year after the date that these consolidated financial statements are issued.

We will seek additional capital through a combination of private and public equity offerings, debt financings and strategic collaborations. However, no assurance can be given that we will be successful in raising adequate funds needed. 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.

We believe that our existing cash and cash equivalents will be sufficient to meet our anticipated cash needs until October 2018. Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for product development sooner than planned. We currently have no credit facility or committed sources of capital. 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 CTP-499 and our other product candidates;
- our ability to enter into and maintain collaboration, licensing and other arrangements and the terms and timing of such arrangements;
- the timing of the NDA submission and marketing approval for CTP-499, if any;
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the receipt of any collaboration or milestone payments;
- the scope, rate of progress, results and cost of our clinical trials, preclinical testing and other related activities;
- the emergence of competing technologies or other adverse market developments;
- the time and costs involved in seeking and obtaining regulatory and marketing approvals in multiple jurisdictions for our product candidates that successfully complete clinical trials;
- the introduction of new product candidates and the number and characteristics of product candidates that we pursue;
- the potential acquisition and in-licensing of other technologies, products or assets.

We will need to raise additional capital to fund our operations in the near future. 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 one or more of our 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 do 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.

Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below.

	For the years ended December 31,	
	2017	2016
Net cash provided by (used in):		
Operating activities	$ (1,654,617)	$ (2,155,037)
Investing activities	1,004,952	(1,043,069)
Financing activities	2,425,200	4,270,000
Net increase in cash and cash equivalents	$ 1,775,535	$ 1,071,894

Net cash used in operating activities

Net cash used in operating activities was $1.65 million and $2.15 million for the years ended December 31, 2017 and 2016, respectively. The reduction in costs used in operating activities is primarily related to the payment of vendor deposits in 2016 that were applied to obligations due for research and development activities in 2017. Additionally, the contract and licensing costs incurred under the Drexel agreement was substantially completed in 2016 and the contract was officially terminated in June 2017. However, the CoNCERT Pharmaceuticals, Inc. license and option agreement for the replacement compound CTP-499 was not executed until October 2017. As a result, research and development costs for program costs, testing and licensing declined in 2017 compared to 2016. This decline was partially offset by increased salaries and wages and payroll related costs from employee hiring in both the research and development and general and administrative functions, professional fees related to operating as a publically-traded company, office rental costs and one-time transaction costs related to the reverse acquisition of Heatwurx by Promet, which closed on October 4, 2017.

We anticipate our research and development efforts and on-going general and administrative costs will generate negative cash flows from operating activities for the foreseeable future. As the Company is still in the process of developing its products, we do not currently sell or distribute pharmaceutical products. We do not currently have sales or marketing capabilities.

Net cash provided by (used in) in investing activities

Net cash provided by investing activities was $1.00 million for the year ended December 31, 2017. This was due to proceeds from the maturity of the certificates of deposit purchased in 2016, partially offset by software acquisition costs. Net cash used in investing activities was $1.04 million for the year ended December 31, 2016. This was due primarily to the purchase of certificates of deposit and the purchase of property and equipment and software acquisition costs.

Net cash provided by financing activities

Net cash provided by financing activities was $2.43 million for the year ended December 31, 2017 from the proceeds of the issuance of $2.58 million of 8% Senior Convertible Notes, partially offset by approximately $155,000 of debt issuance costs. Net cash provided by financing activities was $4.27 million for the year ended December 31, 2016 from the proceeds of the initial issuance of the private placement of equity for Promet.

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 the Company's ability to continue as a going concern as noted under Going Concern above.

Off Balance Sheet Arrangements

At December 31, 2017 and December 30, 2016, we did not have any off-balance sheet arrangements.

Contractual Obligations and Commitments

The following summarizes our contractual obligations and commitments as of December 31, 2017:

	Payments due by period				
Contractual Obligations	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Senior convertible notes	$ 2,786,400	$ 2,786,400	$ -	$ -	$ -
Operating lease obligations	171,528	90,061	81,468	-	-
Purchase obligations	895,740	895,740	-	-	-
Total contractual obligations	$ 3,853,668	$ 3,772,201	$ 81,468	$ -	$ -

On October 4, 2017 certain entities affiliated with current shareholders purchased $1.25 million of our Senior Notes in a bridge financing undertaken by us to support our operations. On November 21, 2017, additional third party accredited investors contributed $1.33 million in financing proceeds. As of December 31, 2017, $2.58 million of Senior Notes were issued and outstanding. Principal and interest under each Senior Note is due on the earlier of (i) the mandatory and automatic conversion of the Senior Note into the next Private Investment in Public Equity ("PIPE") financing we undertake, provided the PIPE financing yields gross proceeds of at least $4 million at a conversion price per share equal to the lower of (a) $72 million pre-money valuation or (b) a 10% discount to the pre-money valuation (Qualified Financing) or (ii) the one-year anniversary of that Senior Note (Maturity Date). The Senior Notes bear interest at 8% per year and are payable in kind (in common stock). At the Maturity Date, the outstanding principal and accrued interest on the Senior Note will be automatically converted into shares of common stock of the Company equal to the lesser of (i) $72 million pre-money valuation or (ii) any adjusted price resulting from the application of down round pricing during the anti-dilution period through December 31, 2018. In such event, the anti-dilution period, as defined, will be extended for a further 12 months. Upon a change in control event or an event of default the holder can be repaid in cash as defined in the agreement. The Company can prepay the Senior Notes at any time with 7 days' notice to the holder.

The operating lease obligations consist of an office space lease and equipment lease from third parties under non-cancelable operating leases. The office lease commenced on October 1, 2016 and expires September 30, 2019 with monthly rent at inception of $5,535 that escalates $1,107 annually on each October plus reimbursement of common operating costs. We recognize rent expense on a straight-line basis over the term of the Lease.

The equipment lease commenced in June 2017 and expires in August 2020. Monthly rent of $586 over the 39-month lease term includes a monthly operating usage cost allowance of $125. Additional charges for excess usage, as defined in the agreement, are charged quarterly. The lessor charges monthly sales tax of 6 percent.

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 had received as of the effective date of the termination and any applicable cancellation fees.

Recently Issued Accounting Pronouncements

From May 2014 through December 2017, the FASB issued several ASUs related to ASU 2014-09, "Revenue from Contracts with Customers (Topic 606)". These ASUs are intended to provide greater insight into both revenue that has been recognized and revenue that is expected to be recognized in the future from existing contracts. The new guidance is effective for interim and annual periods beginning after December 15, 2017, although entities may adopt one year earlier if they choose. The two permitted transition methods under the new standard are the full retrospective method, in which case the standard would be applied to each prior reporting period presented and the cumulative effect of applying the standard would be recognized at the earliest period shown, or the modified retrospective method, in which case the cumulative effect of applying the standard would be recognized at the date of initial application. The Company is currently in the pre-revenue stages of operations; therefore, we do not currently anticipate there would be any change to timing or method of recognizing revenue. As such, we do not believe this new standard will have a material impact on our results of operations, financial condition or cash flows.

In February 2016 through December 2017, the FASB issued several ASUs related to ASU-2016-02, "Leases (Topic 842)." The guidance requires that a lessee recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right of use asset representing its right to use the underlying asset for the lease term. For finance leases: the right-of-use asset and a lease liability will be initially measured at the present value of the lease payments, in the statement of financial position; interest on the lease liability will be recognized separately from amortization of the right-of-use asset in the statement of comprehensive income; and repayments of the principal portion of the lease liability will be classified within financing activities and payments of interest on the lease liability and variable lease payments within operating activities in the statement of cash flows. For operating leases: the right-of-use asset and a lease liability will be initially measured at the present value of the lease payments, in the statement of financial position; a single lease cost will be recognized, calculated so that the cost of the lease is allocated over the lease term on a generally straight-line basis; and all cash payments will be classified within operating activities in the statement of cash flows. Under Topic 842 the accounting applied by a lessor is largely unchanged from that applied under previous GAAP. The amendments in Topic 842 are effective for the Company beginning January 1, 2019. Management is currently evaluating the impact of adopting the new guidance on the Company's financial statements.

Segment Information

We operate in one segment. Management uses one measurement of profitability and does not segregate its business for internal reporting. During 2017 and 2016, substantially all of our long-lived assets were located within the United States.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in interest rates. As of December 31, 2017, we did not hold or issue financial instruments for trading purposes.

Interest rate fluctuation risk

The primary objective of our investment activities is to preserve our capital to fund our operations. We also seek to maximize income from our cash and cash equivalents without assuming significant risk. To achieve our objectives, we invest our cash and cash equivalents in money market funds and short-term certificates of deposit directly or through managed funds, with maturities of six months or less. As of December 31, 2017, we had cash and cash equivalents of $2,847,429 consisting of cash of $1,546,614 and investments of $1,300,815 in highly liquid U.S. money market funds. A portion of our investments may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our investments are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant and a 100-basis point movement in market interest rates would not have a significant impact on the total value of our portfolio. We actively monitor changes in interest rates.

Inflation risk

Inflation may affect us by increasing our cost of labor and study related costs. We do not believe that inflation has had a material effect on our business, financial condition or results of operations for any period presented herein.

Item 8. Financial Statements and Supplementary Data

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Processa Pharmaceuticals, Inc. (formerly Heatwurx, Inc.)

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Processa Pharmaceuticals, Inc. (formerly Heatwurx, Inc.) (the "Company") as of December 31, 2017 and 2016, 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 "financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2017 and 2016, and the consolidated results of their operations and their cash flows for 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 Notes 1 and 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 financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Change in Reporting Entity

On October 4, 2017, as described in Note 3, the Company entered into a reverse acquisition with Promet Therapeutics, LLC which resulted in a change in the historical reporting entity from Heatwurx, Inc. to Promet Therapeutics, LLC. Subsequently, the Company changed its name to Processa Pharmaceuticals, Inc.

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.

[Signature]

Owings Mills, MD
_____, 2018

We have served as the Company's auditor since 2017.

Processa Pharmaceuticals, Inc.
Consolidated Balance Sheets
December 31, 2017 and 2016

	December 31, 2017	December 31, 2016
ASSETS		
Current Assets		
Cash and cash equivalents	$ 2,847,429	$ 1,071,894
Certificates of deposit	-	1,019,294
Due from related party	62,709	-
Vendor deposit	-	227,657
Prepaid expenses	41,446	18,147
Total Current Assets	2,951,584	2,336,992
Property And Equipment		
Software	19,740	15,330
Equipment	9,327	8,445
Total Cost	29,067	23,775
Less: accumulated depreciation	3,246	1,381
Property and equipment, net	25,821	22,394
Other Assets		
Security deposit	5,535	5,535
Total Other Assets	5,535	5,535
Total Assets	$ 2,982,940	$ 2,364,921
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Senior convertible notes, net of debt issuance costs	$ 2,448,570	$ -
Accrued interest	35,693	-
Accounts payable	50,686	14,593
Due to related parties	436	95
Accrued expenses	64,428	83,004
Total Current Liabilities	2,599,813	97,692
Non-current Liabilities		
Accrued rent liability	9,963	-
Total Liabilities	2,609,776	97,692
COMMITMENTS AND CONTINGENCIES - SEE NOTE		
Stockholders' Equity		
Common stock, par value $0.0001, 350,000,000 and 43,261,049 shares authorized; 35,272,626 and 31,745,242 issued and outstanding at December 31, 2017 and 2016, respectively	3,527	3,175
Preferred stock, par value $0.0001, 10,000,000 shares authorized; zero shares issued and outstanding	-	-
Additional paid-in capital	4,228,723	4,266,825
Accumulated deficit	(3,859,086)	(2,002,771)
Total Stockholders' Equity	373,164	2,267,229
Total Liabilities and Stockholders' Equity	$ 2,982,940	$ 2,364,921

The accompanying notes are an integral part of these consolidated financial statements.

Processa Pharmaceuticals, Inc.
Consolidated Statements of Operations
Years Ended December 31, 2017 and 2016

	December 31, 2017	December 31, 2016
Operating Expenses	$ 1,802,433	$ 1,921,520
Operating Loss	(1,802,433)	(1,921,520)
Other Income (Expense):		
Interest expense	(59,063)	-
Interest income	5,181	4,454
Other Income (Expense)	(53,882)	4,454
Net Loss	$ (1,856,315)	$ (1,917,066)
Net Loss Applicable to Common Shares - Basic and Diluted	$ (0.06)	$ (0.07)
Weighted Average Common Shares Used to Compute Net Loss Applicable to Common Shares - Basic and Diluted	32,595,680	29,321,049

The accompanying notes are an integral part of these consolidated financial statements.

Processa Pharmaceuticals, Inc.
Consolidated Statements of Changes in Stockholders' Equity (Deficit)
Years Ended December 31, 2017 and 2016

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount			
Balance, January 1, 2016	-	$ -	$ -	$ (85,705)	$ (85,705)
Issuance of Common Stock, $0.0001 Par Value/Share	31,745,242	3,175	4,266,825	-	4,270,000
Promet Net Loss for the Year Ended December 31, 2016	-	-	-	(1,917,066)	(1,917,066)
Balance, December 31, 2016	31,745,242	3,175	4,266,825	(2,002,771)	2,267,229
Fair value of Heatwurx net liabilities obtained in reverse acquisition	3,527,384	352	(38,102)	-	(37,750)
Net Loss for the Year Ended December 31, 2017	-	-	-	(1,856,315)	(1,856,315)
Balance, December 31, 2017	35,272,626	$ 3,527	$ 4,228,723	$ (3,859,086)	$ 373,164

The accompanying notes are an integral part of these consolidated financial statements.

Processa Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows
Years Ended December 31, 2017 and 2016

	December 31, 2017	December 31, 2016
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (1,856,315)	$ (1,917,066)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,865	1,381
Amortization of debt issuance costs	23,370	-
Impairment of software costs	15,330	-
Net changes in operating assets and liabilities:		
Prepaid expenses	(23,299)	(16,278)
Vendor deposit	227,657	(227,657)
Security deposit	-	(5,535)
Accrued interest	35,693	-
Accounts payable	9,995	3,707
Due to related parties	(62,368)	(69,379)
Accrued rent liability	13,284	-
Accrued liabilities	(39,829)	75,790
Net cash used in operating activities	(1,654,617)	(2,155,037)
CASH FLOWS FROM INVESTING ACTIVITIES		
Proceeds from (purchase of) certificates of deposit	1,019,294	(1,019,294)
Purchase of property and equipment	(20,622)	(23,775)
Cash received in a reverse acquisition transaction	6,280	-
Net cash provided by (used in) investing activities	1,004,952	(1,043,069)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock	-	4,270,000
Proceeds from issuance of senior convertible notes	2,580,000	-
Payment of debt issuance costs	(154,800)	-
Net cash provided by financing activities	2,425,200	4,270,000
NET INCREASE IN CASH	1,775,535	1,071,894
CASH AND CASH EQUIVALENTS - BEG. OF YEAR	1,071,894	-
CASH AND CASH EQUIVALENTS - END OF YEAR	$ 2,847,429	$ 1,071,894

The accompanying notes are an integral part of these consolidated financial statements.

NOTE 1 – NATURE OF BUSINESS

Company Overview

Promet Therapeutics, LLC ("Promet"), a Delaware limited liability company, was a private company founded on August 31, 2015 (inception). On October 2, 2017, Heatwurx, Inc. ("Heatwurx"), a nonoperating public shell corporation, entered into an Asset Purchase Agreement with Promet and Heatwurx's wholly-owned subsidiary, Processa Therapeutics LLC ("Processa"), a Delaware limited liability company, and closed on this agreement effective October 4, 2017. Under this agreement, Heatwurx acquired all of the assets and assumed all the liabilities of Promet, in exchange for 222,217,112 shares of the common stock of Heatwurx, which, at the closing, constituted 90% of the Company's issued and outstanding common stock on a fully diluted basis. Immediately following the closing, there were 246,907,902 shares of common stock issued and outstanding, of which the prior Heatwurx shareholders own 24,690,790 shares after giving effect to 13,673,402 shares issued for Heatwurx's Series D Preferred stock and existing debt that converted into common stock prior to closing of the asset purchase transaction. At the closing, Heatwurx assigned to Processa all of the assets and operations of Promet that constitutes the operating business of Promet. Authorized capital stock consists of 350,000,000 shares of $0.0001 par value common stock and 10,000,000 shares of $0.0001 par value preferred stock.

The closing of the Asset Purchase Agreement on October 4, 2017 resulted in a change in control of Heatwurx by Promet (see Note 3). The Heatwurx executive management, officers and directors resigned and Promet executive management, officers and directors were appointed. Following the closing, Heatwurx changed its trading symbol from "HUWX" to "PCSA" on the OTC Pink exchange effective as of October 10, 2017. Heatwurx changed its name to Processa Pharmaceuticals, Inc. (the "Company") and authorized a one-for-seven exchange, or reverse split, of its shares effective October 23, 2017. On December 8, 2017, the Company received approval from the Financial Industry Regulatory Authority to implement the one-for-seven reverse split in trading markets. As a result, the consolidated financial statements have been retrospectively adjusted to reflect shares outstanding after the one-for-seven reverse split. Following the asset purchase transaction, the Company abandoned Heatwurx's prior business plan and is now only pursuing Promet's proposed business with a focus on developing drugs to treat patients that have a high unmet medical need.

As a result of the above, these consolidated financial statements represent Promet as the accounting acquirer (legal acquiree) and Processa Pharmaceuticals, Inc. from October 4, 2017 forward as the accounting acquiree (legal acquirer) and the legal capital stock (number and type of equity interests issued) is that of Heatwurx, which subsequently changed its name to Processa Pharmaceuticals, Inc., the legal parent, in accordance with guidance on reverse acquisitions accounted for as a capital transaction instead of a business combination (See Note 2 – Basis of Presentation and Earnings Per Share and Note 3 – Reverse Acquisition).

All references to the "Company" and Processa Pharmaceuticals, Inc. refer to Heatwurx, Inc., Processa Therapeutics, LLC, and Promet Therapeutics, LLC, which was assigned at acquisition to Processa Therapeutics, LLC.

Description of Business

We are 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 two indications (i.e., the use of a drug to treat a particular disease) and searching for additional products for our portfolio. Our operations are performed in the state of Maryland and are still in the organizational and research and development phase of operations. As a result, we have a limited operating history and only a preliminary business plan from which investors may evaluate our future prospects. We have not had any sources of revenue from inception through December 31, 2017 and have a history of operating losses from operations.

As of December 31, 2017, the Company had an accumulated deficit of approximately $3.859 million incurred over approximately 28 months of its existence. Our current capital is insufficient to fully fund our total business plan and the development of our planned product candidates. Our ability to achieve revenue-generating operations and, ultimately, achieve profitability will depend on whether we can obtain additional capital when we need it, complete the development of our technology, receive regulatory approval of our planned product candidates and find strategic collaborators that can incorporate our planned product candidates into new or existing drugs which can be successfully commercialized. There can be no assurance that we will ever generate revenues or achieve profitability.

Recent Developments

On or about October 4, 2017, the Company received $1.25 million from the first tranche of Senior Convertible Notes that are expected to convert into securities of the Company that are placed in the next placement round at a price that will not be greater than 90% of the offering price in that placement (See Note 6). This first tranche was from current Heatwurx and Promet shareholders. On November 21, 2017, an additional tranche of $1,330,000 of Senior Convertible Notes was issued to third party accredited investors. We are in the process of raising additional funds by potentially selling additional Senior Convertible Notes, convertible loans or other securities. No assurance however can be given that the Company will be successful in doing so.

On October 4, 2017, the Company and CoNCERT Pharmaceuticals Inc. (“CoNCERT”) entered into an exclusive option and license agreement for the CTP-499 compound. However, under the terms of this agreement, if the Company fails to meet the conditions set forth in the agreement, which include a requirement for us to have not less than $8 million in funding for the support of the drug as defined within the agreement, or if the Company elects not to exercise the option, then the product reverts back to ownership by CoNCERT. Since CPT-499 is currently our drug product lead candidate, should we lose our rights to CTP-499, our planned growth and business plan would be materially and adversely affected. On March 19, 2018, we modified the Option and License Agreement with CoNCERT effective January 2018 (see Notes 10 and 14), which enabled us to exercise our option to license the CoNCERT patent rights and know-how to develop and commercialize compounds (CTP-499 and each metabolite thereof) and products, as defined in the agreement.

Status as an Emerging Growth Company

We are an “emerging growth company” as that term is defined in the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (i.e., those that have not had a registration statement declared effective under the Securities Act of 1933, as amended (the “Securities Act”), or do not have a class of securities registered under the Securities Exchange Act of 1934, as amended (the “Exchange Act”)) are required to comply with such new or revised financial accounting standards.

The JOBS Act also provides that an emerging growth company can elect to opt out of the extended transition period provided by Section 102(b)(1) of the JOBS Act and comply with the requirements that apply to nonemerging growth companies, but any such election to opt out is irrevocable. We may still take advantage of all of the other provisions of the JOBS Act, which include, but are not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, the reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and the exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Earnings per Share

The accompanying consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP"), and reflect all of our activities, including those of our wholly-owned subsidiary. All material intercompany accounts and transactions have been eliminated in consolidation. In the opinion of management, all adjustments considered necessary for a fair presentation have been included. These adjustments consist of normal and recurring accruals, as well as non-recurring charges.

The acquisition of Promet by Heatwurx has been accounted for 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*. Under this method of accounting, Heatwurx, a nonoperating public shell corporation with nominal net liabilities, acquired all the assets of Promet, a private operating entity, through issuance of 90 percent of the issued and outstanding common stock of Heatwurx immediately after the asset acquisition. As a result of the change in control, Promet comprises the ongoing operations and assets of the combined entity and Promet senior management comprises the senior management of the Company and Promet is considered the accounting acquirer. Heatwurx has been treated as the "acquired" company for financial reporting purposes. The transaction is considered to be a capital transaction in substance. Accordingly, for accounting purposes, it is assumed that Promet issued shares to Heatwurx at fair value for Heatwurx's net liabilities to be assumed by Promet at closing of the reverse acquisition. The fair value of the net liabilities assumed from Heatwurx, net of the par value of the assumed shares issued to Heatwurx is recognized as a reduction of additional paid-in capital.

As a result of the above, the operations prior to the asset purchase transaction are those of Promet. The assets and liabilities of Promet are recognized and measured at the historical carrying amounts. The accumulated deficit and other equity balances of Promet have been carried forward and adjusted to reflect the legal shares and par value of Heatwurx with the difference allocated to additional paid-in capital. Additional paid-in capital is also reduced by the fair value over the historical cost of the net liabilities assumed from Heatwurx, since the transaction is accounted for as a capital transaction, not a business combination.

Earnings per share ("EPS") is calculated using the equity structure of Processa Pharmaceuticals, Inc., including the equity interests issued to Promet in the asset acquisition transaction (see Note 3). Prior to the reverse acquisition, EPS is based on Promet's net income and weighted average common shares outstanding that were received in the asset purchase transaction. Subsequent to the reverse acquisition, EPS is based on the actual number of common shares of Processa Pharmaceuticals, Inc. outstanding during that period.

The Company completed a reverse split or a one-for-seven exchange of its shares. As a result, the consolidated financial statements have been retrospectively adjusted to reflect the one-for-seven reverse split.

Segments

The Company operates in one segment. Management uses one measurement of profitability and does not segregate its business for internal reporting. During 2017 and 2016 all of the Company's long-lived assets were located within the United States.

Going Concern and Management's Plan

The Company's consolidated financial statements are prepared using U.S. GAAP and are based on the assumption that the Company will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. The Company faces certain risks and uncertainties that are present in many emerging growth companies 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 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.

The Company has relied exclusively on private placements with a small group of accredited investors to finance its business and operations. We do not have any prospective arrangements or credit facilities as a source of future funds. The Company has had no revenue since inception on August 31, 2015. The Company does not currently have any revenue under contract nor does it have any immediate sales prospects. As of December 31, 2017, the Company had an accumulated deficit of approximately $3.859 million incurred since inception. For the year ended December 31, 2017, the Company incurred a net loss from continuing operations of approximately $1.856 million and used approximately $1.655 million in net cash from operating activities from continuing operations. The Company had total cash and cash equivalents of approximately $2.847 million as of December 31, 2017. We have raised proceeds of $2.58 million from the Senior Convertible Notes issued through December 31, 2017.

No additional Senior Convertible Notes have been issued through the date this report was issued. On March 19, 2018, we modified the Option and License Agreement with CoNCERT Pharmaceuticals, Inc. effective January 2018 (see Notes 10 and 14), which enabled us to exercise our option to license the CoNCERT patent rights and know-how to develop and commercialize compounds (CTP-499 and each metabolite thereof) and products, as defined in the agreement. Although we have other drugs being positioned into our pipeline, the loss of our rights to CTP-499 would have materially and adversely affected our planned growth and business plan. 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.

We are in the process of raising additional funds by potentially selling additional Senior Convertible Notes, convertible loans or other securities. However, no assurance can be given that we will be successful in raising adequate funds needed. 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.

Uncertainty concerning our ability to continue as a going concern may hinder our ability to obtain future financing, as well as adversely affect our collaborative drug development relationships. Continued operations and our ability to continue as a going concern are dependent on our ability to obtain additional funding in the near future and thereafter, and no assurances can be given that such funding will be available at all or will be available in sufficient amounts 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 yielding funds, we will rapidly exhaust our resources and will 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 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 the Company's ability to continue as a going concern within one year after the date that these consolidated financial statements are available to be issued. 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 the Company be unable to continue as a going concern based on the outcome of these uncertainties described above.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the use of estimates and assumptions by management that affect reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. These estimates and assumptions are continuously evaluated and are based on management's experience and knowledge of the relevant facts and circumstances. While management believes 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 includes cash on hand and money market funds. The Company considers all highly liquid investments with a maturity at the date of purchase of three months or less to be cash equivalents. Money market funds were $1,300,815 and $0 at December 31, 2017 and 2016, respectively.

Certificates of Deposit

The certificates of deposit were purchased through an investment company and were held at multiple banks. The maturities of the certificates of deposit are typically six months or less.

Fair Value Measurements and Disclosure

The Company applies 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.

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 convertible notes into the common stock of the Company upon the earlier of (i) meeting certain funding levels on the next Private Investment in Public Equity ("PIPE") financing we undertake or (ii) the one-year anniversary of the issuance of the senior convertible note.

Due From/To Related Parties and Administrative Fees

Administrative fees are collected from a related party, Corlyst, LLC ("Corlyst"), for shared costs related to payroll, health care insurance and rent based on actual costs incurred and recognized as a reduction of the operating expense being reimbursed (see Note 4). Corlyst pays certain operating expenses on behalf of the Company and the Company reimburses Corlyst based on actual costs incurred and recognizes the appropriate expense. The amounts due from and due to Corlyst are billed monthly and are due on demand at the beginning of each month.

Property and Depreciation

Property is stated at cost, less accumulated depreciation. Depreciation is computed under the straight-line method over the estimated useful lives of the assets. Expenditures for maintenance and routine repairs are charged to expense as incurred; expenditures for improvements and major repairs that materially extend the useful lives of assets are capitalized. Depreciation expense for the years ended December 31, 2017 and 2016 was $1,865 and $1,381, respectively.

Following are the estimated useful lives for the various classifications of assets:

Software	3 years
Equipment	5 years

Impairment of Long-lived Assets

The Company periodically reviews its long-lived assets to determine potential impairment by comparing the carrying value of the long-lived assets with the estimated future net undiscounted cash flows expected to result from the use of the assets, including cash flows from disposition, at least annually or more frequently if events or changes in circumstances indicate a potential impairment may exist. Should the sum of the expected future net cash flows be less than the carrying value, the Company would recognize an impairment loss at that date. An impairment loss would be measured by comparing the amount by which the carrying value exceeds the fair value (estimated discounted future cash flows) of the long-lived assets. The Company performs its impairment analysis in October of each year. Based on management's evaluation, $15,330 of carrying costs related to the software was impaired and an impairment loss recorded for the year ended December 31, 2017. No impairment of long-lived assets was recognized for the year ended December 31, 2016.

Debt Issuance Costs

The Company recognizes debt issuance costs incurred on the Senior Convertible Notes as a reduction of the carrying amount of the Senior Convertible Notes on the face of the consolidated balance sheet. The debt issuance costs are amortized to interest expense using the interest method over the term of the Senior Convertible Notes. The amortization of the debt issuance costs was $23,370 for the year ended December 31, 2017 and zero for the year ended December 31, 2016.

Compensated Absences

For the years ended December 31, 2017 and 2016, the Company recorded a liability for paid time off earned by permanent employees but not taken, in accordance with human resource policies.

Advertising Costs

Advertising costs are recognized as expense in the year incurred. Total advertising and marketing expense for the years ended December 31, 2017 and 2016 was $135 and $3,850, respectively.

Research and development

Research and development costs are expensed as incurred and consist of direct and overhead-related expenses. Research and development costs totaled $926,117 and $1,536,996 for the years ended December 31, 2017 and 2016, 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 the Company develops for use in its products is expensed as incurred until technological feasibility has been established after which it is capitalized and depreciated. No costs have been capitalized during the years ended December 31, 2017 and 2016.

Stock-Based Compensation

The Company accounts 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 term of the options will be based on the contractual term of the options as determined by the Board of Directors when the 2011 Equity Incentive Plan is amended or terminated and approved by the stockholders to the extent required by applicable laws and regulations. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. The Company estimates forfeitures at the time of grant and makes revisions, if necessary, at each reporting period if actual forfeitures differ from those estimates. The Company has not estimated future unvested forfeitures since there were no option grants outstanding at December 31, 2017. Upon the issuance of 90% of Heatwurx's common stock to Promet on October 4, 2017, there was a Change in Control event, as defined in the Amended and Restated Heatwurx, Inc. 2011 Equity Incentive Plan. As of September 30, 2017, prior to the Change in Control event, all 269,500 unexercised options and all 40,000-unexercised performance options outstanding at December 31, 2016 were cancelled.

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

Income Taxes

As a result of the asset purchase transaction (see Note 1 Company Overview above and Note 3), there was a change in control of the Company. Prior to the closing of the asset purchase transaction, Promet was treated as a partnership for federal income tax purposes and thus was not subject to income tax at the entity level. Therefore, no provision or liability for income taxes has been included in these financial statements through the date of the asset purchase on 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. The Heatwurx net deferred tax assets were fully reserved with a valuation allowance.

Subsequent to the closing of the asset purchase, Processa Pharmaceuticals, Inc. will file a consolidated federal income tax return in the United States, which includes eligible subsidiaries. In addition, we file income tax returns in state and local jurisdictions as applicable. The Company accounts for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases.

The provision for income taxes includes federal and state income taxes currently payable and deferred taxes resulting from temporary differences between the financial statement and tax basis of assets and liabilities at the enacted tax rates. Changes in deferred income tax assets and liabilities are included as a component of income tax expense. The effect on deferred income tax assets and liabilities attributable to changes in enacted tax rates are charged or credited to income tax expense in the period of enactment. Valuation allowances are recorded to reduce deferred tax assets when it is more-likely-than-not that a tax benefit will not be realized. A full valuation allowance was recorded against the Company's deferred tax assets at December 31, 2017. The Company had no deferred tax assets and no valuation allowance at December 31, 2016.

With respect to uncertain tax positions, the Company would 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. The Company had no unrecognized tax benefits or uncertain tax positions at December 31, 2017 or 2016.

Net Income (Loss) per Share

The Company computes basic and diluted earnings per share amounts pursuant to ASC 260-10-45. Basic earnings per share is computed by dividing net income (loss) available to common shareholders, by the weighted average number of shares of common stock outstanding during the period, as retrospectively restated for the one-for-seven reverse stock split, excluding the effects of any potentially dilutive securities. Diluted earnings per share is computed by dividing net income (loss) available to common shareholders by the diluted weighted average number of shares of common stock during the period. The diluted weighted average number of common shares outstanding is the basic weighted number of shares adjusted for any potentially diluted debt or equity. The computation does not assume conversion, exercise or contingent exercise of securities since that would have an anti-dilutive effect on earnings (loss) during the years ended December 31, 2017 and 2016.

Equity

The asset purchase of Promet by Heatwurx is accounted for as a reverse acquisition. As a result, these consolidated financial statements represent Promet as the accounting acquirer (legal acquiree) and Heatwurx from October 4, 2017 forward as the accounting acquiree (legal acquirer). However, the legal capital stock (number and type of equity interests issued) is that of Heatwurx, which subsequently changed its name to Processa Pharmaceuticals, Inc., the legal parent, in accordance with guidance on reverse acquisitions accounted for as a capital transaction (See Note 2 – Basis of Presentation and Earnings per Share and Note 3 – Reverse Acquisition).

The accumulated deficit and other equity balances of Promet have been carried forward and adjusted to reflect the legal capital shares and par value of Heatwurx, including the shares issued to Promet in the reverse acquisition transaction with the difference allocated to additional paid-in capital. Additional paid-in capital is also reduced by the fair value/ historical cost of the net liabilities assumed from Heatwurx since the transaction is accounted for as a capital transaction, not a business combination.

Subsequent events

The Company has evaluated subsequent events and transactions for potential recognition or disclosure through April 16, 2018, the date the financial statements were issued, in accordance with ASC 855-10-50. Refer to Note 14 below for further information.

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”). The Company has implemented all new accounting pronouncements that are in effect and that may impact its financial statements. It has evaluated recently issued accounting pronouncements and determined that there was no material impact on its financial position or results of operations.

From May 2014 through December 2017, the FASB issued several ASUs related to ASU 2014-09, “Revenue from Contracts with Customers (Topic 606)”. These ASUs are intended to provide greater insight into both revenue that has been recognized and revenue that is expected to be recognized in the future from existing contracts. The new guidance is effective for interim and annual periods beginning after December 15, 2017, although entities may adopt one year earlier if they choose. The two permitted transition methods under the new standard are the full retrospective method, in which case the standard would be applied to each prior reporting period presented and the cumulative effect of applying the standard would be recognized at the earliest period shown, or the modified retrospective method, in which case the cumulative effect of applying the standard would be recognized at the date of initial application. The Company is currently in the pre-revenue stages of operations; therefore, we do not currently anticipate there would be any change to timing or method of recognizing revenue. As such, we do not believe this new standard will have a material impact on our results of operations, financial condition or cash flows.

In February 2016 through December 2017, the FASB issued several ASUs related to ASU-2016-02, "Leases (Topic 842)." The guidance requires that a lessee recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right of use asset representing its right to use the underlying asset for the lease term. For finance leases: the right-of-use asset and a lease liability will be initially measured at the present value of the lease payments, in the statement of financial position; interest on the lease liability will be recognized separately from amortization of the right-of-use asset in the statement of comprehensive income; and repayments of the principal portion of the lease liability will be classified within financing activities and payments of interest on the lease liability and variable lease payments within operating activities in the statement of cash flows. For operating leases: the right-of-use asset and a lease liability will be initially measured at the present value of the lease payments, in the statement of financial position; a single lease cost will be recognized, calculated so that the cost of the lease is allocated over the lease term on a generally straight-line basis; and all cash payments will be classified within operating activities in the statement of cash flows. Under Topic 842 the accounting applied by a lessor is largely unchanged from that applied under previous GAAP. The amendments in Topic 842 are effective for the Company beginning January 1, 2019. Management is currently evaluating the impact of adopting the new guidance on the Company's financial statements.

NOTE 3 – REVERSE ACQUISITION

On October 4, 2017, Heatwurx acquired Promet's net assets of $1,017,342 at historical cost in exchange for approximately 90 percent or 222,217,112 shares of common stock issued by the Company (or 31,745,242 shares post reverse split). Immediately following the transaction, total shares issued and outstanding were 246,907,902 (or 35,272,626 shares post reverse split), representing the total legal capital of the Company. The transaction has been accounted for as a reverse acquisition in accordance with ASC 805-40-45, *Business Combinations - Reverse Acquisitions*. As a result, Heatwurx is considered the acquired company. The consolidated financial statements are under the name of Processa Pharmaceuticals, Inc., the legal parent (accounting acquiree) but represent Promet, the legal subsidiary (accounting acquirer) with an adjustment, to retrospectively adjust Promet's legal capital to reflect the legal capital (number and type of shares) of Processa Pharmaceuticals, Inc. and Heatwurx from October 4, 2017 forward as the accounting acquiree (legal acquirer).

Promet's assets and liabilities are recognized and measured at their precombination carrying amounts. Heatwurx, which subsequently changed its name to Processa Pharmaceuticals, Inc., recognized and measured its assets and liabilities at October 4, 2017 in accordance with guidance applicable to business combinations. The net liabilities were all short term in nature and were recognized at their precombination carrying amounts. The accumulated deficit reflects Promet balances before the reverse acquisition. See Note 2 – Basis of Presentation and Earnings per Share and Note 2 – Equity for the recognition and measurement of common stock and 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. The operating results for Heatwurx are included in the accompanying consolidated financial statements from October 4, 2017 forward.

Heatwurx's assets acquired and liabilities assumed (see below) and the par value of the common stock allocated to Heatwurx stockholders is recognized as a reduction of additional paid-in capital at the acquisition date.

Net recognized values of Heatwurx identifiable assets and liabilities		
Cash	6,280	
Accounts payable	(26,098)	
Accrued expenses	(17,932)	
Net liabilities assumed		$ (37,750)

NOTE 4 – RELATED PARTY TRANSACTIONS

A shareholder, Corlyst, LLC, pays the Company for administrative services performed by the Company. These administrative fees are included as a reduction of the related general and administrative expenses in the Company's statement of operations. These fees were charged beginning in October 2016 and totaled $111,799 and $32,327 for the years ended December 31, 2017 and 2016, respectively. The receivable balances due from Corlyst at December 31, 2017 and 2016 were $62,709 and $0, respectively.

During 2016 and 2017, Corlyst paid certain operating expenses on behalf of the Company and the Company reimbursed Corlyst based on actual costs incurred at later dates. The accounts payable amounts due to Corlyst at December 31, 2017 and 2016 were $336 and $95, respectively. In addition, there was $100 due to an officer included in due to related parties as of December 31, 2017.

A director of the Company is the manager of the JMW Fund, LLC, the San Gabriel Fund, LLC, and the Richland Fund, LLC, collectively known as the "Funds". These Funds own 14,180,543 shares of common stock in the aggregate at December 31, 2017 or 2,025,792 shares of common stock restated for the reverse stock split. In addition, the Funds own $1 million in Senior Convertible Notes at December 31, 2017.

Entities affiliated with the Chairman of the Board of Directors, Chief Executive Officer and Interim Chief Financial Officer of the Company own $250,000 in Senior Convertible Notes at December 31, 2017.

Heatwurx had secured notes payable with the Funds in the aggregate amount of $1,289,361; on September 29, 2017, prior to the asset purchase closing, Heatwurx converted the principal and accrued interest of $412,716 into 8,510,386 shares of common stock or 1,215,813 shares of common stock restated for the reverse stock split. The Funds also had an aggregate principal balance of $138,000 and accrued interest of $50,887 on the Heatwurx revolving line of credit converted into 944,436 shares of common stock on September 29, 2017 or 134,924 shares of common stock restated for the reverse stock split.

NOTE 5– NOTES PAYABLE

On September 29, 2017, prior to the Asset Purchase closing, principal of all existing Heatwurx notes payable in the amount of $1,939,341 and related accrued interest in the amount of $613,114 were converted to 12,953,902 shares of common stock or 1,850,625 shares of common stock restated for the reverse stock split. As of December 31, 2017, there were no Heatwurx notes payable outstanding.

NOTE 6 – SENIOR CONVERTIBLE NOTES

As of October 4, 2017, certain entities affiliated with current shareholders (see Note 4) had purchased $1.25 million of our senior secured convertible notes ("Senior Notes") in a bridge financing undertaken by us to support the Processa operations. On November 21, 2017, additional third party accredited investors contributed $1.33 million in financing proceeds. As of December 31, 2017, $2.58 million of Senior Notes were issued and outstanding.

Principal and interest under each Senior Note is due on the earlier of (i) the mandatory and automatic conversion of the Senior Note into the next Private Investment in Public Equity ("PIPE") financing we undertake, provided the PIPE financing yields gross proceeds of at least $4 million at a conversion price per share equal to the lower of (a) $72 million pre-money valuation or (b) a 10% discount to the pre-money valuation (Qualified Financing) or (ii) the one-year anniversary of that Senior Note (Maturity Date). The Senior Notes bear interest at 8% per year, and are payable in kind (in common stock). At the Maturity Date, the outstanding principal and accrued interest on the Senior Note will be automatically converted into shares of common stock of the Company equal to the lesser of (i) $72 million pre-money valuation or (ii) any adjusted price resulting from the application of down round pricing during the anti-dilution period through December 31, 2018. In such event, the anti-dilution period, as defined, will be extended for a further 12 months. There can be no assurance that we will be successful in achieving the financing levels targeted under the Senior Convertible Notes or the PIPE financing.

Holders of Senior Notes (a) may elect to receive 110% of principal plus accrued interest in the event there is a change of control prior to conversion of the Senior Notes, (b) are entitled to full ratchet 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, (c) are entitled to certain registration rights for the securities underlying the Senior Notes and (d) have been granted certain preemptive rights pro rata to their respective interests through December 31, 2018. The Senior Notes can be prepaid by the Company at any time following the date of issuance with seven days prior written notice to the note holder.

The Senior Notes are secured by a security interest in the assets of the Company and contain negative covenants that do not permit the Company to incur additional indebtedness or liens on property or assets owned, repurchase common stock, pay dividends, or enter into any transaction with affiliates of the Company 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.

The Company retained Boustead Securities Ltd. ("Boustead"), a registered broker-dealer, as its exclusive financial adviser and has agreed to pay Boustead (i) six percent (6%) of gross proceeds received by the Company and (ii) warrants to purchase securities in the amount of three percent (3%) of the equity issued or issuable in connection with the Senior Notes bridge financing. These warrants will be issued upon achieving certain financing levels under the next PIPE financing we undertake. No warrants are issuable, and none have been issued as of December 31, 2017. To the extent that the Company raises more than $8 million (the "Excess Investment") then as to that portion of the Excess Investment that is attributable to funds provided by existing holders of Company equity or by shareholders of the Company, including their respective affiliated holders (the "Affiliated Excess Investment"), the Company shall pay Boustead a cash fee equal to two percent (2%) of the Excess Investment and six percent (6%) of the balance of the Excess Investment, if any. Boustead may allow a portion of its fees payable hereunder to be shared with another registered broker-dealer assisting in the private capital raise.

Senior Notes and the underlying common stock that the Senior Notes will convert into have not been registered under the United States Securities Act of 1933, as amended (the "Act"). The Senior Notes and the underlying common stock that the Senior Notes will convert into shall be issued solely to investors who are "accredited investors" within the meaning of Rule 501(a) of Regulation D promulgated under the Act. There is no public market for the Senior Notes and there is no public market for the securities of the Company (or shares of common stock of the Company issued to Promet at the closing of the Asset Purchase Agreement discussed in Note 1) upon conversion of the Senior Notes.

Debt and accrued interest at December 31, 2017 and interest expense for the year ended December 31, 2017 are as follows:

	Debt Balance	Accrued Interest	Interest Expense
Senior Convertible Notes	$ 2,580,000	$ 35,693	$ 35,693
Unamortized Debt Issuance Cost	(131,430)	-	23,370
Balance, December 31, 2017	$ 2,448,570	$ 35,693	$ 59,063

The Company incurred $154,800 in debt issuance costs on the Senior Notes with Boustead, which were offset against the debt balance. All debt issuance costs are being amortized over the term of the Senior Notes using the effective interest method. The face interest rate of the Senior Notes is 8 percent. The effective interest rate on the Senior Notes was 7.72 percent before debt issuance costs since no payments of interest are due until maturity and 13.96 percent including the debt issuance costs based on the repayment terms of the Senior Notes.

Future maturities of debt and accrued interest, contractual interest expense to be incurred and amortization of debt issuance costs as of December 31, 2017 are $2,580,000, $206,400, $170,707 and $131,430, respectively, for the year ended December 31, 2018.

NOTE 7 – INCOME TAXES

The Company files income tax returns in the U.S. federal jurisdiction and in the state of Maryland. There are currently no income tax examinations underway for these jurisdictions.

The Company provides deferred income taxes for differences between the tax reporting bases and the financial reporting bases of assets and liabilities at the enacted tax rates. The Company determined that it was not required to record a liability related to uncertain tax positions as a result of implementing the requirements of ASC 740-10-25 Income Taxes. Should the Company incur interest and penalties relating to tax uncertainties, such amounts would be classified as a component of interest expense and general and administrative expense, respectively. The liability related to uncertain tax positions is not expected to increase or decrease within the next twelve months.

As of December 31, 2017, the Company's tax year for 2016, 2015 and 2014 are subject to examination by the Internal Revenue Service and the state taxing authorities of Maryland, Colorado, Utah, North Dakota and California.

As discussed in Note 2 – Income Taxes, the historical information presented in the financial statements is that of Promet. Prior to the closing of the asset purchase transaction on October 4, 2017, Promet was treated as a partnership for federal income tax purposes and thus the partners were taxed separately on their proportionate share of Promet's income, deductions, losses and credits. Therefore, no provision or liability for income taxes has been included in these financial statements through the date of the asset purchase on October 4, 2017.

In addition, as a result of the asset purchase transaction, Promet was issued 90 percent of the total issued and outstanding common stock of Heatwurx, including the shares issued to Promet. The transaction resulted in an ownership change as defined by Internal Revenue Code Section 382. The net deferred tax assets of Heatwurx, prior to the asset purchase transaction, were principally federal and state net operating loss carry forwards. The Heatwurx net deferred tax assets were fully reserved with a valuation allowance.

The Company has no current federal or state tax provision recognized in the consolidated financial statements. Since the asset purchase transaction, the Company has incurred operating losses of approximately $606,400. The total deferred tax asset as of December 31, 2017 includes approximately $347,500 ($95,632 net of tax) of general and administrative expenses treated as deferred start-up expenditures for tax purposes and approximately $258,600 ($71,155 net of tax) of tax losses resulting in tax loss carryforwards. The Company has 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 and the tax loss carryforwards, a full valuation allowance against any potential deferred tax assets has been recognized for the year ended December 31, 2017 as discussed below.

As of December 31, 2017, the Company is evaluating its qualified research expenditures for application to federal and state research and development tax credits to offset potential future tax liabilities. The federal research and development tax credits have a 20-year carryforward period. The Maryland research and development tax credits have a 7-year carryforward period. There is no recognition of a deferred tax asset for research and development tax credits as of December 31, 2017.

The Company is subject to U.S. Federal and state income taxes. The provision (benefit) for income taxes for the tax years ended December 31, 2017 and 2016 are as follows:

	Years Ended December 31,	
	2017	2016
Current:		
Federal	$ -	$ -
State	-	-
Total current	-	-
Deferred:		
Federal	(116,783)	-
State	(50,004)	-
Total deferred tax benefit	(166,787)	-
Valuation allowance	166,787	-
Net deferred tax benefit	-	-
Total tax provision (benefit)	$ -	$ -

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. 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.

Upon the enactment of the TCJA, we recorded a reduction in our deferred income tax assets of approximately $72,300 for the effect of the aforementioned change in the U.S. statutory income tax rate with an offsetting decrease in the valuation allowance established against the deferred tax assets. As a result, there was no change or recognition of an income tax provision or benefit in the consolidated statement of operations for the year ended December 31, 2017.

In December 2017, the Securities and Exchange Commission 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.

Deferred Income Taxes - The Company does not recognize the deferred income tax asset at this time because the realization of the asset is not more-likely-than-not. As of December 31, 2017, the Company had deferred start-up expenditures and net operating losses for both federal and state income tax purposes of approximately $166,787 as described above. As of December 31, 2016, the Company had no net operating losses for federal and state income tax purposes since Promet's partners were taxed separately on their proportionate share of Promet's income, deductions, losses and credits.

The net operating losses are available for application against future taxable income for 20 years, expiring in 2037. The benefit associated with the amortization of the deferred start-up expenditures and the net operating loss carry forward 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 the financial statements.

	December 31, 2017	December 31, 2016
Deferred Tax Assets:		
Non-current		
Net operating loss carry forward - Federal	$ 49,822	$ -
Net operating loss carry forward - State	21,333	-
Start-up expenditures and amortization	95,632	-
Total non-current deferred tax assets	166,787	-
Valuation allowance for deferred tax assets	(166,787)	-
Total deferred tax assets	$ -	$ -

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 full reserve has been established against this asset. The change in the valuation allowance in 2017 and 2016 was $166,787 and $0, respectively.

A reconciliation of the Company's effective income tax rate and statutory income tax rate at December 31, 2017 and 2016 is as follows:

	December 31, 2017	December 31, 2016
Federal statutory income tax rate	34.00%	0.00%
State tax rate, net	5.45%	0.00%
Permanent differences	-0.02%	0.00%
Impact of change in federal income tax rates	-11.92%	0.00%
Deferred tax asset valuation allowance	-27.51%	0.00%
Effective income tax rate	0.00%	0.00%

NOTE 8 –STOCKHOLDERS' EQUITY

On December 8, 2017, we completed a one-for-seven reverse split in trading markets. As a result, the consolidated financial statements have been retrospectively adjusted to reflect shares outstanding after the one-for-seven reverse split.

Common Stock – As of December 31, 2017 and 2016, the Company had authorized 350,000,000 and 43,261,049 shares of common stock with a $0.0001 par value. At December 31, 2017 and 2016 there were 35,272,626 and 31,745,242 common shares issued and outstanding, respectively. Common shares attributable to Promet's controlling interest were 31,745,242 at December 31, 2017 and 2016. Common shares attributable to the minority shareholders' interest were 3,527,384 and zero at December 31, 2017 and 2016, respectively.

Preferred Stock - As of December 31, 2017, the Company has authorized 10,000,000 shares of Preferred Stock with a $0.0001 par value. No shares were issued and outstanding.

On September 29, 2017, prior to the asset purchase closing, Heatwurx converted 178,924 shares of Series D Preferred Stock and all accrued dividends in the amount of $118,658 into 719,500 shares of common stock or 102,789 shares of common stock restated for the reverse stock split.

Stock and Performance Options - The Amended and Restated Heatwurx, Inc. 2011 Equity Incentive Plan (the "Plan") approved by the Heatwurx Board of Directors and stockholders in October 2012 has 1,800,000 shares of common stock or 257,143 shares of common stock after the reverse-split reserved for issuance under the Plan. The Plan is being reviewed by the new Promet appointed Board of Directors and may be amended or terminated. Amendments are subject to stockholder approval to the extent required by applicable laws and regulations. Unless terminated sooner, the Plan will automatically terminate on April 15, 2021. There are currently no outstanding option grants to officers, directors, employees and consultants under the Plan. If unexercised options expire or are terminated, the underlying shares will again become available for grants under the Plan.

During the year ended December 31, 2016, there were no options or performance options granted or exercised and 321,667 unexercised options with a weighted average exercise price of $1.69 were cancelled. At December 31, 2016, there were 269,500 unexercised options with a weighted average exercise price of $1.88 and a weighted average remaining life of 2.04 years and 40,000 unexercised performance options with a weighted average exercise price of $2.00. Upon the issuance of 90% of Heatwurx's common stock to Promet on October 4, 2017, there was a Change in Control event, as defined in the Plan. As of September 30, 2017, prior to the Change in Control event, all 269,500 unexercised options and all 40,000-unexercised performance options outstanding at December 31, 2016 were cancelled. No stock-based compensation expense was recognized for the years ended December 31, 2017 and 2016.

Warrants - During the year ended December 31, 2016, there were no warrants granted, exercised or cancelled. At December 31, 2016, there were 2,000,304 warrants outstanding with a weighted average exercise price of $2.36 and a weighted average remaining life of 0.63 years. During the nine months ended September 30, 2017, 723,181 warrants with a weighted average exercise price of $2.99 were cancelled a result of non-exercise prior to their exercise date. At September 30, 2017, there were 1,277,123 warrants with a weighted average exercise price of $2.00 and a weighted average remaining life of 0.08 years that were cancelled in October 2017 as a result of non-exercise prior to their exercise date. As a result, there were no warrants issued, issuable or outstanding at December 31, 2017. See Note 6 for discussion of warrants.

NOTE 9 – NET LOSS PER COMMON SHARE

The Company computes loss per share of common stock using the two-class method required for participating securities. The Company's participating securities include all series of its convertible preferred stock. Undistributed earnings allocated to these participating securities are added to net loss in determining net loss applicable to common stockholders. The Company has preferred stock authorized but no preferred stock issued and outstanding at December 31, 2017 and 2016.

The dilutive effect of convertible securities, including the preferred stock, if issued, and the Senior Convertible Notes, are reflected in diluted earnings per share using the if-converted method. As a result, (i) the preferred dividends applicable to the convertible preferred stock are deducted from income from continuing operations and net income in computing income available to common stockholders and, (ii) the interest expense and nondiscretionary adjustments on income that would have been calculated differently had the interest on the Senior Convertible Notes never been recognized, both net of income tax, are added back to the numerator. The convertible preferred stock and the Senior Convertible Notes assume the conversion to common stock at the beginning of the period or the date of issuance, if later, resulting in common shares being included in the denominator.

Other convertible securities that may be dilutive on their own but antidilutive when included with other potential common shares in computing diluted earnings per share include options and warrants since the treasury stock method applied to options and warrants has no effect on the numerator in the calculation. However, including potential common shares in the denominator (including convertible preferred stock and Senior Convertible Notes) of a diluted per share computation for continuing operations will always result in an antidilutive per share amount when the Company reports a loss from continuing operations or a loss from continuing operations available to common stockholders (after any preferred dividend deductions).

No potential common shares shall be included in the computation of any diluted per share amount when a loss from continuing operations or a loss from continuing operations available to common stockholders (after preferred dividend deduction) exists, even if the entity reports net income (as a result of discontinued operations) since it would be antidilutive. As a result, if there is a loss from continuing operations or a loss from continuing operations available to common stockholders, diluted earnings per share would be computed in the same manner as basic loss per share.

There were no outstanding options or warrants issued for the period from August 31, 2015 (inception) through December 31, 2017. See Notes 6 and 8 for further discussion of warrants related to the Senior Convertible Notes and the PIPE financing.

The Company has reported a loss from continuing operations and a loss from continuing operations available to common stockholders for all periods presented. As a result, there is no assumed conversion, exercise or contingent exercise of potential common shares included in the computation of the diluted per share amounts since it would have an antidilutive effect, therefore, basic and diluted loss per share are computed by dividing net loss applicable to common stockholders by the weighted-average number of shares of common stock outstanding.

The calculation of the numerator and denominator for basic and diluted net loss per common share is shown in the table below. The weighted-average shares of common stock used in calculating basic earnings per share for the 2017 calculation uses the number of shares issued to Promet in the asset purchase transaction from January 1, 2017 through the acquisition date of October 4, 2017 plus all the legal capital issued and outstanding of Heatwurx, including Promet's shares, from the closing date through December 31, 2017. All shares were restated for the one-for-seven reverse split.

The 2016 calculation uses the common shares issued to Promet in the asset purchase transaction, restated for the one-for-seven reverse split and weighted for the issuance dates of Promet's member interests.

	For the year ended	
	December 31, 2017	December 31, 2016
Net loss from continuing operations	$ (1,856,315)	$ (1,917,066)
Less: Preferred stock dividends	-	-
Net loss from continuing operations applicable to common stockholders - basic	(1,856,315)	(1,917,066)
Dilution adjustments (not computed since they are antidilutive):		
Preferred stock dividend	-	-
Interest on senior convertible notes, net of tax	-	-
Net loss from continuing operations applicable to common stockholders - diluted	$ (1,856,315)	$ (1,917,066)
Promet common shares issued and outstanding	31,745,242	31,745,242
Heatwurx common shares issued and outstanding	3,527,384	-
Total common shares issued and outstanding - basic	35,272,626	31,745,242
Potential common shares (not computed since they are antidilutive):		
Warrants	-	-
Conversion of preferred stock to common shares	-	-
Conversion of senior convertible notes to common shares	-	-
Total common shares issued and outstanding - diluted	35,272,626	31,745,242
Weighted average shares outstanding used in calculating net loss per common share - basic	32,595,680	29,321,049
Weighted average shares outstanding used in calculating net loss per common share - diluted	32,595,680	29,321,049
Net loss per share - basic	$ (0.06)	$ (0.07)
Net loss per share - diluted	$ (0.06)	$ (0.07)

NOTE 10 – COMMITMENTS AND CONTINGENCIES

Operating Lease Obligations

The Promet leases office space and equipment from third parties under non-cancelable operating leases. The office lease commenced on October 1, 2016 and expires September 30, 2019 with monthly rent at inception of $5,535 that escalates $1,107 annually on each October. Rent expense under the current office lease for the years ended December 31, 2017 and 2016 was $105,954 and $50,997, respectively. Rent expense for the year ended December 31, 2017 includes straight-line rent expense of $13,284 and $22,929 of common area maintenance and real estate tax reimbursements. At December 31, 2017, the accrued rent liability was $13,284, of which $3,321 was a current liability and $9,963 was a non-current liability.

The equipment lease commenced in June 2017 and expires in August 2020. Monthly rent of $586 over the 39-month lease term includes a monthly operating usage cost allowance of $125. Additional charges for excess usage, as defined in the agreement, are charged quarterly. The lessor charges monthly sales tax of 6 percent. Rent expense under the equipment lease for the years ended December 31, 2017 and 2016 was $6,626 and $5,362, respectively.

Future minimum rental payments under the leases as of December 31, 2017, are as follows:

	Office	Equipment	Total
2018	$ 83,025	$ 7,036	$ 90,061
2019	69,741	7,036	76,777
2020	-	4,691	4,691
Total future minimum lease payments	$ 152,766	$ 18,762	$ 171,528

Option and License Agreement with CoNCERT Pharmaceuticals

On October 4, 2017, Promet entered into an option and license agreement with CoNCERT Pharmaceuticals, Inc. (“CoNCERT”). The agreement provides the Company with an option to license the CoNCERT patent rights and know-how to develop and commercialize compounds (CTP-499 and each metabolite thereof) and products, as defined in the agreement. The option period ends, and the agreement terminates nine months from the date of the agreement if not exercised. Promet has the right to exercise the option during the option period; provided Promet (i) has raised gross proceeds of at least $8 million in one or more equity or other financings after the date of the agreement, and (ii) has a post-money valuation, following its then most recent equity financing, of at least $40.5 million.

Upon exercise of the option, Promet will have an exclusive, royalty-bearing right and license, including a right to sublicense, under CoNCERT intellectual property and joint intellectual property, to develop, manufacture, use and commercialize, including filing for, obtaining and maintaining regulatory approval for, products in all medical fields on a global basis. Promet shall control and be solely responsible for the commercialization of products in all medical fields on a global basis, including all costs and expenses. On March 19, 2018, we modified the Option and License Agreement with CoNCERT effective March 2018 (see Note 14), which enabled us to exercise our option to license the CoNCERT patent rights and know-how to develop and commercialize compounds (CTP-499 and each metabolite thereof) and products, as defined in the agreement.

In addition, Promet will have the right and license, including a right to sublicense, under CoNCERT intellectual property and joint intellectual property, to develop compounds and products in all medical fields on a global basis. Promet shall control and be solely responsible for the development of and regulatory activities with respect to compounds and products in all medical fields on a global basis, including all costs and expenses.

Promet shall use commercially reasonable efforts 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. Failure to comply with the diligence obligation under the license agreement may result in the termination of the license agreement by CoNCERT in accordance with the relevant terms of the agreement.

In partial consideration for the rights granted to Promet , if the option is exercised, pursuant to the terms of a customary stock purchase agreement on mutually acceptable terms based on shares issued that enabled Promet to exercise the option under the license agreement discussed above, Promet shall issue to CoNCERT, for no additional consideration, shares representing the lesser of (a) the number of shares determined by dividing $8 million by the price per share paid by other investors in the financing round that enabled Promet to exercise the option under the license agreement discussed above or (b) the number of shares rounded down to the nearest whole share equal to 19.9 percent of the issued and outstanding shares of Promet immediately following the issuance of shares to CoNCERT. Following the execution of the stock purchase agreement, CoNCERT shall also be entitled to the same right to participate in future financing rounds of Promet (and subject to the same exceptions) as applicable to any investor in the financing round that enabled Promet to exercise the option under the license agreement.

Promet will incur royalty obligations to CoNCERT on a country-by-country and product-by-product basis that commence on the date of this agreement and expire on a country-by-country and product-by-product basis on the later of (i) expiration or invalidation of the last valid claim covering such product in such country or (ii) the tenth anniversary of the date of the first commercial sale to a non-sublicensee third party of such product in such country. Promet shall pay to CoNCERT royalties, on a product-by-product basis, on worldwide net sales of products during each year as follows: (a) four percent (4%) of sales less than or equal to $100 million; (b) five percent (5%) of sales greater than $100 million and less than or equal to $500 million; (c) six percent (6%) of sales greater than $500 million and less than or equal to $1 billion; and, (d) for that portion greater than $1 billion, (i) with respect to net sales made by Promet or any of its affiliates, ten percent (10%) of net sales, and (ii) with respect to net sales made by any sub-licensee, the greater of (1) 6% of such net sales or (2) 50% of all payments received by Promet or any of its affiliates with respect to such net sales. Royalties are subject to adjustment as provided in the terms of the agreement.

CoNCERT shall have one Board observer to attend all Board meetings of the Company in a nonvoting observer capacity subject to the Company’s right to exclude the CoNCERT observer for confidentiality and other reasons as defined in the agreement. CoNCERT’s Board Observer right will expire when CoNCERT’s ownership interest in Promet decreases below ten percent of the outstanding voting stock of Promet.

The term of the agreement commences on the date of the agreement and shall continue in full force and effect until the expiration of the last royalty term. On a country-by-country and product-by-product basis, upon the expiration of the royalty term in such country with respect to such product, Promet shall have a fully paid-up, perpetual, irrevocable license under the CoNCERT intellectual property and CoNCERT’s interest in the joint intellectual property with respect to such product in such country.

Purchase Obligations

The Company enters into contracts in the normal course of business with contract research organizations and subcontractors to further develop its products. The contracts are cancellable, with varying provisions regarding termination. If a contract with a specific vendor were to be terminated, the Company would only be obligated for products or services that it received as of the effective date of the termination and any applicable cancellation fees. The Company had purchase obligations of $895,740 and $0 at December 31, 2017 and 2016, respectively.

NOTE 11 – CONCENTRATION OF CREDIT RISK

The Company maintains its operating cash 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 $2,900,393 and the second bank held a cash balance of $2,184 at December 31, 2017.

NOTE 12 – SUPPLEMENTAL CASH FLOW INFORMATION

	December 31, 2017	December 31, 2016
Supplemental cash flow information		
Cash paid for interest	$ -	$ -
Cash paid for income taxes	$ -	$ -
Noncash financing and investing activities		
Assumption of liabilities related to reverse acquisition		
Accounts payable	$ 26,098	$ -
Accrued expenses	17,932	-
Issuance of common stock related to reverse acquisition recognized in:		
Common stock	352	-
Additional paid-in capital	(38,102)	-
Total	(37,750)	-
Cash received related to net liabilities assumed in a reverse acquisition transaction	$ 6,280	$ -

NOTE 13 – QUARTERLY DATA

A summary of revenues, operating expenses, other income and net loss attributable to common stockholders for each of the last two years follows (this information is unaudited):

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	Annual
2017					
Revenues	$ -	$ -	$ -	$ -	$ -
Operating expenses	(233,940)	(280,335)	(712,852)	(575,306)	(1,802,433)
Interest expense	-	-	-	(59,063)	(59,063)
Other income	1,498	1,889	1,285	509	5,181
Net loss attributable to common stockholders	$ (232,442)	$ (278,446)	$ (711,567)	$ (633,860)	$ (1,856,315)
Weighted-average common shares - basic and diluted	31,745,242	31,745,242	31,745,242	35,119,261	32,595,680
Net loss per common share - basic and diluted	$ (0.01)	$ (0.01)	$ (0.02)	$ (0.02)	$ (0.06)
2016					
Revenues	$ -	$ -	$ -	$ -	$ -
Operating expenses	(280,956)	(575,281)	(829,064)	(236,219)	(1,921,520)
Interest expense	-	-	-	-	-
Other income	7	869	1,698	1,880	4,454
Net loss attributable to common stockholders	$ (280,949)	$ (574,412)	$ (827,366)	$ (234,339)	$ (1,917,066)
Weighted-average common shares - basic and diluted	26,870,217	26,870,217	31,745,242	31,745,242	29,321,049
Net loss per common share - basic and diluted	$ (0.01)	$ (0.02)	$ (0.03)	$ (0.01)	$ (0.07)

NOTE 14 – SUBSEQUENT EVENTS

Amendment of Option and License Agreement between Promet Therapeutics, LLC and CoNCERT Pharmaceuticals, Inc.

Promet Therapeutics, LLC ("Promet") and CoNCERT Pharmaceuticals Inc. ("CoNCERT") entered into an exclusive option and license agreement for the CTP-499 compound (the "Agreement") in October 2017 (see Note 10). On March 19, 2018, Promet and CoNCERT amended the Agreement and Promet exercised the exclusive option for the CTP-499 compound and assigned the Agreement to Processa. The option was exercised in March 2018 in exchange for CoNCERT receiving (i) $8 million of common stock of Processa that was owned by Promet or approximately 2,090,300 shares representing 6.58% of Promet's common stock holding or 5.93% of total Processa common stock issued and outstanding, and (ii) 15% of any sublicense revenue earned by Processa for a period equivalent to the royalty term (as defined in the Agreement) until (a) Processa raises $8 million of gross proceed; after the $8M is raised CoNCERT receives 0% sublicense revenue and (b) CoNCERT can sell its shares of Processa common stock without restrictions pursuant to the terms of the amended Agreement. All other terms of the Agreement remain unchanged.

Cybersecurity Fraud

In January 2018, we incurred a loss of $144,200 due to fraud from a cybersecurity breach. As a result, we have implemented certain review and approval procedures internally and with our banks; our technology consultants have implemented system changes; and, we reported the fraud to our banks and to a national law enforcement agency. We do not have insurance coverage against the type of fraud that occurred, therefore, recovery of the loss is remote. While we are taking steps to prevent such an event from reoccurring, we cannot provide assurance that similar issues will not reoccur. Failure of our control systems to prevent or detect and correct errors or fraud could have a material and adverse effect on our financial condition.

Item 9. Changes in and Disagreements with Accountants

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Principal Executive Officer and Principal Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (Exchange Act), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's (SEC) rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective at the reasonable assurance level as of December 31, 2017 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in Internal Control —Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on this assessment, management has concluded that its internal control over financial reporting was not effective as of December 31, 2017.

Our independent registered public accounting firm, BD & Company, Inc., is not required to and has not issued an attestation report as of December 31, 2017 due to a transition period established by the rules of the SEC for newly public companies that have not lost their "emerging growth company" status as defined in the JOBS Act and our status as a smaller reporting company.

Changes in Internal Control Over Financial Reporting

Evaluation of disclosure controls and procedures

Our management, with the participation of our Chief Executive Officer, who also serves as our Chief Financial Officer, has concluded, based on evaluation, as of the end of the period covered by this report, that our disclosure controls and procedures (as defined in Rule 15d-15(e) under the Exchange Act) are (1) not effective to ensure that material information required to be disclosed by us in reports filed or submitted by us under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission due to the material weakness noted below, and (2) lacking design to ensure that material information required to be disclosed by us in such reports is accumulated, organized and communicated to our management, including our principal executive officer and principal financial officer, as appropriated, to allow timely decisions regarding required disclosure.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of our company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of our management and director; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed our internal control over financial reporting as of December 31, 2017, the end of our fiscal year. Management based its assessment on criteria established in *Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework)* Management's assessment included evaluation of such elements as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment.

Based on our assessment, management has concluded that our internal control over financial reporting was not effective, as of the end of the fiscal year, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with generally accepted accounting principles.

In light of the material weaknesses described below, we performed additional analysis and other post-closing procedures to ensure that our financial statements were prepared in accordance with generally accepted accounting principles. Accordingly, we believe that the financial statements included in this report fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented.

Material Weaknesses and Related Remediation Initiatives

Our management concluded that as of December 31, 2017, the following material weaknesses existed:

Due to the Company's budget constraints, the Company's accounting department does not maintain the number of accounting personnel (either in-house or external) necessary to ensure more complete and effective financial reporting and disclosure controls. Through the efforts of management and external consultants, we have developed a specific action plan to remediate the material weaknesses. Due to the limited number of employees and limited financial resources to hire required accounting and finance staff to implement the controls and procedures, the Company was unable to remediate the material weakness during 2017.

In January, we incurred a loss of approximately $144,000 due to fraud from a cybersecurity breach. We notified our banks and reported the fraud to the Federal Bureau of Investigation Cyber Crimes Unit. As a result, we have implemented certain review and approval procedures internally and with our banks as a preventative control and procedure. Our technology consultants have implemented system changes to enhance system access controls and limit the ability of hackers to gain access to internal systems to provide preventative measures to safeguard Company assets. We do not have insurance coverage against this type of fraud, therefore, the probability of recovery of the loss is remote.

While we are taking steps to prevent these control weaknesses from reoccurring, we cannot provide assurance that we will be successful. We are in the early stages of operations and fund raising so we currently lack the financial resources necessary to implement an effective internal control system to prevent and/or detect and correct material misstatements due to fraud or error. 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.

We have fewer than 300 stockholders on record and are not a mandatory filer of reports under Section 13 or 15(d) of the Exchange Act. As a voluntary filer, we may choose to cease filing Exchange Act reports at any time.

Changes in internal control over financial reporting

Except as described above, there has been no change in our internal control over financial reporting, as defined in Rules 13a-15(f) of the Exchange Act, for the year ended December 31, 2017, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Management recognizes that a control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or error, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Item 9B. ***Other Information***

Not applicable.

Part III

Item 10. Directors, Executive Officers and Key Employees

MANAGEMENT

The following table sets forth the names and ages of the members of our executive officers and the positions held by each as of March 31, 2018.

NAME	AGE	PRINCIPAL OCCUPATION/POSITION WITH PROCESSA
David Young - Pharm.D., Ph.D.	64	Chief Executive Officer and Interim Chief Financial Officer
Patrick Lin	52	Chief Business & Strategy Officer
Sian Bigora, Pharm.D.	57	Chief Development Officer
Wendy Guy	53	Chief Administrative Officer

The following is a brief account of the education and business experience during at least the past five years of each director, executive officer and key employee of our company, indicating the person's principal occupation during that period, and the name and principal business of the organization in which such occupation and employment were carried out.

David Young, Pharm.D., Ph.D.
Chief Executive Officer, Interim Chief Financial Officer and Founder

Dr. Young has over 30 years of pharmaceutical research, drug development, and corporate experience. He was a Founder and CEO of Promet Therapeutics, LLC since its formation in August 2015. Dr. Young was Chief Scientific Officer of Questcor Pharmaceuticals from 2009-2014 and was responsible for working with the FDA on modernizing the Acthar Gel label and in obtaining FDA approval in Infantile Spasms. From 2006-2009 prior to joining the executive management team, Dr. Young served as an independent Director on the Questcor Board of Directors. During the eight years that Dr. Young was involved with Questcor, Questcor transitioned to an orphan drug specialty pharmaceutical company, moving from near bankruptcy in 2007 to a valuation of 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., 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 lead to the SUPAC and IVIVC FDA Guidance's, for 5 years taught FDA reviewers as part of the UMAB-FDA contract, has served on 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
Chief Business and Strategy Officer and Founder

Mr. Lin 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 past 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.

Sian Bigora, Pharm.D.
Chief Development Officer and Founder

Dr. Bigora 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.

Wendy Guy
Chief Administrative Officer and Founder

Ms. Guy 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, HR, 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.

The following table sets forth the names and ages of our present Board of Directors as of October 4, 2017. Additional Directors are being identified with a plan to include two internal Directors and 3-4 independent Directors.

NAME	AGE	BOARD OF DIRECTORS
David Young - Pharm.D., Ph.D.	64	Chairman; Chief Executive Officer and Interim CFO
Patrick Lin	52	Internal Director: Chief Business & Strategy Officer
Justin Yorke	51	Director
Virgil Thompson	78	Director

Executive Biographies

The biographies of Dr. Young and of Patrick Lin are found above.

Justin W. Yorke

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 a director of the Company in September 2017. For more than the past 10 year he has been a manager of the San Gabriel Fund, JMW Fund and the Richland Fund whose primary activity is investing 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.

Virgil Thompson

Mr. Thompson has served as a Director of the company since October 2017 and previously served on the Board of Directors at Promet Therapeutics, LLC and Mallinckrodt Pharmaceuticals (formerly Questcor Pharmaceuticals) where he also served on its Human Resources and Compensation Committee.

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 of that company. Mr. Thompson is also the Chairman of the Board of Aradigm Corporation and a Director of Genz Corporation.

Mr. Thompson served as a Director of Questcor Pharmaceuticals, Inc., from 1996 and more recently served as Chairman of its board of directors until Questcor was acquired by Mallinckrodt in August 2014. Mr. Thompson served as the President, Chief Executive Officer and as a Director of Angstrom Pharmaceuticals, Inc. from 2002 until 2007. From 2000 until 2002, Mr. Thompson was President, 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.

Family Relationships

There is no family relationship between any of our officers.

No Involvement in Certain Legal Proceedings

To our knowledge, during the last 10 years, none of our executive officers, directors (including those of our subsidiaries), promoters or control persons has:

- had a bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;
- been convicted in a criminal proceeding or been subject to a pending criminal proceeding, excluding traffic violations and other minor offenses;
- been subject to any order, judgment or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities or banking activities;
- been found by a court of competent jurisdiction (in a civil action), the Securities and Exchange Commission or the Commodities Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended or vacated; or
- been the subject to, or a party to, any sanction or order, not subsequently reverse, suspended or vacated, of any self-regulatory organization, any registered entity, or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

Board Leadership Structure and Role in Risk Oversight

Our Board evaluates its leadership structure and role in risk oversight on an ongoing basis. At the present time our CEO serves as the Chairman of the Board. The Board does not currently have a policy, one way or the other, with respect to whether the same person should serve as both the chief executive officer and chair of the Board or, if the roles are separate, whether the chair of the Board should be selected from the non-employee directors or should be an employee.

In evaluating director nominees, our Company expects to consider the following factors:

- The appropriate size of the Board;
- Our needs with respect to the particular talents and experience of our directors;
- The knowledge, skills and experience of nominees;
- Experience with accounting rules and practices; and
- The nominees' other commitments.

Our Company's goal is to always have a Board of Directors that brings our Company a variety of perspectives and skills derived from high quality business, professional and personal experience.

Corporate Governance

Board Committees

We presently do not have an audit committee, compensation committee or nominating committee or committee performing similar functions. Our new Board expects to establish an audit or compensation committee in the near future. We envision that the audit committee will be primarily responsible for reviewing the services performed by our independent auditors and evaluating our accounting policies and systems of internal controls. We envision that the compensation committee will be primarily responsible for reviewing and approving our salary and benefits policies and other compensation of our executive officers. Until these committees are established, these decisions will continue to be made by our Board of Directors.

Director Independence

The Board has determined that none of our directors is independent as the term "independent" is defined by the rules of NASDAQ Rule 5605.

Code of Ethics and Business Conduct

We maintain a Code of Ethics and Business Conduct, which applies to all of our employees, officers and directors. It establishes standards of conduct for individuals and also individual standards of business conduct and ethics.

Item 11. Executive Compensation

Summary Compensation Table

The following sets forth all compensation awarded, earned or paid for services rendered in all capacities to our chief executive officers during prior fiscal years. No executive officer received compensation in excess of $100,000 in 2017. No executive officer or director of Processa received or had vested options to acquire securities of Processa in 2017.

The following table summarizes the compensation paid by us in each of the last two recently completed fiscal years for our current and former Chief Executive Officers:

Name and Principal Position	Year	Base Salary	Option Awards	Other Compensation	Total Compensation
David Young Chief Executive Officer	2017	$ -	$ -	$ -	$ -
John McGrain	2017	$ -	$ -	$ -	$
Former Interim Chief Executive Officer	2016	$ 1	$ -	$ -	$ 1

Through March 31, 2018, we have paid $43,750 in salary to our executive officers and employment agreements will be put in place in the very near future. At this time, we do provide compensation to our Independent Directors, although we expect a plan will be put in place in the near future.

Outstanding Equity Awards at Year-End

The Company recognizes the value of providing equity-based incentives to its employees and intends to adopt an equity incentive plan in the near future. There are no currently outstanding equity awards to any of our named executive officers.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth the number of shares of our common stock beneficially owned as of March 19, 2018 by each director, executive officer and beneficial owners of more than 5% of the outstanding shares of the common stock based on shares of common stock issued and outstanding. Unless otherwise indicated, the address of each person listed below is c/o 7380 Coca Cola Drive, suite 106, Hanover, Maryland 21076.

Name of Beneficial Owner	Shares of Common Stock Beneficially Owned	% of Shares of Common Stock Beneficially Owned
Officers and Directors		
David Young[1]	5,719,927	16.22%
Sian Bigora	3,483,850	9.88%
Patrick Lin	2,314,022	6.56%
Wendy Guy	2,194,075	6.22%
Virgil Thompson	601,807	1.71%
Helen Pentikis	507,218	1.44%
Justin Yorke	11,000	0.03%
5% Stockholders		
Promet Therapeutics, LLC[2]	15,149,449	42.95%
Neal Bradsher[3]	1,774,894	5.03%
CoNCERT Pharmaceuticals, Inc.	2,090,301	5.00%

1. *Dr. Young has invested $200,000 as part of the Senior Bridge Note that has a mandatory conversation upon raising $4M.*
2. *The Processa equity listed in this table under Promet Therapeutics, LLC are the total Processa shares owned by Promet Therapeutics, LLC which have been awarded to members in Promet who are not already listed on this table and who individual do not have a greater than a 5% net ownership in Processa. Since the shares are still under the ownership of Promet, the shares have not been listed in the table.*
3. *Neal Bradsher was a Founding Investor in Promet and owns 5.9% of Promet.*

Item 13. Certain Relationships and Related Transactions, and Director Independence

Transactions Prior to the October 2017 Promet Transaction:

Transactions with JMW Fund, LLC

JMW Fund, LLC, managed by Mr. Yorke a director, beneficially owns more than 5% of the outstanding shares of Company common stock. JMW Fund, LLC owns 2,203,707 common shares and warrants to purchase 573,407 shares. During the year ended December 31, 2015 the Company entered into a $2 Million Loan agreement with the JMW Fund, LLC, and issued senior secured promissory notes payable in the total amount of $390,744. The Company issued additional senior secured promissory notes payable in the amount of $15,000 during the year ended December 31, 2016. As of December 31, 2016, the Company has senior secured notes outstanding in the amount of $405,774 and accrued interest of $122,187 with the JMW Fund, LLC. The Company assumed the Revolving line of credit from Dr. Pave, LLC during 2016, and as of December 31, 2016, had a balance of $46,000 with accrued interest of $13,552 was outstanding with the JMW Fund, LLC. The notes have been satisfied.

Transactions with San Gabriel Fund, LLC

San Gabriel Fund, LLC, managed by Mr. Yorke a director, beneficially owns more than 5% of the outstanding shares of Company common stock. San Gabriel Fund, LLC owns 2,036,619 common shares and warrants to purchase 411,279 shares. During the year ended December 31, 2015 the Company entered into a $2 Million Loan agreement with the San Gabriel Fund, LLC, and issued senior secured promissory notes payable in the total amount of $290,744. As of December 31, 2016, the Company has senior secured notes outstanding in the amount of $290,774 and accrued interest of $89,990 with the San Gabriel Fund, LLC. The Company assumed the Revolving line of credit from Dr. Pave, LLC during 2016, and as of December 31, 2016, had a balance of $46,000 with accrued interest of $13,084 was outstanding with the San Gabriel Fund, LLC. The notes have been satisfied.

Transactions with Richland Fund, LLC

Richland Fund, LLC, managed by Mr. Yorke a director, beneficially owns more than 5% of the outstanding shares of Company common stock. The Richland Fund, LLC owns 485,395 common shares and warrants to purchase 293,500 shares. During the year ended December 31, 2015 the Company entered into a $2 Million Loan agreement with the Richland Fund, LLC, and issued senior secured promissory notes payable in the total amount of $245,872 and converted the December 11, 2014 short-term unsecured note payable into a senior secure promissory note in the amount of $20,000. As of December 31, 2016, the Company has senior secured notes outstanding in the amount of $265,872 and accrued interest of $80,526 with the Richland Fund, LLC. The Company assumed the Revolving line of credit from Dr. Pave, LLC during 2016, and as of December 31, 2016, had a balance of $46,000 with accrued interest of $13,226 was outstanding with the Richland Fund, LLC. The notes have been satisfied.

CorLyst, LLC

CorLyst, LLC ("CorLyst") was a related party to Promet Therapeutics, LLC ("Promet") as one of the largest investors in Promet. During the asset purchase with Heatwurx, all of Promet's assets were purchased in exchange for equity in the company and CorLyst is now considered a related party to Processa Pharmaceuticals, Inc., ["Processa"] by association. CorLyst and Processa share administrative fees (salaries, healthcare and office space).

Indemnification of Directors and Officers

Our bylaws provide for the indemnification of our directors to the fullest extent permitted by the Delaware General Corporation Law and may, if and to the extent authorized by our Board of Directors, so indemnify our officers and any other person whom we have the power to indemnify against liability, reasonable expense or other matter. This indemnification policy could result in substantial expenditure by us, which we may be unable to recoup.

Insofar as indemnification by us for liabilities arising under the Securities Exchange Act may be permitted to our directors, officers and controlling persons pursuant to provisions of the Certificate of Incorporation and bylaws, or otherwise, we have been advised that in the opinion of the SEC, such indemnification is against public policy and is, therefore, unenforceable. In the event that a claim for indemnification by such director, officer or controlling person of us in the successful defense of any action, suit or proceeding is asserted by such director, officer or controlling person in connection with the securities being offered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by us is against public policy as expressed in the Securities Exchange Act and will be governed by the final adjudication of such issue.

We currently do not have a Director's and Officers insurance policy in place at this time, however, we intend to obtain coverage by April 30, 2018.

Item 14. Principal Accounting Fees and Services

Pritchett, Siler & Hardy PC ("**PS&H**") previously served as the Company's independent registered public accounting firm since November 2015 and audited its financial statements for the years ended December 31, 2015 and 2016. On October 31, 2017, (the "Dismissal Date") our Board of Directors dismissed Pritchett, Siler & Hardy, P.C. ("Pritchett") as our independent registered public accounting firm. The report of Pritchett on the Company's consolidated financial statements for the year ended December 31, 2016 and 2015 did not contain an adverse opinion or disclaimer of opinion, and such reports were not qualified or modified as to uncertainty, audit scope, or accounting principle, other than to indicate that there was substantial doubt as to the Company's ability to continue as a going concern. During the year ended December 31, 2016 and through the Dismissal Date, there have been no disagreements with Pritchett on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements if not resolved to the satisfaction of Pritchett would have caused them to make reference thereto in their report on the financial statements. During the year ended December 31, 2016 and through the Dismissal Date, there were no reportable events, as defined in Item 304(a)(1)(v) of Regulation S-K of the Securities Exchange Act of 1934, as amended.

On October 31, 2017 (the "Engagement Date"), the Company engaged BD & Company, Inc. ("BD"), as its new independent registered public accounting firm. The engagement of BD was approved by the Company's Board of Directors on October 31, 2017. During the years ended December 31, 2016 and 2017 and through the Engagement Date, we did not consult with BD regarding (i) the application of accounting principles to a specified transaction, (ii) the type of audit opinion that might be rendered on the Company's financial statements by BD, in either case where written or oral advice provided by BD would be an important factor considered by the Company in reaching a decision as to any accounting, auditing or financial reporting issues or (iii) any other matter that was the subject of a disagreement between us and our former auditor or was a reportable event (as described in Items 304(a)(1)(iv) or Item 304(a)(1)(v) of Regulation S-K, respectively).

For the year ended December 31, 2016, the aggregate fees billed by PS&H to the Company were as follows:

		Year ended December 31, 2016
Audit fees [(1)]	$	24,683
Audit-related fees		-
Tax fees		-
All other fees		-
Total accounting fees and services	$	24,683

For the year ended December 31, 2017, the aggregate fees billed by BD to the Company were as follows:

		Year ended December 31, 2017
Audit fees [(1)]	$	40,000
Audit-related fees		-
Tax fees		-
All other fees		3,625
Total accounting fees and services	$	43,625

[(1)] Audit fees includes the aggregate fees billed for professional services for the audit of our annual financial statements for the years ended December 31, 2017 and the review of the financial statements included in our quarterly reports on Form 10-Q filed during the year ended December 31 of the respective years.

Part IV

Item 15. Exhibits, Financial Statement Schedules

(a)(1) and (2) Financial Statements and Schedules:

See Part II, Item 8, of this Annual Report on Form 10-K.

(3) Exhibits

Exhibit Number	Description of Exhibit
2.1	Asset Purchase Agreement. Dated October 2, 2017, among the Company, Promet Therapeutics LLC and Processa Therapeutics LLC (incorporated by reference to exhibit 2.1 accompanying Form 8-K filed on October 5, 2017)
3.1	Fourth Amended and Restated Certificate of Incorporation of Heatwurx, Inc. (incorporated by reference to exhibit 3.1 to Form 8-K/A filed on October 17, 2017)
3.1.1	Amendment to Fourth Amended and Restated Certificate of Incorporation of Heatwurx, Inc. (incorporated by reference to exhibit 3.1 to Form 8-K filed on October 23, 2017)
3.2	Bylaws (incorporated by reference to exhibit 3.2 to Form 10-K filed on March 27, 2014)
10.1	Form of Lock Up Agreement – Heatwurx (incorporated by reference to exhibit 10.1 to Form 8-K/A filed on October 12, 2017)
10.2	Form of Lock Up/Leak Out Agreement – Promet (incorporated by reference to exhibit 10.1 to Form 8-K/A filed on October 12, 2017)
10.3+	Amended and Restated 2011 Equity Incentive Plan (incorporated by reference to exhibit 10.10 to Form S-1 filed on November 14, 2012)
10.4	License Option Agreement with CoNCERT
10.5	Amendment to License Agreement and Securities Purchase Agreement with CoNCERT Pharmaceuticals
10.6	Convertible Note
21.1*	List of Subsidiaries
23.1*	Consent of Independent Registered Public Accounting Firm
31.1*	Certification of Chief Executive and Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
99.1*	XBRL Files

* Filed herewith.
+ Indicates management contract or compensatory plan.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

PROCESSA PHARMACEUTICALS, INC.

By: */s/ David Young*
David Young
Chief Executive Officer and Acting Chief Financial Officer
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

Dated: April 16, 2018

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons in the capacities and on the dates indicated.

Name	Capacity	Date
/s/ David Young David Young	Chairman	April 16, 2018
/s/ Patrick Lin Patrick Lin	Director	April 16, 2018
/s/ Justin Yorke Justin Yorke	Director	April 16, 2018
/s/ Virgil Thompson Virgil Thompson	Director	April 16, 2018

EXECUTION COPY

OPTION AND LICENSE AGREEMENT

BY AND BETWEEN

PROMET THERAPEUTICS, LLC

AND

CONCERT PHARMACEUTICALS, INC.

DATED AS OF OCTOBER 4th, 2017

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OPTION AND LICENSE AGREEMENT

THIS OPTION AND LICENSE AGREEMENT is entered into this ___ day of October, 2017 (the "Effective Date"), by and between Promet Therapeutics, LLC, a limited liability company organized under the laws of _____, having a business address at 7380 Coca Cola Drive, Suite 106, Hanover, MD 21076 ("Promet"), and CoNCERT Pharmaceuticals, Inc., a corporation organized under the laws of Delaware, having a business address at 99 Hayden Avenue, Suite 500, Lexington, MA 02421 ("CoNCERT").

WHEREAS, CoNCERT has developed or obtained rights to CoNCERT Know-How, CoNCERT Patent Rights and the CoNCERT Compound (each as defined below); and

WHEREAS, Promet desires to obtain an option to license the CoNCERT Patent Rights and the CoNCERT Know-How to Develop and Commercialize Compounds and Products (each as defined below), under the terms and conditions set forth herein, and CoNCERT desires to grant such an option;

NOW, THEREFORE, the Parties agree as follows:

ARTICLE I
DEFINITIONS

The following terms, whether used in the singular or plural, shall have the following meanings:

1.1 "Act". Act means both the U.S. Federal Food, Drug, and Cosmetic Act, as amended from time to time, and the regulations promulgated under the foregoing, as amended from time to time.

1.2 "Affiliate". Affiliate means any Person directly or indirectly controlled by, controlling or under common control with, a Party, but only for so long as such control shall continue. For purposes of this definition, "control" (including, with correlative meanings, "controlled by", "controlling" and "under common control with") means, with respect to a Person, possession, direct or indirect, of (a) the power to direct or cause direction of the management and policies of such Person (whether through ownership of securities or partnership or other ownership interests, by contract or otherwise), or (b) at least 50% of the voting securities (whether directly or pursuant to any vested and exercisable option, warrant or other similar arrangement) or other comparable equity interests. For clarity, neither of the Parties shall be deemed to be an "Affiliate" of the other.

1.3 "Bankruptcy Code". Bankruptcy Code means Title 11 of the U.S. Code, as amended from time to time.

1.4 "Business Day". Business Day means a day that is not a Saturday, Sunday or a day on which banking institutions in Boston, Massachusetts are authorized by Law to remain closed.

1.5 "Calendar Quarter". Calendar Quarter means each of the periods ending on March 31, June 30, September 30 and December 31 of any Calendar Year.

1.6 "Calendar Year". Calendar Year means each calendar year during the Term.

1.7 "Combination Product". Combination Product means (a) any pharmaceutical product that is a single formulation consisting of a Compound and one or more other active compounds or active ingredients, which other active compounds or active ingredients are not Compounds ("Other API") or (b) any combination of a Compound sold together with any separately formulated Other API for a single invoiced price.

1.8 "Commercialization" or "Commercialize". Commercialization or Commercialize means activities directed to obtaining pricing and reimbursement approvals, marketing, promoting, Manufacturing commercial supplies of, distributing, importing, offering for sale or selling a product.

1.9 "Commercially Reasonable Efforts". Commercially Reasonable Efforts means, with respect to an objective, the reasonable, diligent, good faith efforts of a Party (including the efforts of its Affiliates and Sublicensees) to accomplish such objective that a biopharmaceutical company of comparable size and resources would normally use to accomplish a similar objective under similar circumstances, and, specifically with respect to obligations hereunder relating to a Compound or Product, the carrying out of such obligations with those efforts and resources that a biopharmaceutical company of comparable size and resources would use were it Developing, Manufacturing or Commercializing its own pharmaceutical products that are at a similar stage of development or product life cycle and of similar market potential as the Compound or Product, taking into account actual and potential issues of safety, efficacy or stability, product profile (including product modality, category and mechanism of action), stage of development or life cycle status, product labeling or anticipated labeling, the present and future market potential, past performance of the Compound or Product, actual and projected Development, Regulatory Approval, pricing and reimbursement approval, Manufacturing and Commercialization costs, existing or projected pricing, sales, reimbursement and financial return, medical and clinical considerations, present and future regulatory environment, any issues regarding the ability to Manufacture the Compound or Product, the likelihood and timing of obtaining Regulatory Approvals and pricing and reimbursement approvals, proprietary position, strength and duration of patent protection and anticipated exclusivity, competitive Third Party products at the time and the likely competitive environment at the time of projected entry into the market and thereafter, and any other relevant scientific, technical, operational and commercial factors, all as measured by the facts and circumstances at the time such efforts are due. Commercially Reasonable Efforts will be determined on a country-by-country and indication-by-indication basis for the Compound or Product, and the level of effort is expected to change over time, reflecting changes in the status and value of the Compound or Product and the market conditions and country(ies) involved.

1.10 "Compound". Compound means CTP-499 and each metabolite thereof.

1.11 "CoNCERT Intellectual Property". CoNCERT Intellectual Property means the CoNCERT Know-How and the CoNCERT Patent Rights.

1.12 "CoNCERT Know-How". CoNCERT Know-How means all Know-How that is Controlled by CoNCERT or any of its Affiliates as of the Effective Date or thereafter during the Term (other than any Know-How included in Joint Intellectual Property) that is necessary or useful to Develop, Manufacture or Commercialize any Compound or Product; provided, however, that, if CoNCERT is acquired by a Third Party, "CoNCERT Know-How" shall exclude any Know-How that (a) is Controlled by such Third Party or the Affiliates of such Third Party (other than CoNCERT and the Persons that were CoNCERT's Affiliates immediately prior to the closing of such acquisition transaction (such Affiliates, "CoNCERT Pre-Existing Affiliates")) ("CoNCERT Excluded Affiliates") and (b) was not Controlled by CoNCERT or any of the CoNCERT Pre-Existing Affiliates immediately prior to the closing of such acquisition transaction; provided further that, if, after the closing of such acquisition, any such CoNCERT Excluded Affiliate Develops or Commercializes any Compound or Product or otherwise performs any activities or obtains any rights with respect to any Compound or Product, such Affiliate will cease to be a CoNCERT Excluded Affiliate and applicable Know-How that is Controlled by such Affiliate shall be included in CoNCERT Know-How.

1.13 "CoNCERT Patent Rights". CoNCERT Patent Rights means all Patent Rights in the Territory that are Controlled by CoNCERT or any of its Affiliates as of the Effective Date or thereafter during the Term (other than Joint Patent Rights) that Cover any Compound or Product. The CoNCERT Patent Rights existing as of the Effective Date are set forth on Schedule 1.13; provided, however, that, if CoNCERT is acquired by a Third Party, "CoNCERT Patent Rights" shall exclude any Patent Rights that (a) are Controlled by such Third Party or the Affiliates of such Third Party (other than CoNCERT and CoNCERT Pre-Existing Affiliates) and (b) were not Controlled by CoNCERT or any of the CoNCERT Pre-Existing Affiliates immediately prior to the closing of such acquisition transaction; provided further that, if, after the closing of such acquisition, any such CoNCERT Excluded Affiliate Develops or Commercializes any Compound or Product or otherwise performs any activities or obtains any rights with respect to any Compound or Product, such Affiliate will cease to be a CoNCERT Excluded Affiliate and applicable Patent Rights that are Controlled by such Affiliate shall be included in CoNCERT Patent Rights.

1.14 "Control" or "Controlled". Control or Controlled means, with respect to any tangible property or intellectual property right or other intangible property, the possession (whether by ownership or license (other than by grant of a license to one Party by the other Party pursuant to this Agreement or by grant of a license or sublicense to a Sublicensee by Promet pursuant to a license or sublicense agreement)) by a Person of the ability to grant to another Person access to such tangible property or access to or a license or sublicense to such intellectual property right or other intangible property, as provided herein without violating the terms of any agreement with any other Person.

1.15 "Cover", "Covering" or "Covered". Cover, Covering or Covered means, with respect to a compound, product, technology, process or method that, in the absence of ownership of or a license granted under a Patent Right, the manufacture, use, offer for sale, sale or importation of such compound or product or the practice of such technology, process or method would infringe such Patent Right (or, in the case of a Patent Right that has not yet issued, would infringe such Patent Right if it were to issue).

1.16 "Development" or "Develop". Development or Develop means pre-clinical, non-clinical and clinical drug research, discovery and development activities, including IND-enabling toxicology and other IND-enabling pre-clinical development efforts, stability testing, process development, compound property optimization, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, clinical pharmacology, Manufacturing supplies of compounds and products for pre-clinical, non-clinical and clinical use, clinical studies (including pre- and post-approval studies and investigator sponsored clinical studies), regulatory affairs, and Regulatory Approval and clinical study regulatory activities (excluding regulatory activities directed to obtaining pricing and reimbursement approvals).

1.17 "EMA". EMA means the European Medicines Agency and any successor agency.

1.18 "FDA". FDA means the U.S. Food and Drug Administration and any successor agency.

1.19 "Field". Field means all medical uses.

1.20 "First Commercial Sale". First Commercial Sale means, with respect to a Product in a country, the first sale of such Product in such country by Promet, any of its Affiliates or any Sublicensee to the first unrelated Third Party (excluding any Sublicensee) in such country for use or consumption of such Product in such country after receipt of the first Regulatory Approval for such Product in such country.

1.21 "Governmental Authority". Governmental Authority means any national, federal, state or local government, or political subdivision thereof, or any multinational organization or authority or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body.

1.22 "IND". IND means an investigational new drug application filed with the FDA with respect to a Compound or Product, or an equivalent application filed with the Regulatory Authority of a country or regulatory jurisdiction in the Territory other than the U.S., and all amendments and supplements thereto.

1.23 "Joint Intellectual Property". Joint Intellectual Property means the Joint Inventions and Joint Patent Rights.

1.24 "Know-How". Know-How means all unpatented technical information, trade secrets, formulae, standards, knowledge, directions, instructions, test protocols, procedures and results, studies, analyses, raw material sources, data, manufacturing data, and any other confidential or proprietary interest in information.

1.25 "Law" or "Laws". Law or Laws means all laws, statutes, rules, regulations, orders, judgments or ordinances of any Governmental Authority.

1.26 "Losses". Losses means any and all (a) claims, losses, liabilities, damages, fines, royalties, governmental penalties or punitive damages, deficiencies, interest, awards, judgments, and settlement amounts (including special, indirect, incidental, and consequential damages, lost profits, and Third Party punitive and multiple damages), and (b) in connection with all of the items referred to in clause (a) above, any and all costs and expenses (including reasonable counsel fees and all other expenses reasonably incurred in investigating, preparing or defending any litigation or proceeding, commenced or threatened).

1.27 "Major European Country". Major European Country means France, Germany or the United Kingdom.

1.28 "Major Markets". Major Markets means, collectively, the U.S., each of the Major European Countries and Japan, and Major Market means any one of the foregoing.

1.29 "Manufacture" or "Manufacturing". Manufacture or Manufacturing means activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and storage of a product.

1.30 "MHLW". MHLW means the Japanese Ministry of Health, Labour and Welfare, and any successor agency.

1.31 "MTA". MTA means the Material Transfer Agreement by and between the Parties, dated as of May 2, 2017, as amended.

1.32 "NDA". NDA means a New Drug Application, as defined in the Act, filed with the FDA with respect to a Compound or Product, or an equivalent application filed with the Regulatory Authority of a country in the Territory other than the U.S., and all amendments and supplements thereto.

1.33 "Net Sales". Net Sales means the gross amounts billed or invoiced by Promet, or any of its Affiliates or Sublicensees, to any Third Party that is not a Sublicensee with respect to sales of Products in the Territory, calculated in the same manner as reported in such Person's audited financial statements, less the following:

(a) Volume, cash or trade discounts, credits or allowances, including discounts in the form of inventory management fees paid to wholesalers and distributors;

(b) Credits, refunds or allowances granted upon returns, rejections or recalls and for retroactive price reductions or billing errors;

(c) Freight, postage, shipping and insurance costs incurred in transporting the applicable Products;

(d) Amounts paid (including rebates and chargeback payments or credits or other equivalents thereof) to formularies, government or government agency programs, trade customers, managed health care organizations and pharmacy benefit managers (or equivalents thereof) to obtain listing or purchase of the applicable Products;

(e) Bad debts and uncollectible amounts relating to the sale of Products that are actually written off; and

(f) Taxes, tariffs, duties or other governmental charges (other than income taxes) levied on, absorbed, or otherwise imposed on the sales, transportation, delivery, use, exportation, or importation of the applicable Products.

Sales of Products between Promet and its Affiliates or Sublicensees for resale shall be excluded from the computation of Net Sales, provided that the subsequent resale of such Products to a Third Party are included in the computation of Net Sales. Disposal or use of Products at or below cost for marketing, regulatory, development or charitable purposes, such as clinical trials, compassionate use, named patient use, or indigent patient programs, shall not be deemed a sale hereunder.

If a Product is sold as part of a Combination Product, Net Sales will be the product of (x) Net Sales of the Combination Product calculated as above (*i.e.*, calculated as for a non-Combination Product) and (y) the fraction (A/(A+B)), where:

(i) A is the average selling price of the Product comprising a Compound as the sole therapeutically active ingredient during the most recently completed Calendar Quarter during which such non-Combination Product was sold in such country; and

(ii) B is the average selling price in such country of products containing the Other API contained in the Combination Product as the sole therapeutically active ingredient when sold separately during the most recently completed Calendar Quarter during which such products were sold in such country.

If both A and B cannot be determined by reference to non-Combination Product sales as described above, then Net Sales for purposes of determining royalty payments will be calculated as above, but the average selling price in the above equation shall be determined by mutual agreement reached in good faith by the Parties prior to the end of the accounting period in question based on an equitable method of determining same that takes into account, in the applicable country, variations in dosage units and the relative fair market value of each therapeutically active ingredient in the Combination Product. If the Parties are unable to reach such an agreement prior to the end of the applicable accounting period, then the Parties will refer such matter to a jointly selected Third Party with expertise in the pricing of pharmaceutical products that is not an employee, consultant, legal advisor, officer, director or stockholder of, and does not have any conflict of interest with respect to, either Party for resolution, which will be final and binding on the Parties.

1.34 "Option Period". Option Period means the period of time beginning on the Effective Date and ending on the date nine (9) months after the Effective Date.

1.35 "Party". Party means either CoNCERT or Promet; "Parties" means both CoNCERT and Promet.

1.36 "Patent Rights". Patent Rights means all patent applications, patents, certificates of invention, applications for certificates of invention and priority patent filings, including any continuations, continuations-in-part, renewals, requests for continued examination and divisions of any such patents and patent applications, any patents or certificates of invention issuing from any of the foregoing, any extensions, reissues, reexaminations, substitutions, confirmations, registrations, revalidations, revisions, additions or supplementary patent certificates thereto, and all foreign counterparts thereof.

1.37 "Payments". Payments means royalties and other amounts payable by Promet to CoNCERT pursuant to this Agreement.

1.38 "Person". Person means any natural person or any corporation, company, partnership, joint venture, firm, Governmental Authority or other entity, including a Party.

1.39 "Product". Product means any pharmaceutical preparation containing one or more Compounds as its only active ingredient(s) or any Combination Product. For the avoidance of doubt, nothing in this Agreement grants to Promet any right or license under any Patent Rights or Know-How Controlled by CoNCERT with respect to any Other API.

1.40 "Promet Intellectual Property" means, collectively, Promet Know-How and Promet Patent Rights.

1.41 "Promet Know-How". Promet Know-How means all Know-How Controlled as of the Effective Date or thereafter during the Term by Promet or any of its Affiliates (other than any Know-How included in Joint Intellectual Property) that is used by Promet or any of its Affiliates in the Development, Manufacture or Commercialization of any Compound or Product; provided, however, that, if Promet is acquired by a Third Party, "Promet Know-How" shall exclude any Know-How that (a) is Controlled by such Third Party or the Affiliates of such Third Party (other than Promet and the Persons that were Promet's Affiliates immediately prior to the closing of such acquisition transaction (such Affiliates, "Promet Pre-Existing Affiliates")) ("Promet Excluded Affiliates") and (b) was not Controlled by Promet or any of the Promet Pre-Existing Affiliates immediately prior to the closing of such acquisition transaction; provided further that, if, after the closing of such acquisition, any such Promet Excluded Affiliate Develops or Commercializes any Compound or Product or otherwise performs any activities or obtains any rights with respect to any Compound or Product, such Affiliate will cease to be a Promet Excluded Affiliate and applicable Know-How that is Controlled by such Affiliate shall be included in Promet Know-How.

1.42 "Promet Patent Rights". Promet Patent Rights means all Patent Rights in the Territory Controlled as of the Effective Date or thereafter during the Term by Promet or any of its Affiliates (other than Joint Patent Rights) that Cover any Compound or Product and are used by Promet or any of its Affiliates in the Development, Manufacture or Commercialization of any Compound or Product; provided, however, that, if Promet is acquired by a Third Party, "Promet Patent Rights" shall exclude any Patent Rights that (a) are Controlled by such Third Party or the Affiliates of such Third Party (other than Promet and Promet Pre-Existing Affiliates) and (b) were not Controlled by Promet or any of the Promet Pre-Existing Affiliates immediately prior to the closing of such acquisition transaction; provided further that, if, after the closing of such

acquisition, any such Promet Excluded Affiliate Develops or Commercializes any Compound or Product or otherwise performs any activities or obtains any rights with respect to any Compound or Product, such Affiliate will cease to be a Promet Excluded Affiliate and applicable Patent Rights that are Controlled by such Affiliate shall be included in Promet Patent Rights.

1.43 "Regulatory Approval". Regulatory Approval means an approval by the applicable Regulatory Authority of an NDA and any other approval, license, registration, permit, notification or authorization (or waiver) of the applicable Regulatory Authority, which is necessary for the manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale, or other commercialization of pharmaceutical products in a given country or regulatory jurisdiction, other than any pricing or reimbursement approval.

1.44 "Regulatory Authority". Regulatory Authority means any Governmental Authority with responsibility for granting licenses or approvals necessary for the development, manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale or other commercialization of pharmaceutical products in a country or regulatory jurisdiction, including the FDA, EMA or MHLW.

1.45 "Regulatory Exclusivity". Regulatory Exclusivity means exclusive marketing rights or data protection or other exclusivity rights conferred by any Regulatory Authority with respect to a Product in a country or regulatory jurisdiction within the Territory, other than a Patent Right, including orphan drug exclusivity, pediatric exclusivity and rights conferred in the U.S. under the Hatch-Waxman Act.

1.46 "Satisfactory Financing Round". Satisfactory Financing Round means the first financing round that enables Promet to satisfy all of the conditions in Sections 2.1(b)(i) and (ii).

1.47 "Satisfactory Financing Round Securities". Satisfactory Financing Round Securities means shares of the same class and series of capital stock of Promet issued to other investors in the Satisfactory Financing Round.

1.48 "Senior Executive". Senior Executive means, with respect to CoNCERT, the Chief Executive Officer of CoNCERT, or his or her designee, and, with respect to Promet, the _____ of Promet, or his or her designee. "Senior Executives" means the applicable officers of CoNCERT and Promet.

1.49 "Sublicensee". Sublicensee means a Third Party that has been granted a sublicense under the rights granted to Promet pursuant to Section 2.2 of this Agreement, beyond the mere right to purchase Compound or Product from Promet or its Affiliates or Sublicensees.

1.50 "Territory". Territory means all countries of the world.

1.51 "Third Party". Third Party means any Person other than CoNCERT or Promet or any of their respective Affiliates.

1.52 "U.S.". U.S. means the United States of America, including its territories and possessions.

1.53 "Valid Claim". Valid Claim means any claim of (a) an issued and unexpired patent within the CoNCERT Patent Rights that has not been revoked or held unenforceable or invalid by a final decision of a court or other Governmental Authority of competent jurisdiction, or that has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise; or (b) a patent application within the CoNCERT Patent Rights; provided that such a claim within a patent application has not been canceled, withdrawn, or abandoned or been pending for more than seven (7) years from the date of its first priority filing in the applicable country. For clarity, a claim of a patent that, pursuant to clause (b), had ceased to be a Valid Claim before it issued but that subsequently issues and is otherwise described by clause (a), shall again be considered to be a Valid Claim once it issues until it is no longer considered a Valid Claim in accordance with clause (a).

1.54 Additional Definitions. Each of the following definitions is set forth in the Section of this Agreement indicated below:

Definition:	**Section:**
Abandoned Patents	Section 7.2(a)
Agents	Section 8.1
Board	Section 2.6
Commercialization Plan	Section 4.2
CoNCERT	Preamble
CoNCERT Excluded Affiliates	Section 1.12
CoNCERT Observer	Section 2.6
CoNCERT Parties	Section 10.1
CoNCERT Pre-Existing Affiliates	Section 1.12
CoNCERT Sole Inventions	Section 7.1(b)
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1.55 Captions; Certain Conventions; Construction. All headings and captions herein are for convenience only and shall not be interpreted as having any substantive meaning. The Schedules to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. Unless otherwise expressly provided herein or the context of this Agreement otherwise requires:

(a) words of any gender include each other gender;

(b) words such as "herein", "hereof" and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear;

(c) words using the singular shall include the plural, and vice versa;

(d) the words "include," "includes" and "including" shall be deemed to be followed by the phrase "but not limited to", "without limitation", "inter alia" or words of similar import;

(e) the word "or" shall be deemed to include the word "and" (*i.e.*, shall mean "and/or")

(f) references to "Article," "Section," "subsection", "paragraph", "clause" or other subdivision, or to a Schedule, without reference to a document, are to the specified provision or Schedule of this Agreement; and

(g) references to "$" or "dollars" shall be references to U.S. Dollars.

This Agreement shall be construed as if the Parties drafted it jointly.

ARTICLE II
GRANTS OF RIGHTS

2.1 Option.

(a) Grant. CoNCERT hereby grants to Promet the exclusive option, exercisable at Promet's sole discretion, to obtain the exclusive license set forth in Section 2.2(a) (the "Option").

(b) Option Exercise. Promet shall have the right to exercise the Option by written notice to CoNCERT solely during the Option Period; provided that Promet (i) has raised gross proceeds of at least Eight Million Dollars ($8,000,000) (such amounts raised shall include

any grants or other non-dilutive amounts received by Promet after the Effective Date) in one or more equity or other financings after the Effective Date, and (ii) has a post-money valuation, following the closing of its then most recent equity financing and based on the terms of such financing, of at least Forty Million Five Hundred Thousand Dollars ($40,500,000). The date on which Promet exercises the Option, if any, shall be the "Option Exercise Date."

(c) Expiration of the Option. If, for any reason (including a failure to meet the conditions in Sections 2.1(b)(i) and (ii) prior to the end of the Option Period), Promet does not exercise the Option within the Option Period, then (a) such Option shall terminate and be of no further force or effect as of the expiration of the Option Period and (b) this Agreement shall terminate in accordance with Section 11.2.

2.2 Licenses.

(a) Commercialization License. Subject to the terms of this Agreement, upon Promet's exercise of the Option pursuant to Section 2.1, CoNCERT shall, and hereby does, grant to Promet an exclusive (even as to CoNCERT and its Affiliates), royalty-bearing right and license, including the right to sublicense in accordance with Section 2.2(c), under the CoNCERT Intellectual Property and CoNCERT's interest in the Joint Intellectual Property, to Develop, Manufacture, use and Commercialize, including filing for, obtaining and maintaining Regulatory Approval for, Products in the Field in the Territory.

(b) Development License. Subject to the terms of this Agreement, CoNCERT hereby grants to Promet, for the duration of the Option Period, an exclusive (even as to CoNCERT and its Affiliates, but subject to the rights of CoNCERT and its Affiliates to Develop Compounds and Products as specifically set forth in this Agreement), right and license, including the right to sublicense in accordance with Section 2.2(c), under the CoNCERT Intellectual Property and CoNCERT's interest in the Joint Intellectual Property, to Develop Compounds and Products in the Field in the Territory.

(c) Sublicenses. From and after the Option Exercise Date, Promet shall have the right to grant sublicenses under the licenses to CoNCERT Intellectual Property and CoNCERT's interest in the Joint Intellectual Property granted to Promet under Section 2.2(a) and Section 2.2(b) to its Affiliates and to Third Parties without CoNCERT's prior written approval but with written notice to CoNCERT; provided, however, that any such sublicense shall be subject to all applicable terms and conditions of this Agreement. Promet shall use Commercially Reasonable Efforts to cause each agreement with each Sublicensee to include grants of rights sufficient to enable Promet to grant substantially the rights set forth in Sections 11.8(b) through 11.8(f) with respect to (i) all Know-How and Patent Rights (including all applicable pre-clinical and clinical data, including pharmacology and biology data; Manufacturing documents and materials; and Manufacturing technologies) Controlled by such Sublicensee during the Term and used by such Sublicensee in the Development, Manufacture or Commercialization of any Compound or Product (collectively, "Sublicensee Intellectual Property"); (ii) all filings with Regulatory Authorities in the Territory relating to Compounds and Products and Regulatory Approvals relating to Compounds and Products held by such Sublicensee, including related correspondence with Regulatory Authorities; (iii) all Manufacturing agreements to which such Sublicensee is a party that are related to Compounds or Products; (iv) all of such Sublicensee's

inventory of Compounds and Products existing as of the applicable date; and (v) all trademarks owned by such Sublicensee and used solely in connection with the Products, along with all associated goodwill ((i)-(v), collectively, "Sublicensee Materials").

2.3 Rights Retained by the Parties. Any rights of CoNCERT or Promet, as the case may be, not expressly granted to the other Party under the provisions of this Agreement shall be retained by such Party.

2.4 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement, including the licenses granted under Section 2.1, 2.2 or 11.8(e) to Patent Rights and Know-How (including any data included in the Know-How), are and will otherwise be deemed to be for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined in Section 101(35A) of the Bankruptcy Code. Each Party will retain and may fully exercise all of its respective rights and elections under the Bankruptcy Code. The Parties agree that each Party, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code or any other provisions of applicable Law outside the United States that provide similar protection for "intellectual property."

2.5 Transfer of CoNCERT Know-How. To the extent not addressed in the MTA, during the period beginning on the Effective Date and ending on the date that is three (3) months after the Option Exercise Date, CoNCERT shall transition CoNCERT Know-How to Promet and provide Promet with reasonable amounts of consultation regarding the transferred CoNCERT Know-How.

2.6 Board Observer. CoNCERT shall be entitled to have one representative of CoNCERT (the "CoNCERT Observer") attend all regularly held and special meetings of the Board of Directors of Promet (the "Board") in a nonvoting observer capacity and to receive notice of all meetings of the Board, and Promet shall give such CoNCERT Observer copies of all notices, minutes, consents and other material that it provides to its directors at or about the same time as delivered to such directors; provided, however, that the CoNCERT Observer shall agree to hold in confidence and trust and to act in a fiduciary manner with respect to all information and materials so provided and Promet reserves the right to exclude the CoNCERT Observer from any meeting or portion thereof of the Board or from access to any material or portion thereof if Promet reasonably believes that such exclusion or withholding of information with respect thereto is reasonably necessary to (a) preserve attorney-client privilege or (b) comply with the terms and conditions of confidentiality agreements with Third Parties or otherwise protect the confidential information of Promet to the extent there may be a conflict interest on the part of CoNCERT. CoNCERT's right under this Section 2.6 shall expire if and when CoNCERT's ownership interest in Promet first decreases below ten percent (10%) of the outstanding voting stock of Promet. CoNCERT shall bear any costs and expenses of performance of the CoNCERT Observer pursuant to this Agreement.

2.7 Transition Alliance Managers. CoNCERT and Promet each acknowledge and agree that it would be beneficial for each to have a representative with a general understanding of the Development, Manufacturing and Commercialization issues relating to the Compounds and Products to act as a transition alliance manager ("Transition Alliance Manager"), and each Party

will appoint such a person promptly after the Option Exercise Date. It is envisioned that the Transition Alliance Managers will serve as a single point of contact within each Party with responsibility for facilitating communication and collaboration between the Parties, including by aiding in the transfer of documents and materials between the Parties. Each Party may replace its Transition Alliance Manager with an alternative representative at any time with prior written notice to the other Party. A Party shall bear any costs and expenses of performance by its Transition Alliance Manager pursuant to this Agreement. Each Party's Alliance Manager and any substitute for an Alliance Manager shall be bound by obligations of confidentiality and non-use applicable to the other Party's Confidential Information that are at least as stringent as those set forth in ARTICLE VIII.

ARTICLE III
DEVELOPMENT

3.1 General. From and after the Effective Date, and subject to the terms of this Agreement, including the requirements of ARTICLE V, Promet (or its Affiliates or Sublicensees) shall control and be solely responsible for the Development of and regulatory activities with respect to Compounds and Products in the Field in the Territory, including all costs and expenses relating thereto; provided, however, that, prior to the Option Exercise Date, CoNCERT will reasonably cooperate with Promet, as Promet may reasonably request and at Promet's expense, to enable Promet to interact with FDA in order to discuss the Development of and regulatory activities with respect to Compounds and Products for the indications Promet desires to pursue with respect to such Compounds and Products. If Promet requests CoNCERT's cooperation as described above, the Parties shall mutually agree in advance on a budget therefor, and Promet shall reimburse CoNCERT for any expenses incurred by CoNCERT under this Section 3.1 within thirty (30) days after receiving an invoice therefor.

3.2 Exchange of Information Regarding Development. At least once each Calendar Year (or, from and after the date on which CoNCERT's right under Section 2.6 expires, at least once each six (6) months), beginning on the Effective Date and ending on the date on which Promet obtains the first Regulatory Approval for a Product in a Major Market, Promet shall provide CoNCERT with a reasonably detailed report describing Promet's Development activities and the summary results thereof with respect to all Compounds and Products.

ARTICLE IV
COMMERCIALIZATION

4.1 General. From and after the Option Exercise Date, and subject to the terms of this Agreement, including the requirements of ARTICLE V, Promet (or its Affiliates or Sublicensees) shall control and be solely responsible for the Commercialization of Products in the Field in the Territory, including all costs and expenses relating thereto.

4.2 Commercialization Plans. During the Royalty Term with respect to each Product, at least thirty (30) days prior to the commencement of each Calendar Year, Promet shall provide CoNCERT, for information purposes only, a summary of the planned Commercialization activities to be conducted by or on behalf of Promet and its Affiliates and Sublicensees with

respect to such Product in each country in the Territory during such Calendar Year (each such plan, a "Commercialization Plan").

ARTICLE V
DILIGENCE

5.1 Commercially Reasonable Efforts. During the Term, Promet shall, directly or through its Affiliates or Sublicensees, use Commercially Reasonable Efforts, from and after the Option Exercise Date, to (a) Develop and obtain Regulatory Approval for one (1) Product in the Field in the U.S. and at least one (1) other Major Market and (b) subject to obtaining Regulatory Approval in the applicable Major Market if required, Commercialize one (1) Product in the Field in the U.S. and at least one (1) other Major Market.

5.2 Termination for Failure to Meet Diligence Obligation. If, at any time during the Term, CoNCERT reasonably believes that Promet (itself and through its Affiliates and Sublicensees) has not complied with its obligations under Section 5.1 to Develop one (1) Compound or Product in the Field in the U.S. and at least one (1) other Major Market for any consecutive nine (9) month period following the Option Exercise Date, CoNCERT shall provide written notice to Promet specifying the nature of such reasonable belief, and CoNCERT may terminate this Agreement pursuant to Section 11.5.

ARTICLE VI
FINANCIAL PROVISIONS

6.1 Equity Investment. In partial consideration for the rights granted to Promet hereunder, if Promet exercises the Option pursuant to Section 2.1, within five (5) Business Days following the Option Exercise Date, pursuant to the terms of a customary stock purchase agreement between Promet and CoNCERT on mutually acceptable terms (which shall include a reasonable and customary lock up provision in connection with any public offering applicable to the Satisfactory Financing Round Securities on terms consistent with those applicable to the shares purchased by any other investor in the Satisfactory Financing Round), Promet shall issue to CoNCERT, for no additional consideration, shares of Satisfactory Financing Round Securities representing the lesser of (a) the number of shares determined by dividing Eight Million Dollars ($8,000,000) by the price per share paid by other investors in the Satisfactory Financing Round or (b) the number of shares rounded down to the nearest whole share equal to nineteen and nine tenths percent (19.9%) of the issued and outstanding shares of Promet immediately following the issuance of such shares to CoNCERT. Following the execution of such stock purchase agreement, CoNCERT shall be entitled to the same right to participate in future financing rounds of Promet (and subject to the same exceptions) as applicable to any investor in the Satisfactory Financing Round.

By way of example, if Promet has a pre-investment valuation of Eighty Million Dollars ($80,000,000) and Ten Million Shares are authorized pre-investment, the value per share pre-investment would be Eight Dollars per share ($8.00/share). If gross proceeds of Eight Million Dollars ($8,000,000) are raised, the new investor(s) would receive One Million shares (1,000,000) and CoNCERT would receive One Million shares (1,000,000) with a new total of authorized shares of Twelve Million shares (12,000,000) post-investment.

6.2 Development and Commercialization Costs. For clarity, following the Effective Date, Promet shall be solely responsible for all costs it incurs in Developing and Commercializing Compounds and Products, including all Manufacturing costs.

6.3 Product Royalties.

(a) Royalty Rate. Promet shall pay to CoNCERT royalties, on a Product-by-Product basis, on worldwide Net Sales of Products in the Territory during each Calendar Year during the applicable Royalty Term as follows:

Worldwide Annual Net Sales of Products	Royalty Rate
For that portion less than or equal to One Hundred Million Dollars ($100,000,000)	4%
For that portion greater than One Hundred Million Dollars ($100,000,000) and less than or equal to Five Hundred Million Dollars ($500,000,000)	5%
For that portion greater than Five Hundred Million Dollars ($500,000,000) and less than or equal to One Billion Dollars ($1,000,000,000)	6%
For that portion greater than One Billion Dollars ($1,000,000,000)	With respect to Net Sales made by Promet or any of its Affiliates, 10% of such Net Sales With respect to Net Sales made by any Sublicensee, the greater of (i) 6% of such Net Sales or (ii) 50% of all payments received by Promet or any of its Affiliates with respect to such Net Sales

For purposes of calculating royalties, in each Calendar Quarter in which cumulative Net Sales of Products for the applicable Calendar Year exceed One Billion Dollars ($1,000,000,000), the royalty shall first be calculated using the applicable royalty rates applied to Net Sales of Promet and its Affiliates and next using the applicable royalty rates applied to Net Sales of Sublicensees or fifty percent (50%) of payments received by Promet or any of its Affiliates with respect to such Net Sales, as applicable (as illustrated in the Q3 row of the table in the third example below).

By way of example, if worldwide Net Sales by Promet's Sublicensees in a Calendar Year are Two Billion Dollars ($2,000,000,000), neither Promet nor any of its Affiliates made any Net Sales in such Calendar Year, and Promet's Sublicensees are required to pay Promet and its Affiliates a royalty of eighteen percent (18%) of worldwide annual Net Sales made by such Sublicensees greater than One Billion Dollars ($1,000,000,000), then Promet will pay CoNCERT a royalty of One Hundred Forty-Four Million Dollars ($144,000,000), comprising Four Million Dollars ($4,000,000) on that portion of Net Sales that is less than or equal to One Hundred Million Dollars ($100,000,000), Twenty Million Dollars ($20,000,000) on that portion of Net Sales that is greater than One Hundred Million Dollars ($100,000,000) and less than or equal to Five Hundred Million Dollars ($500,000,000), Thirty Million Dollars ($30,000,000) on that portion of Net Sales that is greater than Five Hundred Million Dollars ($500,000,000) and less than or equal to One Billion Dollars ($1,000,000,000), and Ninety Million Dollars

($90,000,000) on that portion of Net Sales in excess of One Billion Dollars ($1,000,000,000) (which equals fifty percent (50%) of the One Hundred Eighty Million Dollars ($180,000,000) of royalties on Net Sales in excess of One Billion Dollars ($1,000,000,000) received by Promet from its Sublicensees).

By way of further example, if worldwide annual Net Sales by Promet's Sublicensees in a Calendar Year are Two Billion Dollars ($2,000,000,000), neither Promet nor any of its Affiliates made any Net Sales in such Calendar Year, and Promet's Sublicensees are required to pay Promet and its Affiliates a royalty of ten percent (10%) of worldwide annual Net Sales made by such Sublicensees greater than One Billion Dollars ($1,000,000,000), then Promet will pay CoNCERT a royalty of One Hundred Fourteen Million Dollars ($114,000,000), comprising Four Million Dollars ($4,000,000) on that portion of Net Sales that is less than or equal to One Hundred Million Dollars ($100,000,000), Twenty Million Dollars ($20,000,000) on that portion of Net Sales that is greater than One Hundred Million Dollars ($100,000,000) and less than or equal to Five Hundred Million Dollars ($500,000,000), Thirty Million Dollars ($30,000,000) on that portion of Net Sales that is greater than Five Hundred Million Dollars ($500,000,000) and less than or equal to One Billion Dollars ($1,000,000,000), and Sixty Million Dollars ($60,000,000) on that portion of Net Sales in excess of One Billion Dollars ($1,000,000,000) (which equals six percent (6%) of that portion of Net Sales in excess of One Billion Dollars ($1,000,000,000), because it is greater than fifty percent (50%) of the One Hundred Million Dollars ($100,000,000) of royalties on Net Sales in excess of One Billion Dollars ($1,000,000,000) received by Promet from its Sublicensees).

By way of further example, and as illustrated in the table below, if worldwide annual Net Sales are Three Billion Dollars ($3,000,000,000), of which Promet and its Affiliates made Net Sales of One Billion Five Hundred Fifty Million Dollars ($1,550,000,000) and Promet's Sublicensees made Net Sales of One Billion Four Hundred Fifty Million Dollars ($1,450,000,000) in such Calendar Year, and Promet's Sublicensees are required to pay Promet and its Affiliates a royalty of ten percent (10%) of worldwide annual Net Sales made by such Sublicensees, then Promet will pay CoNCERT a royalty of Two Hundred Six Million Dollars ($206,000,000), comprising Four Million Dollars ($4,000,000) on that portion of Net Sales that is less than or equal to One Hundred Million Dollars ($100,000,000), Twenty Million Dollars ($20,000,000) on that portion of Net Sales that is greater than One Hundred Million Dollars ($100,000,000) and less than or equal to Five Hundred Million Dollars ($500,000,000), Thirty Million Dollars ($30,000,000) on that portion of Net Sales that is greater than Five Hundred Million Dollars ($500,000,000) and less than or equal to One Billion Dollars ($1,000,000,000), Eighty Million Dollars ($80,000,000) on that portion of Net Sales made by Promet and its Affiliates in excess of One Billion Dollars ($1,000,000,000) and Seventy-Two Million Dollars ($72,000,000) on that portion of Net Sales made by Promet's Sublicensees in excess of One Billion Dollars ($1,000,000,000) (which equals six percent (6%) of that portion of Net Sales in excess of One Billion Dollars ($1,000,000,000), because it is greater than fifty percent (50%) of the One Hundred Twenty Million Dollars ($120,000,000) of royalties on Net Sales in excess of One Billion Dollars ($1,000,000,000) received by Promet from its Sublicensees).

	Promet & Affiliates	Sublicensees

	Sales	Royalty %	Royalty Payment to CoNCERT	Sales	Royalty %	Royalty Payment to CoNCERT
Q1	$50M	4%	$2M	$50M	4%	$2M
Total Q1 Net Sales: $100M						
Q2	$200M	5%	$10M	$200M	5%	$10M
Total Q1 + Q2 Net Sales: $500M						
Q3	$600M: $500M $100M	 6% 10%	 $30M $10M	$500M	Greater of (i) 6% or (ii) 50% of all payments received by Promet or any of its Affiliates with respect to such Net Sales	$30M
Total Q1 + Q2 +Q3 Net Sales: $1.6B						
Q4	$700M	10%	$70M	$700M	Greater of (i) 6% or (ii) 50% of all payments received by Promet or any of its Affiliates with respect to such Net Sales	$42M
Total Annual Promet Sales: $1.55B						
Total Annual Sublicensee Sales: $1.45B						
Total Annual Net Sales: $3B						
Total Annual Royalty Payment to CoNCERT: $206M						

(b) Royalty Term and Adjustments. Promet's royalty obligations to CoNCERT under this Section 6.3 shall commence on a country-by-country and Product-by-Product basis on the Effective Date and shall expire on a country-by-country basis and Product-by-Product basis on the later of (i) expiration or invalidation of the last Valid Claim Covering

such Product in such country or (ii) the tenth (10^{th}) anniversary of the date of the First Commercial Sale by Promet or any of its Affiliates or Sublicensees to a non-Sublicensee Third Party of such Product in such country (the "Royalty Term"); provided that, during any period within the Royalty Term remaining after the expiration of all Valid Claims Covering such Product in such country and all Regulatory Exclusivity as to such Product in such country, the royalties payable as to such Product in such country under this Section 6.3 shall be reduced to fifty percent (50%) of the royalties otherwise payable as to such Product in such country pursuant to Section 6.3(a). Such royalty reduction will be calculated by determining the portion of total Net Sales of the relevant Product in a Calendar Quarter that is attributable to the applicable country in which such reduction applies, and by determining the total royalties without reduction, and then reducing by fifty percent (50%) the applicable portion (based on Net Sales) of total royalties attributable to the country in which such reduction applies.

(c) Third Party Payments. If, in order to Develop, Manufacture, use or Commercialize a Product in the Field in a country of the Territory, Promet or its Affiliate or Sublicensee is obligated to obtain a license or comparable grant of rights (*e.g.*, a covenant not to sue) under any Patent Rights from a Third Party ("Third Party Patent License") and pay a royalty under such Third Party Patent License with respect to such Product in such country, then, subject to Section 6.3(d), one hundred percent (100%) of such royalties actually paid by Promet, its Affiliates or Sublicensees shall be creditable against royalties payable to CoNCERT hereunder with respect to such Product in such country; provided that, if Promet is obligated to enter into any Third Party Patent License, Promet shall use Commercially Reasonable Efforts to minimize the royalties owed by Promet under such Third Party Patent License.

(d) Limitation on Royalty Reductions. Notwithstanding anything to the contrary in this Section 6.3, in no event shall the royalties payable under this Section 6.3 with respect to Net Sales of any Product in any country in any Calendar Quarter be reduced to less than fifty percent (50%) of the royalties payable under Section 6.3(a) with respect to Net Sales of such Product in such country in such Calendar Quarter; provided, however, that any amount which is entitled to be credited under Section 6.3(c) but is not credited as a result of the foregoing limitation in this Section 6.3(d) shall be carried over and applied against royalties payable to CoNCERT in respect of such Product in such country in subsequent periods of the Royalty Term until the full deduction is taken.

6.4 Reports; Payments. Within forty-five (45) days after the end of each Calendar Quarter during which there are Net Sales giving rise to a payment obligation under Section 6.3, Promet shall submit to CoNCERT a report identifying, for each Product, the gross sales, itemized deductions and Net Sales for such Product for each country in the Territory for such Calendar Quarter and the basis for any reduction in royalties pursuant to any subsection of Section 6.3. Concurrently with each such report, Promet shall pay to CoNCERT all royalties payable by it under Section 6.3.

6.5 Books and Records; Audit Rights. Promet shall keep complete and accurate records of the underlying revenue and expense data relating to the calculations of Net Sales and payments required by Section 6.3. CoNCERT shall have the right, once annually at its own expense, to have an independent, certified public accounting firm, selected by CoNCERT and reasonably acceptable to Promet, review any such records of Promet in the location(s) where

such records are maintained by Promet upon reasonable notice (which shall be no less than fourteen (14) days prior notice) and during regular business hours and under obligations of strict confidence, for the sole purpose of verifying the basis and accuracy of payments made under Section 6.3 within the thirty-six (36) month period preceding the date of the request for review. The report of such accounting firm shall be limited to a certificate stating whether any report made or payment submitted by Promet during such period is accurate or inaccurate and the actual amounts of Net Sales, and royalties due, for such period. Promet shall receive a copy of each such report concurrently with receipt by CoNCERT. Should such inspection lead to the discovery of a discrepancy to CoNCERT's detriment, Promet shall pay within five (5) Business Days after its receipt from the accounting firm of the certificate the amount of the discrepancy plus interest calculated in accordance with Section 6.9. CoNCERT shall pay the full cost of the review unless the underpayment of royalties is greater than five percent (5%) of the amount due for any applicable Calendar Year, in which case Promet shall pay the reasonable cost charged by such accounting firm for such review. Any overpayment by Promet revealed by an examination shall be fully creditable against future Payments.

6.6 Tax Matters. Except as expressly provided below, no payments to be made to CoNCERT by Promet hereunder shall be reduced by or on account of any taxes, levies, imposts, duties, charges, assessments or fees (collectively, "Taxes"). Notwithstanding the immediately preceding sentence, if any applicable Law requires (with due regard to any relief to which CoNCERT may be entitled) that Taxes be deducted and withheld from any payment made to CoNCERT by Promet under this Agreement, Promet shall (a) deduct those Taxes, together with any interest and penalties properly assessed thereon, from such payment or from any other payment owed by Promet hereunder; (b) transmit the amounts so deducted to the proper Governmental Authority; (c) send evidence of the requirement together with proof of due transmission of the amounts described in clause (b) to CoNCERT promptly following such payment; and (d) remit to CoNCERT the net amount of such payment after taking account of such deduction. In determining whether to deduct any amount hereunder, Promet shall take due account of all documentation supplied by CoNCERT, and of other facts known to Promet, supporting a reduction in any Tax otherwise required to be deducted, or a credit therefor or refund thereof. Promet will reasonably cooperate with CoNCERT in respect of Tax matters relating to payments made by Promet to CoNCERT under this Agreement and any disputes with a Governmental Authority regarding such matters, including without limitation: (y) complying with reasonable requests from CoNCERT to change the form, place or other circumstances of payments to be made to CoNCERT by Promet under this Agreement so as to reduce the incidence of Taxes on such payments or recover any Taxes imposed on such payments (any such recovery to be for the benefit of CoNCERT); and (z) in connection with any official or unofficial audit or contest relating to such payments.

6.7 Payment Method and Currency Conversion. All Payments shall be made in U.S. dollars in immediately available funds via either a bank wire transfer, an ACH (automated clearing house) mechanism, or any other means of electronic funds transfer, at Promet's election, to CoNCERT's bank account at Silicon Valley Bank, or to such other bank account as CoNCERT shall designate in a notice at least ten (10) days before the payment is due. CoNCERT's wiring instructions are set forth on Schedule 6.7. For the purposes of determining the amount of any royalties due for the relevant Calendar Quarter under Section 6.3, the amount of Net Sales in any foreign currency shall be converted into U.S. dollars in accordance with the

prevailing rates of exchange for the relevant month for converting such first currency into such other currency used by Promet's (or its Sublicensee's) internal accounting systems, which are independently audited on an annual basis. Upon request by CoNCERT, Promet shall disclose the bases for the rates of exchange used for purposes of assuring that such rates reflect prevailing rates of exchange.

6.8 Blocked Payments. If by reason of applicable Laws in any country in the Territory, it becomes impossible or illegal for Promet or any of its Affiliates or Sublicensees to transfer, or have transferred on its behalf royalties or other payments to CoNCERT or to Promet or its Affiliates or Sublicensees, Promet shall promptly notify CoNCERT of the conditions preventing such transfer. To the extent any payments to CoNCERT cannot be transferred pursuant to the preceding sentence, such amounts shall be deposited in local currency in the relevant country to the credit of CoNCERT in a recognized banking institution designated by CoNCERT or, if none is designated by CoNCERT within a period of thirty (30) days, in a recognized banking institution selected by Promet or its Affiliate or Sublicensee, as the case may be, and identified in a notice given to CoNCERT. If so deposited in a foreign country, Promet shall provide, or cause its Affiliate or Sublicensee to provide, reasonable cooperation to CoNCERT so as to allow CoNCERT to assume control over such deposit as promptly as practicable.

6.9 Late Payments. If a Party shall fail to make a timely payment pursuant to the terms of this Agreement, the other Party shall provide written notice of such failure to the non-paying Party (a "Late Payment Notice"), and interest shall accrue on the past due amount starting on the date of the Late Payment Notice at the thirty (30) day U.S. dollar London Interbank Offered Rate effective for the date that payment was due (as published in the Wall Street Journal) plus five percent (5%) per annum, computed for the actual number of days after the date of the Late Payment Notice that the payment was past due.

ARTICLE VII
INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION AND RELATED MATTERS

7.1 Ownership of Inventions.

(a) MTA. If, for any reason (including a failure to meet the conditions in Sections 2.1(b)(i) and 2.1(b)(ii) prior to end of the Option Period), Promet does not exercise the Option within the Option Period, all Promet Sole Inventions and Joint Inventions made after the Effective Date shall be governed by the terms of the MTA and Promet shall, and hereby does, assign the same to CoNCERT to the extent set forth the MTA upon the expiration of the Option Period; provided, however, that, notwithstanding the terms of the MTA, Promet shall not be required to assign such inventions to CoNCERT prior to the end the of Option Period. If Promet does exercise the Option within the Option Period, ownership of all Promet Sole Inventions and Joint Inventions made after the effective date of the MTA (*i.e.*, May 2, 2017) shall be governed by the terms of this Agreement.

(b) Sole Inventions. Subject to Section 7.1(a), each Party shall exclusively own all inventions relating to any Compound or Product or its manufacture or use made solely

by such Party, its employees, agents and consultants ("Sole Inventions"). Sole Inventions made solely by Promet, its employees, agents and consultants are referred to herein as "Promet Sole Inventions". Sole Inventions made solely by CoNCERT, its employees, agents and consultants are referred to herein as "CoNCERT Sole Inventions".

(c) Joint Inventions. Subject to Section 7.1(a), the Parties shall jointly own all inventions relating to any Compound or Product or its manufacture or use made jointly by employees, agents and consultants of Promet, on the one hand, and employees, agents and consultants of CoNCERT, on the other hand, on the basis of each Party having an undivided interest in the whole ("Joint Inventions"). Subject to the licenses and other provisions of this Agreement (including Section 7.1(a)), each Party shall have the unrestricted right to use and license Joint Inventions without obtaining consent from, or accounting to, the other Party.

(d) Inventorship. For purposes of determining whether an invention is a Promet Sole Invention, a CoNCERT Sole Invention or a Joint Invention, questions of inventorship shall be resolved in accordance with United States patent Laws.

(e) Further Assurances. Each Party shall execute such documents and take such actions as may be reasonably requested by the other Party to confirm and give further effect to the provisions of this Section 7.1.

7.2 Prosecution and Maintenance of Patent Rights.

(a) Prosecution of CoNCERT Patent Rights. With respect to CoNCERT Patent Rights, CoNCERT and Promet shall cooperate in good faith in connection with the continued prosecution and maintenance by CoNCERT of such CoNCERT Patent Rights. If Promet exercises the Option pursuant to Section 2.1, the out-of-pocket costs and expenses incurred by CoNCERT after the Option Exercise Date to obtain, prosecute and maintain CoNCERT Patent Rights shall be borne one hundred percent (100%) by Promet. CoNCERT shall notify Promet at least ninety (90) days prior to the deadline for entering into national phase with respect to any PCT application included in CoNCERT Patent Rights. No later than sixty (60) days prior to entry into national phase, Promet shall provide CoNCERT with a list of any countries in which Promet would like CoNCERT to file. CoNCERT shall file international patent applications, or designate for national filing and file, in all countries requested by Promet. CoNCERT shall promptly deliver to Promet copies of all official correspondence with the applicable patent and trademark offices in the Territory relating to the CoNCERT Patent Rights and, after the Option Exercise Date shall promptly provide Promet drafts of all proposed material filings and correspondence to any patent authority with respect to the CoNCERT Patent Rights for Promet's review and comment prior to the submission of such proposed filings and correspondences. CoNCERT shall keep Promet informed of the status of all pending patent applications that pertain to any Compound or Product. CoNCERT, its agents and attorneys shall not unreasonably decline to implement or incorporate any comments of Promet regarding any aspect of such patent prosecutions. CoNCERT shall not abandon any CoNCERT Patent Rights (the "Abandoned Patents") without at least ninety (90) days' prior notice to Promet. If CoNCERT decides to abandon any CoNCERT Patent Rights, Promet shall have the option to continue to prosecute and maintain the Abandoned Patents in CoNCERT's name.

(b) Prosecution of Joint Patent Rights. Promet shall be responsible for obtaining, prosecuting and/or maintaining patents and patent applications, in any countries in the Territory, Covering Joint Inventions ("Joint Patent Rights"). The out-of-pocket costs and expenses incurred to obtain, prosecute and maintain Joint Patent Rights shall be borne one-hundred percent (100%) by Promet. Promet shall keep CoNCERT informed of the status of all pending Joint Patent Rights. Promet, its agents and attorneys shall not unreasonably decline to implement or incorporate any comments of CoNCERT regarding any aspect of such patent prosecutions. Promet shall not abandon any Joint Patent Right without at least ninety (90) days' prior notice to CoNCERT. If Promet decides to abandon any Joint Patent Right, CoNCERT shall have the option to continue to prosecute and maintain such Joint Patent Right jointly in both Parties' names, at CoNCERT's sole expense.

(c) Prosecution of Promet Patent Rights. Promet has the sole right, but not the responsibility, to obtain, prosecute and/or maintain the Promet Patent Rights.

(d) Cooperation. Each Party agrees to cooperate fully in the preparation, filing, prosecution, and maintenance of CoNCERT Patent Rights and Joint Patent Rights pursuant to this Section 7.2 and in the obtaining and maintenance of any patent term extensions, supplementary protection certificates, pediatric extensions, and their equivalent with respect thereto. Such cooperation includes: (i) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, so as enable the other Party to apply for and to prosecute patent applications in any country as permitted by this Section 7.2; and (ii) promptly informing the other Party of any matters coming to such Party's attention that may affect the preparation, filing, prosecution, or maintenance of any such patent applications.

7.3 Third Party Infringement.

(a) Notice. Each Party shall promptly report in writing to the other Party during the Term any known or suspected (i) infringement of any of the CoNCERT Patent Rights or Joint Patent Rights, or (ii) unauthorized use or misappropriation of any of the CoNCERT Know-How or Joint Inventions, in the case of either clause (i) or clause (ii), that could reasonably be expected to impact the (A) Development, Manufacture, use or Commercialization of a Compound or Product in the Field in the Territory, or (B) scope of the rights licensed to Promet under ARTICLE II (an "Infringement Claim"), of which such Party becomes aware, and shall provide the other Party with all available evidence supporting such Infringement Claim.

(b) Initial Right to Enforce. Subject to Section 7.3(c), Promet (itself or through its Affiliate or Sublicensee) shall have the first right, but not the obligation, to initiate a suit, or take other appropriate action that it believes is reasonably required to protect (*i.e.*, prevent or abate actual or threatened infringement or misappropriation of) or otherwise enforce the CoNCERT Intellectual Property and Joint Intellectual Property with respect to an Infringement Claim; provided, however, that Promet shall (i) consult with CoNCERT in good faith with respect to any claim that any CoNCERT Patent Right or Joint Patent Right is invalid or unenforceable and (ii) implement any reasonable comment from CoNCERT regarding any aspect of defending against any such claim described in clause (i). Any such suit by Promet shall be brought either in the name of CoNCERT or its Affiliate, the name of Promet or its Affiliate, or the names of Promet, CoNCERT and their respective Affiliates, as may be required by the

Law of the forum. For this purpose, CoNCERT shall execute such legal papers and cooperate in the prosecution of such suit, including providing full access to documents, information and witnesses as reasonably requested by Promet in connection with such suit, as may be reasonably requested by Promet; provided that Promet shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by CoNCERT in connection with such cooperation. For clarity, as between CoNCERT and Promet, (A) CoNCERT shall have the sole right, but not the obligation, to protect CoNCERT Intellectual Property against any suspected misappropriation or infringement that does not constitute an Infringement Claim and (B) the Parties shall jointly determine by mutual agreement whether and how to protect Joint Intellectual Property against any suspected misappropriation or infringement that does not constitute an Infringement Claim, and the provisions of this ARTICLE VII shall not apply with respect thereto.

(c) Step-In Right. If Promet does not initiate a suit or take other appropriate action that it has the initial right to initiate or take with respect to an Infringement Claim pursuant to Section 7.3(b), then CoNCERT may, in its discretion, provide Promet with notice of CoNCERT's intent to initiate a suit or take other appropriate action. If CoNCERT provides such notice and Promet does not initiate a suit or take such other appropriate action within thirty (30) days after receipt of such notice from CoNCERT, then CoNCERT shall have the right to initiate a suit or take other appropriate action that it believes is reasonably required to protect the CoNCERT Intellectual Property. Any suit by CoNCERT shall be either in the name of CoNCERT or its Affiliate, the name of Promet or its Affiliate, or the names of Promet, CoNCERT and their respective Affiliates, as may be required by the Law of the forum. For this purpose, Promet shall execute such legal papers and cooperate in the prosecution of such suit, including providing full access to documents, information and witnesses as reasonably requested by CoNCERT in connection with such suit, as may be reasonably requested by CoNCERT; provided that CoNCERT shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by Promet in connection with such cooperation.

(d) Conduct of Certain Actions; Costs. The Party initiating suit or taking other action with respect to an Infringement Claim shall have the sole and exclusive right to select counsel for, and otherwise control, any suit or action initiated by it pursuant to Section 7.3(b) or 7.3(c). The initiating Party shall assume and pay all of its own out-of-pocket costs incurred in connection with any litigation or proceedings initiated by it pursuant to Sections 7.3(b) and 7.3(c), including the fees and expenses of the counsel selected by it. The other Party shall have the right to participate, but not control, and be represented in, any such suit by its own counsel at its own expense.

(e) Recoveries. Except as otherwise agreed by the Parties as part of a cost-sharing arrangement, any damages, settlements, accounts of profits, or other financial compensation recovered from a Third Party by the Party that assumes control over enforcing any Infringement Claim shall be allocated between the Parties as follows:

(i) first, to reimburse the Parties' actual out-of-pocket expenses (including reasonable counsel fees and expenses) incurred in pursuing such Infringement Claim; and

(ii) second, any remaining amount that represents compensatory damages relating to any Compound or Product (including lost sales or lost profits) shall be deemed Net Sales and paid to Promet, less an amount equal to royalty payments to CoNCERT on such deemed Net Sales in accordance with the royalty provisions of Section 6.3, which amount shall be paid to CoNCERT, and any remaining amount that represents punitive damages shall be shared equally by the Parties.

7.4 Patent Invalidity Claim. Each of the Parties shall promptly notify the other in the event of any legal or administrative action by any Third Party against a CoNCERT Patent Right or Joint Patent Right of which it becomes aware, including any nullity, revocation, reexamination or compulsory license proceeding. CoNCERT shall have the first right, but not the obligation, to defend against any such action involving a CoNCERT Patent Right, and the costs of any such defense shall be at CoNCERT's expense; provided, however, that, in the case of any *inter partes* review or similar post-grant matter before the Patent Trial and Appeal Board or similar administrative body that is based on the same subject matter as any claim or counterclaim in any Infringement Claim or Paragraph IV Claim, Promet shall have the first right, but not the obligation, to defend against any such action involving a CoNCERT Patent Right, and the costs of any such defense shall be at Promet's expense. Promet shall have the first right, but not the obligation, to defend against any such action involving a Joint Patent Right, and the costs of any such defense shall be at Promet's expense. If the Party that has the first right to defend against any such action involving such CoNCERT Patent Right or Joint Patent Right does not do so, then the other Party shall have the right, but not the obligation, to defend such action and any such defense shall be at such other Party's expense. Upon request of the Party that defends against any such action involving a CoNCERT Patent Right or Joint Patent Right, the other Party agrees to join in any such action and to cooperate reasonably with the defending Party, including providing full access to documents, information and witnesses as reasonably requested by the defending Party in connection with such action, provided that the defending Party shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by the other Party in connection with such cooperation.

7.5 Claimed Infringement. Each of the Parties shall promptly notify the other in the event a Party becomes aware that the practice by either Party of the CoNCERT Patent Rights infringes, or is suspected or alleged to infringe, the intellectual property rights of any Third Party in the Territory, and shall promptly provide the other Party with any notice it receives or has received from a Third Party related to such suspected, alleged or actual infringement.

7.6 Patent Term Extensions. Promet shall have the exclusive right and obligation to seek patent term extensions or supplemental patent protection, including supplementary protection certificates, in each country in the Territory in relation to the Products at Promet's expense. CoNCERT and Promet shall cooperate in connection with all such activities, and Promet, its agents and attorneys will give due consideration to all timely suggestions and comments of CoNCERT regarding any such activities; provided that all final decisions shall be made by Promet.

7.7 Patent Marking. Promet shall comply with the patent marking statutes in each country in the Territory in which any Product is sold by Promet, its Affiliates or its Sublicensees.

7.8 Certification under Drug Price Competition and Patent Restoration Act.

(a) Notice. If a Party becomes aware of any certification filed pursuant to 21 U.S.C. § 355(b)(2)(A) or 355(j)(2)(A)(vii)(IV) or its successor provisions, or any similar provision in any country in the Territory other than the U.S., claiming that any CoNCERT Patent Rights or Joint Patent Rights are invalid or otherwise unenforceable, or that infringement will not arise from the manufacture, use, import or sale of a product by a Third Party (a "Paragraph IV Claim"), such Party shall promptly notify the other Party in writing within five (5) Business Days after its receipt thereof.

(b) Control of Response; Recoveries. Promet shall have the first right, but not the obligation, to initiate and control patent infringement litigation for any Paragraph IV Claim; provided, however, that Promet shall (i) consult with CoNCERT in good faith with respect to any claim that any CoNCERT Patent Right or Joint Patent Right is invalid or unenforceable and (ii) implement any comment from CoNCERT regarding any aspect of defending against any such claim. Any suit by Promet shall be brought either in the name of CoNCERT or its Affiliate, the name of Promet or its Affiliate, or the names of Promet, CoNCERT and their respective Affiliates, as may be required by the Law of the forum. For this purpose, CoNCERT shall execute such legal papers and cooperate in the prosecution of such suit, including providing full access to documents, information and witnesses, as may be reasonably requested by Promet; provided that Promet shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by CoNCERT in connection with such cooperation. If Promet elects not to assume control over litigating any Paragraph IV Claim, Promet shall notify CoNCERT as soon as practicable but in any event not later than ten (10) days before the first action required to litigate such Paragraph IV Claim so that CoNCERT may, but shall not be required to, assume sole control over litigating such Paragraph IV Claim using counsel of its own choice. Any suit by CoNCERT shall be either in the name of CoNCERT or its Affiliate, the name of Promet or its Affiliate, or the names of Promet, CoNCERT and their respective Affiliates, as may be required by the Law of the forum. For this purpose, Promet shall execute such legal papers and cooperate in the prosecution of such suit, including providing full access to documents, information and witnesses, as may be reasonably requested by CoNCERT; provided that CoNCERT shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by Promet in connection with such cooperation. Any compensation recovered as a result of such litigation shall be allocated as set forth in Section 7.3(e) above.

7.9 Privileged Communications. In furtherance of this Agreement, it is expected that Promet and CoNCERT will, from time to time, disclose to one another privileged communications with counsel, including opinions, memoranda, letters and other written, electronic and verbal communications. Such disclosures are made with the understanding that they shall remain confidential, that they will not be deemed to waive any applicable attorney-client or attorney work product or other privilege and that they are made in connection with the shared community of legal interests existing between CoNCERT and Promet, including the community of legal interests in avoiding infringement of any valid, enforceable patents of Third Parties and maintaining the validity of CoNCERT Patent Rights, Promet Patent Rights and Joint Patent Rights.

7.10 Settlement. Neither Party shall unilaterally enter into any settlement or compromise of any suit, action or proceeding under this ARTICLE VII that would in any manner alter, diminish, or be in derogation of the other Party's rights under this Agreement without the prior written consent of such other Party, which shall not be unreasonably withheld.

ARTICLE VIII
CONFIDENTIAL INFORMATION

8.1 Treatment of Confidential Information. During the Term and for five (5) years thereafter, each Party shall maintain Confidential Information (as defined in Section 8.2) of the other Party in confidence, and shall not disclose, divulge or otherwise communicate such Confidential Information to others (except for agents, directors, officers, employees, consultants, subcontractors, licensees, sublicensees, partners, Affiliates and advisors who have a need to know such information to perform obligations or exercise rights under this Agreement on behalf of such Party (collectively, "Agents") under obligations of confidentiality no less stringent than those set forth in this ARTICLE VIII) or use it for any purpose other than in connection with the Development, Manufacture, use or Commercialization of Compounds or Products pursuant to this Agreement or otherwise to accomplish the purposes of this Agreement, including exercising its rights or performing its obligations hereunder, and each Party shall exercise Commercially Reasonable Efforts to prevent and restrain the unauthorized disclosure of such Confidential Information by any of its Agents, which efforts shall be at least as diligent as those generally used by such Party in protecting its own confidential and proprietary information, and in any event no less than reasonable efforts. Each Party will be responsible for any breach of this ARTICLE VIII by its Agents. Either receiving Party may disclose Confidential Information of the disclosing Party (a) to Governmental Authorities in order to comply with applicable Laws, respond to inquiries, requests or investigations by Governmental Authorities, including filing, prosecuting or maintaining Patent Rights as permitted by this Agreement; (b) to comply with the regulations or requirements of any stock exchange; (c) to the extent useful to Develop, Manufacture, use or Commercialize any Compound or Product, including making regulatory filings for any Compound or Product, in accordance with this Agreement; (d) to the extent necessary or useful in order to defend or prosecute litigation; and (e) to potential and actual *bona fide* investors, acquirors and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition or collaboration; provided that (x) with respect to any disclosure in accordance with Section 8.1(a), (b) or (d), the receiving Party shall promptly provide prior notice of such disclosure to the disclosing Party and use Commercially Reasonable Efforts to avoid or minimize the degree of such disclosure, (y) with respect to any disclosure in accordance with Section 8.1(a) or (d), the receiving Party will use efforts to secure confidential treatment of such Confidential Information at least as diligent as such Party would use to protect its own confidential information, but in no event less than reasonable efforts, and (z) with respect to any disclosure in accordance with Section 8.1(e),the receiving Party shall obtain the same confidentiality obligations from any Third Parties to which it discloses the Confidential Information of the disclosing Party as it obtains with respect to its own similar types of confidential information, and in any event such obligations shall be no less stringent than those set forth in this ARTICLE VIII.

8.2 Confidential Information. "Confidential Information" means all trade secrets or other proprietary information, including any proprietary data and materials (whether or not

patentable or protectable as a trade secret), that is disclosed by a Party to the other Party. All information disclosed prior to the Effective Date by CoNCERT to Promet pursuant to the Amended and Restated Nondisclosure Agreement by and between the Parties, dated as of February 2, 2017, as amended through the Effective Date (the "Confidentiality Agreement"), shall be deemed "Confidential Information" of CoNCERT. Notwithstanding the foregoing, there shall be excluded from the foregoing definition of Confidential Information any of the foregoing that:

(a) either before or after the date of the disclosure to the receiving Party is lawfully disclosed to the receiving Party by a Third Party without any violation of any obligation to the other Party; or

(b) either before or after the date of the disclosure to the receiving Party, becomes published or generally known to the public through no fault or omission on the part of the receiving Party or its Agents; or

(c) is independently developed by or for the receiving Party without reference to or reliance upon the disclosing Party's Confidential Information as demonstrated by contemporaneous written records of the receiving Party.

8.3 Publications. The Parties recognize the desirability of publishing and publicly disclosing the results of clinical trials of pharmaceutical products. Accordingly, subject to coordination through designated representatives of each Party, Promet shall be free to publicly disclose the results of clinical trials involving Compounds or Products, subject to prior review by CoNCERT for issues of patentability and protection of its Confidential Information, in a manner consistent with all Laws applicable to Promet and best industry practices. In addition, if Promet intends to publish articles in scientific or medical journals or to make presentations of the results of clinical trials involving Compounds or Products, Promet shall provide CoNCERT through the designated representatives of each Party at its earliest opportunity with any proposed abstracts, manuscripts or summaries of presentations that cover the results of Development of any Compound or Product. CoNCERT shall respond promptly through its designated representative, and in any event no later than fifteen (15) days after receipt of such proposed publication or presentation, or such shorter period as may be required by the publication. If timely requested by CoNCERT, Promet agrees to allow a reasonable period (not to exceed thirty (30) days) to permit filings for patent protection and to otherwise address issues of Confidential Information or related competitive harm to the reasonable satisfaction of CoNCERT. In addition, Promet will consider in good faith any comments furnished by CoNCERT to Promet during such period. Promet shall be responsible to assure that its Affiliates and licensees agree to, and comply with, equivalent undertakings in favor of CoNCERT. CoNCERT and its Affiliates may make any publication or public disclosure of any data concerning the Compounds or Products that existed as of the Effective Date, provided that CoNCERT provides Promet at least fifteen (15) days (or such shorter period as may be required by the publication) to review such publication or public disclosure, allows a reasonable period (not to exceed thirty (30) days) to permit filings for patent protection and to otherwise address issues of Confidential Information or related competitive harm to the reasonable satisfaction of Promet, and reasonably considers any timely comments provided by Promet with respect to such publication or public disclosure. CoNCERT shall not, and shall cause each of its Affiliates, licensees and sublicensees not to, make any other

publications or public disclosures regarding the Compounds or Products without Promet's prior written consent. If Promet consents to CoNCERT making such publications, CoNCERT shall provide Promet a reasonable opportunity to comment on any such publications and such comments shall not be unreasonably rejected. All publications involving Compounds or Products shall include appropriate acknowledgement consistent with standard scientific practice of any contributions of each Party to the results being publicly disclosed.

8.4 Press Releases and Other Disclosures. The Parties recognize that each Party may from time to time desire to issue press releases and make other public statements or disclosures regarding the subject matter of this Agreement. In such event, the Party desiring to issue a press release or make a public statement or disclosure shall provide the other Party with a copy of the proposed press release, statement or disclosure for review and approval in advance (except that neither Party shall have any obligation to disclose or approve the disclosure of Confidential Information except to the extent required or permitted pursuant to this ARTICLE VIII). No other public statement or disclosure concerning the existence or terms of this Agreement shall be made, either directly or indirectly, by either Party, without first obtaining the written approval of the other Party. Once any public statement or disclosure has been approved in accordance with this Section 8.4, then either Party may appropriately communicate information contained in such permitted statement or disclosure. Notwithstanding the foregoing provisions of this ARTICLE VIII, a Party may (a) disclose the existence and terms of this Agreement where required, as reasonably determined by the disclosing Party, by applicable Law, by applicable stock exchange regulation or by order or other ruling of a competent court and (b) disclose the existence and terms of this Agreement under obligations of confidentiality no less stringent than those set forth in this ARTICLE VIII to agents, advisors, contractors, licensees, sublicensees, and *bona fide* investors, acquirors and other financial or commercial partners, and to potential agents, advisors, contractors, licensees, sublicensees, and *bona fide* investors, acquirors and other financial or commercial partners. To the extent a Party determines in good faith that it is required by applicable Law to publicly file, register or notify this Agreement with a Governmental Authority, including public filings pursuant to securities Laws, it shall provide a proposed redacted form of the Agreement to the other Party a reasonable amount of time prior to filing for the other Party to review such draft and propose changes to such proposed redactions. The Party making such filing, registration or notification shall incorporate any proposed changes timely requested by the other Party, absent a reasonable basis for not making such changes, and shall use Commercially Reasonable Efforts to seek confidential treatment for any terms that the other Party timely requests be kept confidential, to the extent such confidential treatment is reasonably available consistent with applicable Law. Each Party shall be responsible for its own legal and other external costs in connection with any such filing, registration or notification.

8.5 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that a Party would suffer upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages would not be a sufficient remedy for any breach of this ARTICLE VIII. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this ARTICLE VIII.

ARTICLE IX
REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 CoNCERT's Representations. CoNCERT hereby represents and warrants as of the Effective Date as follows:

(a) CoNCERT has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder. The execution, delivery and performance of this Agreement has been duly and validly authorized and approved by all necessary corporate action on the part of CoNCERT. CoNCERT has taken all other action required by Law, its certificate of incorporation or by-laws or any agreement to which it is a party or by which it or its assets are bound, to authorize such execution, delivery and performance. Assuming due authorization, execution and delivery on the part of Promet, this Agreement constitutes a legal, valid and binding obligation of CoNCERT, enforceable against CoNCERT in accordance with its terms.

(b) The execution and delivery of this Agreement by CoNCERT will not violate any U.S. Law or, to CoNCERT's knowledge, any Law of any Governmental Authority outside the U.S.

(c) The execution and delivery of this Agreement by CoNCERT do not require CoNCERT to obtain any permit, authorization or consent from any Governmental Authority or from any other Person, and such execution and delivery by CoNCERT will not result in the breach of or give rise to any termination of, rescission, renegotiation or acceleration under or trigger any other rights under any agreement or contract to which CoNCERT may be a party that relates to the CoNCERT Patent Rights or the CoNCERT Know-How.

(d) Schedule 1.13 is a complete and correct list of all Patent Rights owned by CoNCERT as of the Effective Date that Cover any Compound or Product. No Patent Right that Covers any Compound or Product has been licensed to CoNCERT.

(e) CoNCERT is the legal and beneficial owner of all the Patent Rights identified on Schedule 1.13, free and clear of any liens, mortgages, security interests or other similar encumbrances. All assignments to CoNCERT of ownership rights relating to such Patent Rights are valid and enforceable. All of the Patent Rights listed identified on Schedule 1.13 that are issued patents are in full force and effect, and all applicable filing, maintenance and other fees required to be paid to a patent office with respect to the Patent Rights listed identified on Schedule 1.13 have been timely paid. CoNCERT has the right to grant the licenses granted by it in this Agreement and has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the CoNCERT Intellectual Property in a manner that conflicts with any rights granted to Promet hereunder.

(f) There is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to CoNCERT's knowledge, threatened against CoNCERT in connection with the Compounds or Products or any CoNCERT Patent Rights, CoNCERT Know-How or against or relating to the transactions contemplated by this

Agreement. CoNCERT has not received any written notice from a Third Party that the Development of any Compound or Product conducted by CoNCERT has infringed, or that any Development or Commercialization of any Compound or Product will infringe, any Patent Rights of any Third Party.

(g) No claim or action has been brought or, to CoNCERT's knowledge, threatened by any Third Party alleging that the CoNCERT Patent Rights are invalid or unenforceable, and no CoNCERT Patent Rights are the subject of any litigation, interference, post-grant review, opposition, cancellation or other proceeding challenging the validity or enforceability of the CoNCERT Patent Rights.

(h) Neither CoNCERT nor, to the knowledge of CoNCERT, any of its directors, officers, employees, agents or subcontractors has been convicted of any crime or engaged in any conduct that has resulted in, or would reasonably be expected to result, in debarment by the FDA under 21 U.S.C. § 335a or any similar state or foreign Law.

9.2 Promet's Representations. Promet hereby represents and warrants as of the Effective Date as follows:

(a) Promet has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder. The execution, delivery and performance of this Agreement has been duly and validly authorized and approved by all necessary corporate action on the part of Promet. Promet has taken all other action required by Law, its certificate of incorporation or by-laws or any agreement to which it is a party or by which it or its assets are bound to authorize such execution, delivery and (subject to obtaining all necessary governmental approvals with respect to the Development, Manufacture, use and Commercialization of Compounds and Products) performance. Assuming due authorization, execution and delivery on the part of CoNCERT, this Agreement constitutes a legal, valid and binding obligation of Promet, enforceable against Promet in accordance with its terms.

(b) The execution and delivery of this Agreement by Promet will not violate any U.S. Law or, to Promet's knowledge, any Law of any Governmental Authority outside the U.S.

(c) There is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to the knowledge of Promet, threatened against Promet in connection with or relating to the transactions contemplated by this Agreement.

(d) The execution and delivery of this Agreement do not require Promet to obtain any permit, authorization or consent from any Governmental Authority or from any other Person, and such execution and delivery by Promet will not result in the breach of or give rise to any termination of, rescission, renegotiation or acceleration under or trigger any other rights under any agreement or contract to which Promet may be a party that relates to the Products, Promet Patent Rights or Promet Know-How.

(e) Neither Promet nor, to the knowledge of Promet, any of its directors, officers, employees, agents or subcontractors has been convicted of any crime or engaged in any

conduct that has resulted in, or would reasonably be expected to result, in debarment by the FDA under 21 U.S.C. § 335a or any similar state or foreign Law.

9.3 CoNCERT Covenants. CoNCERT covenants and agrees during the Term that, subject to Promet's, its Affiliates' and Sublicensees' performance of their obligations under this Agreement:

(a) CoNCERT shall not grant to any Third Party any rights that would be inconsistent or conflict with Promet's rights hereunder.

(b) Subject to Section 12.7, CoNCERT shall not assign, transfer, convey or otherwise encumber its right, title and interest in the CoNCERT Intellectual Property in a manner that conflicts with any rights granted to Promet hereunder.

9.4 Promet Covenant. Promet shall conduct, and shall use Commercially Reasonable Efforts to cause its contractors and consultants to conduct, all of their activities contemplated under this Agreement in accordance with all applicable Laws of the country in which such activities are conducted, including applicable requirements of "good laboratory practices", "good clinical practices" and "good manufacturing practices", as applicable, as defined by the FDA.

9.5 No Warranty. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED. IN PARTICULAR, BUT WITHOUT LIMITATION, EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY CONCERNING WHETHER ANY OF THE COMPOUNDS OR PRODUCTS ARE FIT FOR ANY PARTICULAR PURPOSE OR SAFE FOR HUMAN CONSUMPTION.

ARTICLE X
INDEMNIFICATION

10.1 Indemnification in Favor of CoNCERT. Promet shall indemnify, defend and hold harmless the CoNCERT Parties from and against any and all Losses incurred, suffered or sustained by any of the CoNCERT Parties or to which any of the CoNCERT Parties becomes subject as a result of any Third Party claim, action, suit, proceeding, liability or obligation (which in no event includes any claim by any Promet Party or any CoNCERT Party) (collectively, "Third Party Claims") arising out of, relating to or resulting from:

(a) any misrepresentation or breach of any representation, warranty, covenant or agreement made by Promet in this Agreement; or

(b) the Development and, if the Option is exercised, Manufacture or Commercialization of Compounds or Products by Promet, its Affiliates or Sublicensees, including all Third Party Claims involving death or bodily injury caused or allegedly caused by the use of such a Compound or Product, and even if such a Compound or Product is altered for use for a purpose not intended (any and all such Third Party Claims "Product Liability Claims"); or

(c) any actual or alleged infringement of any trademark, Patent Right or other intellectual property right, or misappropriation of any trade secret, of any Third Party as a result of the Development, Manufacture or Commercialization of Compounds or Products by Promet, its Affiliates or Sublicensees; or

(d) the gross negligence or willful misconduct of any of the Promet Parties (as hereinafter defined) in connection with Promet's performance of this Agreement.

For purposes of this ARTICLE X, "CoNCERT Parties" means CoNCERT, its Affiliates and their respective agents, directors, officers, licensees, sublicensees and employees.

The indemnification obligations set forth in this Section 10.1 shall not apply to the extent that any Loss is the result of (i) a breach of any representation, warranty, covenant or agreement made by CoNCERT in this Agreement or (ii) the gross negligence or willful misconduct of any applicable CoNCERT Party.

10.2 Indemnification in Favor of Promet. CoNCERT shall indemnify, defend and hold harmless the Promet Parties from and against any and all Losses incurred, suffered or sustained by any of the Promet Parties or to which any of the Promet Parties becomes subject as a result of any Third Party Claim arising out of, relating to or resulting from:

(a) any misrepresentation or breach of any representation, warranty, covenant or agreement made by CoNCERT in this Agreement; or

(b) the Development, Manufacture or Commercialization of Compounds or Products by CoNCERT, its Affiliates, licensees (excluding Promet) or sublicensees after any termination of this Agreement, including all Product Liability Claims arising out of any such post-termination Development, Manufacture or Commercialization by CoNCERT, its Affiliates, licensees (excluding Promet) or sublicensees; or

(c) any actual or alleged infringement of any trademark, Patent Right or other intellectual property right, or misappropriation of any trade secret, of any Third Party as a result of the Development, Manufacture or Commercialization of Compounds or Products by CoNCERT, its Affiliates, licensees (excluding Promet) or sublicensees after any termination of this Agreement; or

(d) the gross negligence or willful misconduct of any of the CoNCERT Parties in connection with CoNCERT's performance of this Agreement.

For purposes of this ARTICLE X, "Promet Parties" means Promet, its Affiliates and their respective agents, directors, officers, licensees, sublicensees and employees.

The indemnification obligations set forth in this Section 10.2 shall not apply to the extent that any Loss is the result of (i) a breach of any representation, warranty, covenant or agreement made by Promet in this Agreement, or (ii) the gross negligence or willful misconduct of any applicable Promet Party.

10.3 General Indemnification Procedures.

(a) A CoNCERT Party or Promet Party seeking indemnification pursuant to this ARTICLE X (an "Indemnified Party") shall give prompt notice to the Party from whom such indemnification is sought (the "Indemnifying Party") of the commencement or assertion of any Third Party Claim in respect of which indemnity may be sought hereunder, shall give the Indemnifying Party such information with respect to any indemnified matter as the Indemnifying Party may reasonably request, and shall not make any admission concerning any Third Party Claim, unless such admission is required by applicable Law or legal process, including in response to questions presented in depositions or interrogatories. Any admission made by the Indemnified Party or the failure to give such notice shall relieve the Indemnifying Party of any liability hereunder only to the extent that the ability of the Indemnifying Party to defend such Third Party Claim is prejudiced thereby (and no admission required by applicable Law or legal process shall be deemed to result in prejudice). The Indemnifying Party shall assume and conduct the defense of such Third Party Claim, with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party. Subject to the initial and continuing satisfaction of the terms and conditions of this ARTICLE X by the Indemnifying Party, the Indemnifying Party shall have full control of such Third Party Claim, including settlement negotiations and any legal proceedings. If the Indemnifying Party does not assume the defense of such Third Party Claim in accordance with this Section 10.3, the Indemnified Party may defend the Third Party Claim. If both Parties are Indemnifying Parties with respect to the same Third Party Claim, the Parties shall determine by mutual agreement, within twenty (20) days following their receipt of notice of commencement or assertion of such Third Party Claim (or such lesser period of time as may be required to respond properly to such claim), which Party shall assume the lead role in the defense thereof. Should the Indemnifying Parties be unable to mutually agree on which of them shall assume the lead role in the defense of such Third Party Claim, both Indemnifying Parties shall be entitled to participate in such defense through counsel of their respective choosing.

(b) Any Indemnified Party or Indemnifying Party not managing the defense of a Third Party Claim shall have the right to participate in (but not control), at its own expense (subject to the immediately succeeding sentence), the defense. The Indemnifying Party managing the defense shall not be liable for any litigation cost or expense incurred, without its consent, by the Indemnified Party where the action or proceeding is under the control of such Indemnifying Party; provided, however, that, if the Indemnifying Party managing the defense fails to take reasonable steps necessary to defend such Third Party Claim, the Indemnified Party may assume its own defense, and the Indemnifying Party managing the defense will be liable for all reasonable costs or expenses paid or incurred in connection therewith.

(c) The Indemnifying Party shall not, except with the consent of the Indemnified Party, consent to a settlement of, or the entry of any judgment against, an Indemnified Party arising from any Third Party Claim to the extent such settlement or judgment involves equitable or other non-monetary relief from the Indemnified Party. No Party shall, without the prior written consent of the other Party or the Indemnified Party, enter into any compromise or settlement that commits the other Party or the Indemnified Party to take, or to forbear to take, any action.

(d) The Parties shall cooperate in the defense or prosecution of any Third Party Claim for which indemnity is sought hereunder and shall furnish such records, information and testimony, and attend such conferences, discovery proceedings, hearings, trials and appeals, as may be reasonably requested in connection therewith; provided, however, that the Indemnifying Party shall reimburse the Indemnified Party for any out-of-pocket expenses actually and reasonably incurred in connection with any such cooperation.

(e) Any indemnification hereunder shall be made net of any insurance proceeds actually recovered by the Indemnified Party from unaffiliated Third Parties; provided, however, that if, following the payment to the Indemnified Party of any amount under this ARTICLE X, such Indemnified Party recovers any such insurance proceeds in respect of the claim for which such indemnification payment was made, the Indemnified Party shall promptly pay an amount equal to the amount of such proceeds (but not exceeding the amount of such net indemnification payment) to the Indemnifying Party.

(f) The Parties agree and acknowledge that the provisions of this ARTICLE X represent the Indemnified Party's exclusive recourse with respect to any Losses for Third Party Claims for which indemnification is provided to the Indemnified Party under this ARTICLE X.

10.4 Insurance. During the Term, if the Option is exercised, and thereafter for so long as a Third Party Claim may be brought for which Promet must indemnify CoNCERT pursuant to Section 10.1, Promet shall obtain and maintain, at its sole cost and expense, product liability insurance in amounts that are reasonable and customary in the pharmaceutical industry, but in no event less than $5 million per occurrence or claim, and $10 million in the aggregate, or a comparable program of self-insurance. Such product liability insurance shall insure against all liability, including product liability and property damage arising out of the Development, use or Commercialization of Compounds and Products by Promet, its Affiliates or Sublicensees in the Territory. Without limiting the generality of the foregoing, Promet shall maintain comprehensive general liability insurance, including product liability insurance, to cover its activities and, unless its Affiliates and Sublicensees maintain comparable coverage, the activities of its Affiliates and Sublicensees, with respect to Compounds and Products. Promet shall provide satisfactory evidence of adequate insurance coverage to CoNCERT upon the request of CoNCERT prior to the Option Exercise Date and, upon the written request of CoNCERT, concurrent with any renewal or replacement of such coverage.

ARTICLE XI
TERM AND TERMINATION

11.1 Term. The term of this Agreement (the "Term") shall commence on the Effective Date and, unless earlier terminated as provided in this ARTICLE XI, shall continue in full force and effect until the expiration of the last Royalty Term. On a country-by-country and Product-by-Product basis, upon the expiration of the Royalty Term in such country with respect to such Product, Promet shall have a fully paid-up, perpetual, irrevocable license under the CoNCERT Intellectual Property and CoNCERT's interest in the Joint Intellectual Property with respect to such Product in such country.

11.2 Termination for Failure to Exercise Option. If, for any reason (including a failure to meet the conditions in Section 2.1(b)(i) and (ii) prior to end of the Option Period), Promet does not exercise the Option within the Option Period, then this Agreement shall automatically terminate in its entirety on the day after the last day of the Option Period.

11.3 Termination for Convenience. Promet shall have the right upon sixty (60) days prior written notice to CoNCERT to terminate this Agreement in its entirety for any reason.

11.4 Termination for Cause. In the event of a material breach of this Agreement by a Party, the other Party may give the Party in default notice requiring it to cure such default, which notice shall specify the nature of the breach. If such material breach is not cured within ninety (90) days after receipt of such notice (or within fifteen (15) days in the case of a payment breach), the notifying Party shall be entitled (without prejudice to any other rights conferred on it by this Agreement or under applicable Law) to terminate this Agreement by giving written notice to the defaulting Party. The right of either Party to terminate this Agreement as set forth in this Section 11.4 shall not be affected in any way by its waiver of, or failure to take action with respect to, any previous default.

11.5 Additional Termination by CoNCERT. In the event that CoNCERT has provided written notice to Promet pursuant to Section 5.2, if Promet does not respond to CoNCERT in writing within sixty (60) days of receipt of such notice from CoNCERT and reasonably demonstrate in such response compliance with Promet's obligations under Section 5.1, CoNCERT shall be entitled (without prejudice to any other rights conferred on it by this Agreement or under applicable Law) to terminate this Agreement by giving written notice to Promet.

11.6 Termination for Insolvency. This Agreement may be terminated by a Party upon written notice to the other Party if (a) the other Party shall make an assignment for the benefit of its creditors, file a petition in bankruptcy, petition or apply to any tribunal for the appointment of a custodian, receiver or trustee for it or a substantial part of its assets, or shall commence any proceeding under any bankruptcy, reorganization, readjustment of debt, dissolution or liquidation law or statute of any jurisdiction, whether now or hereafter in effect; or (b) if there shall have been filed against the other Party any such *bona fide* petition or application, or any such proceeding shall have been commenced against it, in which an order for relief is entered or that remains undismissed or unstayed for a period of ninety (90) days or more; or (c) if the other Party by any act or omission shall consent to, approve of or acquiesce in any such petition, application or proceeding or order for relief or the appointment of a custodian, receiver or trustee for it or any substantial part of its assets, or shall suffer any such custodianship, receivership or trusteeship to continue undischarged or unstayed for a period of ninety (90) days or more. Termination shall be effective upon the date specified in such notice.

11.7 Termination for Challenge of CoNCERT Patent Rights. If Promet or any of Promet's Affiliates or Sublicensees commences an action in any court or tribunal of competent jurisdiction that challenges, opposes or disputes the validity, enforceability or patentability of any CoNCERT Patent Rights, or any of the claims thereof, or supports or assists any Third Party that commences such an action in any such court or tribunal, CoNCERT shall have the right to terminate this Agreement upon notice to Promet; provided, however, that CoNCERT shall not

have a right to terminate if the challenge is brought by a Sublicensee, either directly or indirectly through any Third Party, and Promet or the Affiliate, as the case may be, terminates such Sublicensee's sublicense rights hereunder within thirty (30) days after becoming aware of such challenge.

11.8 Consequences of Termination. If this Agreement (w) terminates automatically pursuant to Section 11.2, (x) is terminated by CoNCERT under Section 11.4, 11.5, 11.6 or 11.7, (y) is terminated by Promet under Section 11.3, or (z) is terminated by Promet under Section 11.4 or 11.6, then the licenses granted to Promet in Section 2.2 and, except as provided in this Section 11.8 and Sections 11.9 and 11.10 (and any Articles and Sections referenced therein), all other rights and obligations of the Parties under this Agreement shall terminate. Upon a termination described in clause (x) (but not clause (w), (y) or (z)) of this Section 11.8, clause (a) shall apply, and, upon a termination described in clause (w), (x) or (y) (but not clause (z)), Promet shall grant, and shall cause any applicable Affiliate to grant, CoNCERT any combination of the following clauses (b) through (f) elected by CoNCERT, provided that (i) upon a termination described in clause (w), only clause (c) and, to the extent that any Promet Intellectual Property, Sublicensee Intellectual Property or Joint Intellectual Property exists as of such termination, clause (e) shall apply, and (ii) Promet shall only be required to grant CoNCERT rights to Sublicensee Materials to the extent permitted in the applicable sublicense agreement(s) with Sublicensee(s) to whom CoNCERT has not granted a direct license pursuant to Section 11.8(a):

(a) Sublicenses. CoNCERT hereby grants, effective automatically upon any termination of this Agreement by CoNCERT pursuant to Section 11.4, 11.5, 11.6 or 11.7, a direct license (subject to all applicable limitations and conditions set forth in this Agreement and the applicable sublicense) to each then-existing Sublicensee, provided that (i) such Sublicensee is not in breach under the applicable sublicense, (ii) such Sublicensee's failure to comply with the terms of its sublicense or other actions or omissions were not a basis for such termination, and (iii) such Sublicensee continues to satisfy all obligations under this Agreement applicable to such sublicense, including the diligence obligations set forth in ARTICLE V and all payments to CoNCERT required under Section 6.3, from and after the date that such direct license becomes effective.

(b) Regulatory Matters. Ownership of all filings with Regulatory Authorities in the Territory relating to Compounds and Products and Regulatory Approvals relating to . Compounds and Products held by Promet or its Affiliates or applicable Sublicensees, including related correspondence with Regulatory Authorities, and Promet shall provide copies thereof to CoNCERT;

(c) Pre-clinical and Clinical Matters. Possession of all pre-clinical and clinical data, including pharmacology and biology data, within the Promet Know-How and applicable Sublicensee Intellectual Property;

(d) Manufacturing Matters. At CoNCERT's option, to be exercised no later than the later of (x) thirty (30) days after the effective date of termination or (y) thirty (30) days after CoNCERT's receipt of the applicable Manufacturing agreements;

(i) use of Commercially Reasonable Efforts by Promet and its Affiliates to effect the assignment of each Manufacturing agreement (including any agreement to which any applicable Sublicensee is a party) specific and exclusive to Compounds or Products to CoNCERT, if such agreement is then in effect and such assignment is permitted under such agreement or by the applicable Third Party; provided that Promet and its applicable Affiliates and applicable Sublicensees shall be released to the extent the applicable Third Party will permit from any obligation arising out of such agreement following such assignment and CoNCERT shall execute such documentation reasonably satisfactory to Promet to effectuate such agreement; provided further that, (A) CoNCERT will bear any costs or expenses payable to the applicable Third Party in connection with assignment of any such agreement and (B) if any such agreement is specific but not exclusive to Compounds or Products, or is not assigned to CoNCERT for any reason, Promet will discuss in good faith with CoNCERT terms upon which Promet and its Affiliates shall use Commercially Reasonable Efforts to provide CoNCERT with the benefits of such agreement to the extent it relates to Compounds or Products for a limited period of time (not to exceed six (6) months) and upon payment of a reasonably acceptable fee to Promet;

(ii) for a period of up to six (6) months following the effective date of termination, (A) cooperation with CoNCERT in reasonable respects to transfer Manufacturing documents and materials within the Promet Know-How and applicable Sublicensee Intellectual Property that are used (at the time of the termination) by Promet or its Affiliates or applicable Sublicensees exclusively in the Manufacture of Compounds and Products to the extent such Manufacturing documents and materials are not obtained by CoNCERT pursuant to the assignment of agreements pursuant to paragraph (i) above, and (B) cooperation with CoNCERT to provide CoNCERT with reasonable access to and right to use such Manufacturing documents and materials in Promet's or its Affiliates' or applicable Sublicensees' possession or Control to the extent they relate to, but are not used exclusively in, the Manufacture of Compounds and Products, subject to appropriate confidentiality and limitation on use protections applicable to such Manufacturing documents and materials;

(iii) for a period of up to six (6) months following the effective date of termination, (A) cooperation with CoNCERT in reasonable respects to transfer Manufacturing technologies within the Promet Intellectual Property and applicable Sublicensee Intellectual Property that are used (at the time of the termination) by Promet or its Affiliates or applicable Sublicensees exclusively in the Manufacture of Compounds and Products, and (B) cooperation with CoNCERT to provide CoNCERT with reasonable access to and right to use such Manufacturing technologies Controlled by Promet or its Affiliates (other than Promet Excluded Affiliates) or applicable Sublicensees to the extent they relate to, but are not used exclusively in, the Manufacture of Compounds and Products and that Promet or such Affiliates or Sublicensees are permitted to provide such access to CoNCERT; provided that CoNCERT shall reimburse Promet for Promet's reasonable out-of-pocket expenses to provide such requested assistance, to the extent such Manufacturing technologies are not obtained by CoNCERT pursuant to the assignment of agreements pursuant to paragraph (i) above; and

(iv) sale of Promet's or its Affiliates' or applicable Sublicensees' then-existing inventory of Compounds and Products to CoNCERT, at Promet's or its applicable Affiliates' or applicable Sublicensees' cost of Manufacture, but only if the following conditions

have been met: (A) such Compounds and Products meet the applicable release specifications; and (B) Promet does not reasonably believe the continued use of such Compounds and Products causes safety concerns;

(e) License Grant. At CoNCERT's option, to be exercised by written notice to Promet no later than thirty (30) days after the effective date of termination, a license, with the right to sublicense, under the Promet Patent Rights, Promet Know-How, Promet's interest in the Joint Intellectual Property, and applicable Sublicensee Intellectual Property, solely to make, have made, use, sell, offer for sale and import Compounds and Products in the Field that were Developed or Commercialized prior to the effective date of termination, which license would be, at CoNCERT's election, either (i) non-exclusive, fully paid-up, non-royalty-bearing, irrevocable and perpetual or (ii) exclusive and royalty-bearing subject to mutual agreement by CoNCERT and Promet on commercially reasonable terms; provided that, notwithstanding the foregoing, with respect to any Promet Patent Rights or Promet Know-How that Promet acquired from a Third Party (by license or otherwise), or any applicable Sublicensee Intellectual Property that the applicable Sublicensee(s) acquired from a Third Party (by license or otherwise), Promet shall only be required to grant to CoNCERT a license to such Promet Patent Rights, Promet Know-How or Sublicensee Intellectual Property to the extent permitted under the applicable agreement with such Third Party, and CoNCERT shall pay Promet or such Third Party, as determined by Promet, any payment due to such Third Party relating to the Compounds and Products; provided further that CoNCERT shall execute such documentation reasonably satisfactory to Promet to effectuate such agreement; and if the license granted to CoNCERT is exclusive, CoNCERT shall have the same enforcement rights with respect to any Promet Patent Rights, Joint Patent Rights and Patent Rights within the Sublicensee Intellectual Property that exclusively Cover Products that are licensed to CoNCERT pursuant to this Section 11.8(e) as Promet has with respect to Infringement Claims pursuant to Section 7.3 (to the extent that Promet or the applicable Sublicensee(s) have such rights with respect to such Promet Patent Rights or Patent Rights within the Sublicensee Intellectual Property, as applicable), provided that any enforcement of Promet Patent Rights, Joint Patent Rights or Patent Rights within the Sublicensee Intellectual Property that Cover subject matter other than such Products shall be performed by CoNCERT only with the consultation and prior agreement of Promet or the applicable Sublicensee, which such agreement shall not unreasonably withheld, delayed or conditioned.

(f) Assignment of Trademarks. Assign to CoNCERT all of Promet's or its Affiliates' or applicable Sublicensees' right, title and interest in any trademark owned by Promet or its Affiliates or applicable Sublicensees and used solely in connection with the Products, along with all associated goodwill.

11.9 Effect of Termination or Expiration; Accrued Rights and Obligations. Termination or expiration of this Agreement for any reason shall not release either Party from any liability that, at the time of such termination or expiration, has already accrued or that is attributable to a period prior to such termination (including payment obligations accrued prior to the effective date of termination or expiration pursuant to ARTICLE VI) nor preclude either Party from pursuing any right or remedy it may have hereunder or at law or in equity with respect to any breach of this Agreement.

11.10 Survival. The rights and obligations set forth in this Agreement shall extend beyond the Term or termination or expiration of this Agreement only to the extent expressly provided for in this Agreement or to the extent required to give effect to a termination or expiration of this Agreement or the consequences of a termination or expiration of this Agreement as expressly provided for in this Agreement. Without limiting the generality of the foregoing, it is agreed that the provisions of ARTICLE I, Sections 2.3, 2.4, 6.1, 6.4 (only for thirty-six (36) months after expiration or termination), 6.5 (only for thirty-six (36) months after expiration or termination), 6.6, 6.7, 6.8, 6.9, 7.1, 7.9, 8.1, 8.2, 8.5, 9.5, ARTICLE X, and Sections 11.1 (last sentence as to any such license that became perpetual and irrevocable prior to expiration or termination), 11.8, 11.9, 11.10 and ARTICLE XII shall survive expiration or termination of this Agreement for any reason.

ARTICLE XII
MISCELLANEOUS

12.1 Governing Law; Jurisdiction. This Agreement shall be governed by and interpreted in accordance with the internal laws of the State of Delaware, without regard to its conflicts of laws rules. Each Party (a) irrevocably submits to the exclusive jurisdiction in the U.S. District Court for the Southern District of New York and any state court sitting New York, New York (collectively, the "Courts"), for purposes of any action, suit or other proceeding arising out of this Agreement, and (b) agrees not to raise any objection at any time to the laying or maintaining of the venue of any such action, suit or proceeding in any of the Courts, irrevocably waives any claim that such action, suit or other proceeding has been brought in an inconvenient forum and further irrevocably waives the right to object, with respect to such action, suit or other proceeding, that such Court does not have any jurisdiction over such Party. Either Party may serve any process required by such Courts by way of notice under this Agreement. Notwithstanding anything to the contrary in this Section 12.1, each Party shall have the right to institute judicial proceedings against the other Party or anyone acting by, through or under such other Party, in any court of competent jurisdiction, in order to enforce the instituting Party's rights hereunder through reformation of contract, specific performance, injunction or similar equitable relief.

12.2 Dispute Resolution. In the event of a dispute arising out of or relating to this Agreement, either Party shall provide written notice of the dispute to the other, in which event the dispute shall be referred to the Senior Executives of each Party, for attempted resolution by good faith negotiations within twenty (20) days after such notice is received. In the event the Senior Executives do not resolve such dispute within the allotted twenty (20) days, either Party may, after the expiration of the twenty (20) day period, seek to resolve the dispute in accordance with Section 12.1.

12.3 Waiver. Waiver by a Party of a breach hereunder by the other Party shall not be construed as a waiver of any succeeding breach of the same or any other provision. No delay or omission by a Party to exercise or avail itself of any right, power or privilege that it has or may have hereunder shall operate as a waiver of any right, power or privilege by such Party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.

12.4 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address specified in this Section 12.4 and shall be: (a) delivered personally; (b) sent by registered or certified mail, return receipt requested, postage prepaid; (c) sent via a reputable nationwide overnight courier service; or (d) sent by facsimile or other electronic transmission. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service, or when transmitted with confirmation of receipt, if transmitted by facsimile or other electronic transmission (if such transmission is on a Business Day; otherwise, on the next Business Day following such transmission).

Notices to Promet shall be addressed to:

Promet Therapeutics, LLC
7380 Coca Cola Drive, Suite 106
Hanover, MD 21076
Attn: Chief Executive Officer

Notices to CoNCERT shall be addressed to:

CoNCERT Pharmaceuticals, Inc.
99 Hayden Avenue, Suite 500
Lexington, MA 02421
Attn: Chief Executive Officer

With a copy to:

CoNCERT Pharmaceuticals, Inc.
99 Hayden Avenue, Suite 500
Lexington, MA 02421
Attn: General Counsel

Either Party may change its address by giving notice to the other Party in the manner provided above.

12.5 Entire Agreement. This Agreement (including Schedules) and, prior to the Option Exercise Date and subject to Section 7.1(a), the MTA, contain the complete understanding of the Parties with respect to the subject matter of this Agreement and the MTA and supersede all prior understandings and writings between the Parties relating to such subject matter.

12.6 Severability. If any provision of this Agreement is held unenforceable by a court or tribunal of competent jurisdiction because it is invalid or conflicts with any Law of any relevant jurisdiction, the validity of the remaining provisions shall not be affected. In such event,

the Parties shall negotiate a substitute provision that, to the extent possible, accomplishes the original business purpose.

12.7 Assignment. Neither this Agreement nor any right or obligation hereunder may be assigned or otherwise transferred by any Party without the consent of the other Party; provided, however, that any Party may, without such consent, assign this Agreement, in whole or in part: (a) to any of its respective Affiliates, provided that such Affiliate has acknowledged and confirmed in writing that, effective as of such assignment, such Affiliate shall be bound by this Agreement to the identical extent applicable to the assigning Party; or (b) to any successor in interest by way of merger, acquisition or sale of all or substantially all of its business or assets relating to the subject matter of this Agreement, provided that such successor (if the applicable Party is not the surviving entity in such transaction) agrees in writing to be bound by the terms of this Agreement to the identical extent applicable to the assigning Party. Any purported assignment in violation of this Section 12.7 shall be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement. Notwithstanding anything to the contrary in Section 2.1(b), if Promet assigns this Agreement to a Third Party pursuant to Section 12.7(b) and, at the time of such assignment, such Third Party has (y) cash and cash equivalents that exceed current liabilities by at least Eight Million Dollars ($8,000,000) and (z) a market capitalization or net worth (*i.e.*, total assets minus total liabilities) of at least Forty Million Five Hundred Thousand Dollars ($40,500,000), then such Third Party may exercise the Option at any time after such assignment and before the end of the Option Period.

12.8 Counterparts; Exchange by Facsimile. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and that together shall constitute one and the same instrument. Such counterparts may be exchanged by facsimile or PDF (provided that each executed counterpart is transmitted in one complete transmission or electronic mail message). Where there is an exchange of executed counterparts by facsimile or PDF, each Party shall be bound by the Agreement notwithstanding that original copies of the Agreement may not be exchanged immediately. The Parties shall cooperate after execution of the Agreement and exchange by facsimile or PDF to ensure that each Party obtains an original executed copy of this Agreement with reasonable promptness.

12.9 Force Majeure. No Party shall be liable for failure of or delay in performing obligations set forth in this Agreement, and no Party shall be deemed in breach of its obligations, if such failure or delay is due to a natural disaster, explosion, fire, flood, tornadoes, thunderstorms, earthquake, war, terrorism, riots, embargo, losses or shortages of power, labor stoppage, substance or material shortages, damage to or loss of product in transit not due to a failure by such Party or its Affiliates to exercise reasonable care, events caused by reason of Laws of any Governmental Authority, events caused by acts or omissions of a Third Party not induced or solicited by such Party or its Affiliates, or any other cause reasonably beyond the control of such Party or its Affiliates; provided that such Party uses Commercially Reasonable Efforts to overcome the difficulties created by such force majeure event and to resume performance of its obligations as soon as practicable.

12.10 Third-Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party other than a CoNCERT Party or a Promet Party, as applicable, that is an Indemnified Party under ARTICLE X, and no Third Party shall obtain

any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against either Party.

12.11 Relationship of the Parties. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other, except as expressly provided in this Agreement. Neither Party shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said other Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, the legal relationship under this Agreement of each Party to the other Party shall be that of independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint venturers between the Parties.

12.12 Performance by Affiliates. To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations.

12.13 No Consequential or Punitive Damages. NEITHER PARTY WILL BE LIABLE FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY OR PUNITIVE DAMAGES, INCLUDING LOST PROFITS, ARISING FROM OR RELATING TO THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTHING IN THIS SECTION 12.13 IS INTENDED TO LIMIT OR RESTRICT (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY UNDER THIS AGREEMENT WITH RESPECT TO THIRD PARTY CLAIMS, OR (B) DAMAGES TO WHICH A PARTY MAY BE ENTITLED FOR BREACH OF CONFIDENTIALITY AND LIMITATION ON USE OBLIGATIONS SET FORTH IN THIS AGREEMENT, OR (C) DAMAGES TO WHICH A PARTY MAY BE ENTITLED FOR THE WILLFUL MISCONDUCT, INTENTIONAL BREACH OR FRAUD OF THE OTHER PARTY.

[Signature page follows]

IN WITNESS WHEREOF, the Parties have signed this Agreement as of the Effective Date.

PROMET THERAPEUTICS, LLC

By: _____

Name: David Young

Title: Chief Executive Officer

CoNCERT Pharmaceuticals, Inc.

By: _____

Name: Roger Tung, President & CEO

Title: _____

Schedule 1.13 Current as of [redacted], 2017

Schedule 6.7

CoNCERT Wiring Instructions

Beneficiary Bank: Silicon Valley Bank

Beneficiary Bank Address: 3003 Tasman Drive, Santa Clara, CA 95054

Routing & Transit: 121140399

Beneficiary Name: Concert Pharmaceuticals, Inc.

Beneficiary Account #: 3300530507

EXECUTION COPY

Amendment to Option and License Agreement

THIS AMENDMENT TO OPTION AND LICENSE AGREEMENT (this "Amendment") is entered into as of this 19th day of March, 2018 (the "Amendment Effective Date"), by and between CoNCERT Pharmaceuticals, Inc., a corporation organized under the laws of Delaware, having a business address at 99 Hayden Avenue, Suite 500, Lexington, MA 02421 ("CoNCERT"), Promet Therapeutics, LLC, a limited liability company organized under the laws of Delaware, having a business address at 7380 Coca Cola Drive, Suite 106, Hanover, MD 21076 ("Promet") and Processa Pharmaceuticals, Inc., a corporation organized under the laws of Delaware, having a business address at 7380 Coca Cola Drive, Suite 106, Hanover, MD 21076 ("Processa").

WHEREAS, CoNCERT and Promet entered into an Option and License Agreement as of October 4, 2017 (the "Agreement"), pursuant to which CoNCERT granted to Promet an Option to obtain an exclusive license under CoNCERT Intellectual Property (the "Exclusive License");

WHEREAS, Promet will be assigning the Agreement to Processa; and

WHEREAS, the Parties wish to amend the Agreement to grant Processa the Exclusive License as of the Amendment Effective Date;

NOW, THEREFORE, the parties hereto, intending to be legally bound, hereby agree as follows:

1. Capitalized terms used in this Amendment that are not defined herein shall have the meanings ascribed to them in the Agreement.

2. Promet and Processa hereby notify CoNCERT that, as of the Amendment Effective Date, Promet assigned the Agreement, in its entirety, to Processa and Processa hereby agrees to be bound by the terms of the Agreement to the identical extent such terms are applicable to Promet.

3. The Parties hereby agree that Processa is hereby deemed to have exercised the Option effective as of the Amendment Effective Date.

4. Section 6.1 of the Agreement is hereby amended and restated in its entirety to read as follows:

   6.1 Equity Investment. On the Amendment Effective Date, CoNCERT, Promet and Processa are entering into a Securities Purchase Agreement pursuant to which Promet is selling and transferring to CoNCERT Two Million Ninety Thousand Three Hundred and One (2,090,301) shares of Processa's Common Stock, $0.0001 par value per share (the "Processa Common Stock").

5. Section 6.5 of the Agreement is hereby amended and restated in its entirety to read as follows:

6.5 Books and Records: Audit Rights. Processa shall keep complete and accurate records of the underlying revenue and expense data relating to the calculations of Net Sales and Payments required by Sections 6.3 and 6.10. CoNCERT shall have the right, once annually at its own expense, to have an independent, certified public accounting firm, selected by CoNCERT and reasonably acceptable to Processa, review any such records of Processa in the location(s) where such records are maintained by Processa upon reasonable notice (which shall be no less than fourteen (14) days prior notice) and during regular business hours and under obligations of strict confidence, for the sole purpose of verifying the basis and accuracy of reports and Payments made under Sections 6.3 and 6.10 within the thirty-six (36) month period preceding the date of the request for review. The report of such accounting firm shall be limited to a certificate stating whether any report made or Payment submitted by Processa during such period is accurate or inaccurate and the actual amounts of Net Sales, and Payments due, for such period. Processa shall receive a copy of each such report concurrently with receipt by CoNCERT. Should such inspection lead to the discovery of a discrepancy to CoNCERT's detriment, Processa shall pay within five (5) Business Days after its receipt from the accounting firm of the certificate the amount of the discrepancy plus interest calculated in accordance with Section 6.9. CoNCERT shall pay the full cost of the review unless the review reveals an underpayment greater than five percent (5%) of the amount due for any applicable Calendar Year, in which case Processa shall pay the reasonable cost charged by such accounting firm for such review. Any overpayment by Processa revealed by such review shall be fully creditable against future Payments.

6. A new Section 6.10 is hereby inserted in the Agreement immediately following Section 6.9 thereof as follows:

6.10 Sublicensing Revenues. If, prior to the earliest date following the Amendment Effective Date (as defined in the Amendment to this Agreement dated as of March 19, 2018) on which (a) Processa has raised gross proceeds of at least Eight Million Dollars ($8,000,000) (such amounts raised to include any grants or other non-dilutive amounts raised by Processa after the Effective Date) in one or more equity or other financings after the Effective Date and (b) CoNCERT can sell its shares of the Processa Common Stock without restriction pursuant to Paragraph b(1) of Rule 144 under the Securities Act of 1933, as amended, or any similar successor provision and the Leak-out provisions in the Sales and Transfer Agreement, Processa grants to any Third Party a sublicense under any of the CoNCERT Intellectual Property to Commercialize a Product in the Territory, Processa shall pay to CoNCERT, within forty-five (45) days after the end of each Calendar Quarter during the Term, fifteen percent (15%) of Sublicensing Revenues received by Processa or its Affiliates during such Calendar Quarter from such Sublicensee in consideration for such sublicense. For the purposes of this Section 6.10, "Sublicensing Revenues" means upfront payments, license fees, milestone payments, and any other payments other than royalties received by Processa or any of its Affiliates from a Sublicensee in consideration for a sublicense under any of the CoNCERT Intellectual Property to Develop, Manufacture, use or Commercialize a Product, but excludes (x) all royalties on sales of Products, (y) the portions of payments for debt or equity securities of Processa equal to the fair market value thereof and (z) funding or reimbursement for

actual costs of *bona fide* research and development activities performed by Processa or its Affiliates after the execution of, and pursuant to, such sublicense.

7. As amended by this Amendment, the Agreement remains in full force and effect.

8. This Amendment may be executed in two or more counterparts, including by facsimile or PDF signature pages, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument.

[Signature page follows]

IN WITNESS WHEREOF, CoNCERT, Promet and Processa have caused this Amendment to be executed by their duly authorized representatives as of the Amendment Effective Date.

PROMET THERAPEUTICS, LLC

By: _____

Name: David Young

Title: CEO

CoNCERT PHARMACEUTICALS, INC.

By: _____

Name: Nancy Stuart

Title: COO

PROCESSA PHARMACEUTICALS, INC.

By: _____

Name: David Young

Title: CEO

SECURITIES PURCHASE AGREEMENT

This SECURITIES PURCHASE AGREEMENT (this "Agreement") is made and entered into as of March 19, 2018 by and among Processa Pharmaceuticals, Inc., a Delaware corporation (the "Company"), Promet Therapeutics, LLC, a Delaware limited liability company (the "Selling Stockholder"), and CoNCERT Pharmaceuticals, Inc., a Delaware corporation (the "Investor").

RECITALS

A. The Selling Stockholder and the Investor are parties to an Option and License Agreement, dated as of October 4, 2017 (the "License Agreement"), pursuant to which the Investor granted to the Selling Stockholder an option to obtain an exclusive license under certain intellectual property of the Investor (the "Option");

B. The Selling Stockholder, the Company and the Investor intend to enter into an amendment to the License Agreement concurrently with entering into this Agreement to permit the Selling Stockholder to exercise the Option for consideration of 2,090,301 shares (the "Shares") of the Company's Common Stock, $0.0001 par value per share (the "Common Stock"), upon the terms and subject to the conditions stated in this Agreement; and

C. The Investor wishes to acquire from the Selling Stockholder, and the Selling Stockholder wishes to transfer to the Investor, the Shares, upon the terms and subject to the conditions stated in this Agreement, as consideration for the exercise of the Option;

In consideration of the mutual promises made herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Definitions. For the purposes of this Agreement, the following terms shall have the meanings set forth below:

"1933 Act" means the Securities Act of 1933, as amended, or any successor statute, and the rules and regulations promulgated thereunder.

"1934 Act" means the Securities Exchange Act of 1934, as amended, or any successor statute, and the rules and regulations promulgated thereunder.

"Affiliate" means, with respect to any Person, any other Person which directly or indirectly through one or more intermediaries Controls, is controlled by, or is under common Control with, such Person.

"Board" means the Board of Directors of the Company.

"Business Day" means a day, other than a Saturday or Sunday, on which banks in New York City are open for the general transaction of business.

"Closing" has the meaning set forth in Section 2.

"Common Stock" has the meaning ascribed to such term in the recitals to this Agreement.

"Company" has the meaning ascribed to such term in the preamble to this Agreement.

"Company Intellectual Property" has the meaning set forth in Section 4.13.

"Company's Knowledge", or "knowledge" with respect to the Company, means the actual knowledge of the executive officers (as defined in Rule 405 under the 1933 Act) of the Company, after reasonable due inquiry and investigation.

"Company Party" shall have the meaning set forth in Section 7.2(b).

"Control" (including the terms "controlling", "controlled by" or "under common control with") means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise.

"Damages" has the meaning set forth in Section 7.2(a).

"Derivative Securities" means any securities or rights convertible into, or exercisable or exchangeable for (in each case, directly or indirectly), Common Stock, including options and warrants.

"GAAP" has the meaning set forth in Section 4.8.

"Intellectual Property" means all of the following: (i) patents, patent applications, patent disclosures and inventions (whether or not patentable and whether or not reduced to practice); (ii) trademarks, service marks, trade dress, trade names, corporate names, logos, slogans and Internet domain names, together with all goodwill associated with each of the foregoing; (iii) copyrights and copyrightable works; (iv) registrations, applications and renewals for any of the foregoing; and (v) proprietary computer software (including, but not limited to, data, data bases and documentation).

"Investor" has the meaning ascribed to such term in the preamble to this Agreement.

"Investor Party" has the meaning set forth in Section 7.2(a).

"License Agreement" has the meaning ascribed to such term in the recitals to this Agreement.

"Material Adverse Effect" means a material adverse effect on (i) the assets, liabilities, results of operations, financial condition, business or prospects of the Company and its Subsidiaries taken as a whole, or (ii) the ability of the Company to perform its obligations under this Agreement.

"Material Contract" means any contract, instrument or other agreement to which the Company is a party or by which it is bound coming within the description of Item 601(b)(4) or Item 601(b)(10) of Regulation S-K as applied to the Company.

"New Securities" means, collectively, equity securities of the Company, whether or not currently authorized, as well as rights, options or warrants to purchase such equity securities, or securities of any type whatsoever that are, or may become, convertible or exchangeable into or exercisable for such equity securities.

"Offer Notice" has the meaning set forth in Section 6.4(a).

"Option" has the meaning ascribed to such term in the recitals to this Agreement.

"Person" means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.

"Public Reporting Company" means a Person subject to the reporting requirements set forth in Section 13(a) or Section 15(d) of the 1934 Act.

"ROFO Period" has the meaning set forth in Section 6.4(b).

"Rule 144" means Rule 144 under the 1933 Act or any successor rule thereto.

"SEC" means the U.S. Securities and Exchange Commission.

"SEC Filings" has the meaning set forth in Section 4.7.

"Selling Stockholder" has the meaning ascribed to such term in the preamble to this Agreement.

"Shares" has the meaning ascribed to such term in the recitals to this Agreement.

"Subsidiary" of any Person means another Person, an amount of the voting securities, other voting ownership or voting partnership interests of which is sufficient to elect at least a majority of its board of directors or other governing body (or, if there are no such voting interests, 50% or more of the equity interests of which) is owned directly or indirectly by such first Person.

2. Closing. Concurrently with the execution and delivery of this Agreement by all parties hereto, the Selling Stockholder will deliver, or cause to be delivered to the Investor, the Shares, registered in the name of the Investor, as consideration for the exercise of the Option (the "Closing").

3. Representations and Warranties of the Selling Stockholder. The Selling Stockholder hereby represents and warrants to the Investor that the statements contained in this Section 3 are complete and accurate:

3.1. Organization and Existence. The Selling Stockholder is a validly existing limited liability company and has all requisite limited liability company power and

authority to enter into and consummate the transactions contemplated by this Agreement and to carry out its obligations hereunder.

3.2. Authorization. The Selling Stockholder has taken all requisite action necessary for, and no further action on the part of the Selling Stockholder, its officers or members is necessary for (i) the authorization, execution and delivery of this Agreement and (ii) the authorization of the performance of all obligations of the Selling Stockholder hereunder.

3.3. Due Execution; Enforceability. This Agreement has been duly executed and delivered by the Selling Stockholder. This Agreement constitutes the valid and legally binding obligation of the Selling Stockholder, enforceable against the Selling Stockholder in accordance with its terms, subject to (i) applicable bankruptcy, insolvency, fraudulent transfer, moratorium, reorganization or other similar laws of general application relating to or affecting the enforcement of creditors' rights generally and (ii) general principles of equity.

3.4. Ownership of Shares. The Selling Stockholder has good and marketable title to all of the Shares, free and clear of any liens, encumbrances, equities and claims and, upon the delivery of the Shares pursuant to this Agreement, the Investor will acquire good and marketable title thereto, free and clear of any liens, encumbrances, equities and claims (other than those created by the Investor).

3.5. No Offers or Sales Requiring Registration. The offer, issuance and sale by the Company of the Shares to the Selling Stockholder were made in compliance with all applicable law and neither the Selling Stockholder nor any Person acting on its behalf has, directly or indirectly, made any offers or sales of any security or the right to purchase any security, or solicited any offers to buy any security or any such right, under circumstances that would require registration of the Shares under the 1933 Act.

3.6. Consents; No Conflict, Breach, Violation or Default. The execution, delivery and performance by the Selling Stockholder of its obligations under this Agreement require no consent of, action by or in respect of, or filing with, any Person, governmental body, agency or official. The execution, delivery and performance of this Agreement by the Selling Stockholder will not conflict with or result in a breach or violation of any of the terms and provisions of, or constitute a default under, the Selling Stockholder's organizational documents or any applicable statute, rule, regulation or order of any governmental agency or body or any court, domestic or foreign, having jurisdiction over the Selling Stockholder, or any of its assets or properties.

4. Representations and Warranties of the Company. The Company hereby represents and warrants to the Investor that, except as described in any disclosure schedule of the Company delivered to the Investor on or prior to the execution of this Agreement, the statements contained in this Section 4 are complete and accurate:

4.1. Organization, Good Standing and Qualification. Each of the Company and its Subsidiaries is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation and has all requisite corporate power and authority to carry on its business as now conducted and to own or lease its properties. Each of

the Company and its Subsidiaries is duly qualified to do business as a foreign corporation and is in good standing in each jurisdiction in which the conduct of its business or its ownership or leasing of property makes such qualification or leasing necessary unless the failure to so qualify has not had and would not reasonably be expected to have a Material Adverse Effect.

4.2. Authorization. The Company has the requisite corporate power and authority and has taken all requisite corporate action necessary for, and no further action on the part of the Company, its officers, directors and stockholders is necessary for (i) the authorization, execution and delivery of this Agreement and (ii) the authorization of the performance of all obligations of the Company hereunder. The Board has determined, at a duly convened meeting or pursuant to a unanimous written consent, that the consummation of the transactions contemplated this Agreement are in the best interest of the Company.

4.3. Due Execution; Enforceability. This Agreement has been duly executed and delivered by the Company and constitutes a valid and legally binding obligation of the Company, enforceable against the Company in accordance with its terms, subject to (i) applicable bankruptcy, insolvency, fraudulent transfer, moratorium, reorganization or other similar laws of general application relating to or affecting the enforcement of creditors' rights generally and (ii) general principles of equity.

4.4. Capitalization. The authorized capital of the Company consists of 350,000,000 shares of Common Stock, of which 35,272,558 shares are issued and outstanding, and 10,000,000 shares of Series D Preferred Stock $0.0001 par value per share, of which no shares are issued or outstanding. All of the outstanding shares of Common Stock have been duly authorized, are fully paid and nonassessable and were issued in compliance with all applicable federal and state securities laws. None of such shares were issued in violation of any pre-emptive rights and such shares were issued in compliance in all material respects with any rights of third parties. The Company does not have outstanding stockholder purchase rights or "poison pill" or any similar arrangement in effect giving any Person the right to purchase any equity interest in the Company upon the occurrence of certain events.

4.5. Valid Issuance. The Shares have been duly authorized and validly issued and are fully paid and nonassessable, and free and clear of any liens, encumbrances, equities and claims (other than those created by the Selling Stockholder).

4.6. Consents; No Conflict, Breach, Violation or Default. The execution, delivery and performance by the Company of its obligations under this Agreement require no consent of, action by or in respect of, or filing with, any Person, governmental body, agency or official. The execution, delivery and performance of this Agreement by the Company will not (i) conflict with or result in a breach or violation of (a) any of the terms and provisions of, or constitute a default under, the Company's Certificate of Incorporation or the Company's By-laws, both as in effect on the date hereof or (b) any applicable statute, rule, regulation or order of any governmental agency or body or any court, domestic or foreign, having jurisdiction over the Company, or any of its assets or properties, or (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any lien, encumbrance or other adverse claim upon any of the properties or assets of the Company or give to others any rights of termination, amendment, acceleration or cancellation

(with or without notice, lapse of time or both) of, any Material Contract, except, in the case of clauses (i)(b) and (ii) only, for such conflicts, breaches, violations and defaults as have not, and would not reasonably be expected to have a Material Adverse Effect.

4.7. SEC Filings. The Company has made all filings that would have been required to be made pursuant to the 1934 Act during the twelve months preceding the date hereof if the Company were a Public Reporting Company for the entirety of such period of time. At the times of filing thereof, the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2017 and the Company's Current Report on Form 8-K/A (Amendment No. 2) filed with the SEC on January 24, 2018 (including all exhibits and schedules thereto and the documents incorporated by reference) (collectively, the "SEC Filings") complied as to form in all material respects with the requirements of the 1934 Act that would have been applicable to the Company if it were a Public Reporting Company at the respective times of such filings and did not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements made therein, in the light of the circumstances under which they were made, not misleading.

4.8. Financial Statements. The financial statements included in each SEC Filing comply in all material respects with applicable accounting requirements and the rules and regulations of the SEC with respect thereto as in effect at the time of filing (or to the extent corrected by a subsequent restatement) that would have been applicable to the Company if it were a Public Reporting Company at the time of such filing and present fairly, in all material respects, the financial position of the Company as of the dates shown and its results of operations and cash flows for the periods shown, subject in the case of unaudited financial statements to normal, immaterial year-end audit adjustments, and such financial statements have been prepared in conformity with United States generally accepted accounting principles applied on a consistent basis during the periods involved ("GAAP"). Except as set forth in the financial statements of the Company included in the SEC Filings, the Company has not incurred any liabilities, contingent or otherwise, except those incurred in the ordinary course of business, consistent (as to amount and nature) with past practices since the date of such financial statements, none of which, individually or in the aggregate, have had or would reasonably be expected to have a Material Adverse Effect.

4.9. Absence of Changes. Since September 30, 2017, except as identified and described in the SEC Filings, there has not been:

(i) any change in the assets, liabilities, financial condition or operating results of the Company from that reflected in the financial statements included in the SEC Filings, except for changes in the ordinary course of business which have not had and would not reasonably be expected to have a Material Adverse Effect, individually or in the aggregate;

(ii) any declaration or payment by the Company of any dividend, or any authorization or payment by the Company of any distribution, on any of the capital stock of the Company, or any redemption or repurchase by the Company of any securities of the Company;

(iii) any material damage, destruction or loss, whether or not covered by insurance, to any assets or properties of the Company;

(iv) any satisfaction or discharge of any lien, claim or encumbrance or payment of any obligation by the Company, except in the ordinary course of business and which is not material to the assets, properties, financial condition, operating results or business of the Company (as such business is presently conducted);

(v) any change or amendment to the Company's Certificate of Incorporation or By-laws, or material change to any Material Contract or arrangement by which the Company is bound or to which any of its assets or properties is subject;

(vi) any material transaction entered into by the Company other than in the ordinary course of business;

(vii) any action taken by the by the Company or a Subsidiary of the Company to seek protection pursuant to any law or statute relating to bankruptcy, insolvency, reorganization, receivership, liquidation or winding up, nor does the Company have any knowledge that any of the creditors of the Company or a Subsidiary of the Company intend to initiate involuntary bankruptcy proceedings, nor has the Company or any Subsidiary of the Company received any notice from any such creditor threatening any such action; or

(viii) any other event or condition of any character that has had or would reasonably be expected to have a Material Adverse Effect.

4.10. Tax Matters. The Company and each Subsidiary of the Company has timely prepared and filed all tax returns required to have been filed by the Company or such Subsidiary of the Company with all appropriate governmental agencies and timely paid all taxes shown thereon or otherwise owed by it. The charges, accruals and reserves on the books of the Company in respect of taxes for all fiscal periods are adequate in all material respects, and there are no material unpaid assessments against the Company or any Subsidiary of the Company nor, to the Company's Knowledge, any basis for the assessment of any additional taxes, penalties or interest for any fiscal period or audits by any federal, state or local taxing authority except for any assessment which is not material to the Company. All taxes and other assessments and levies that the Company or any Subsidiary of the Company is required to withhold or to collect for payment have been duly withheld and collected and paid to the proper governmental entity or third party when due. There are no tax liens or claims pending or, to the Company's Knowledge, threatened against the Company or any Subsidiary of the Company or any of their respective assets or property. There are no outstanding tax sharing agreements or other such arrangements between the Company or any Subsidiary of the Company and any other corporation or entity.

4.11. Title to Properties. The Company and each Subsidiary of the Company (a) has good and marketable title to all real properties and all other properties and assets owned by it, in each case free from liens, encumbrances and defects that would materially affect the value thereof or materially interfere with the use made or currently planned to be made thereof by it and (b) holds any leased real or personal property under valid and enforceable leases with

no exceptions that would materially interfere with the use made or currently planned to be made thereof by it.

4.12. Certificates, Authorities and Permits. The Company and each Subsidiary of the Company possesses adequate certificates, authorities or permits issued by appropriate governmental agencies or bodies necessary to conduct the business now operated by it, and neither the Company nor any Subsidiary of the Company has received any notice of proceedings relating to the revocation or modification of any such certificate, authority or permit that would reasonably be expected to have a Material Adverse Effect, individually or in the aggregate, on the Company.

4.13. Intellectual Property. The Company, together with its Subsidiaries, owns, possesses, licenses or has other rights to use all material Intellectual Property as necessary for use in connection with its business (the "Company Intellectual Property"). There is no pending or, to the Company's Knowledge, threatened action, suit, proceeding or claim by any Person that the Company's business as now conducted infringes or otherwise violates any Intellectual Property rights of any third party or any confidentiality obligations owed to a third party. To the Company's Knowledge, there is no existing infringement by another Person of any of the Company Intellectual Property that would have or would reasonably be expected to have a Material Adverse Effect. The Company has taken reasonable security measures to protect the secrecy, confidentiality and value of all of the Company Intellectual Property, except where failure to do so would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

4.14. Legal Proceedings. There are no legal, governmental or regulatory investigations, actions, suits or proceedings pending to which the Company is a party or to which any property of the Company is subject that, individually or in the aggregate, would reasonably be expected to have a Material Adverse Effect and, to the Company's Knowledge, no such investigations, actions, suits or proceedings are threatened or contemplated by any governmental or regulatory authority or threatened by others. The SEC has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company under the 1933 Act or the 1934 Act and no stop order or suspension of trading has been imposed by any other governmental or regulatory body with respect to public trading in the Common Stock.

4.15. Transactions with Affiliates. None of the officers or directors of the Company and, to the Company's Knowledge, none of the employees of the Company is presently a party to any transaction with the Company or any Subsidiary of the Company (other than as holders of stock options and/or warrants, and for services as employees, officers and directors) within the description of Section 404 of Regulation S-K as applied to the Company.

4.16. Required Filings. No event or circumstance has occurred or information exists with respect to the Company or its business, properties, operations or financial condition, which, under applicable law, rule or regulation, requires public disclosure or announcement by the Company, or would require public disclosure or announcement by the Company if the Company were a Public Reporting Company, that has not been so publicly announced or disclosed.

4.17. No Offers or Sales Requiring Registration. The offer, issuance and sale by the Company of the Shares to the Selling Stockholder were made in compliance with all applicable law and neither the Company nor any Person acting on its behalf has, directly or indirectly, made any offers or sales of any security or the right to purchase any security, or solicited any offers to buy any security or any such right, under circumstances that would require registration under the 1933 Act of the disposition of the Shares by the Selling Stockholder to the Investor contemplated under this Agreement.

4.18. Exchange Listing. The Common Stock is listed for trading on the Pink Open Market of the OTC Markets Group and the Company is in compliance in all respects with the Company's obligations under the rules of such exchange.

5. Representations and Warranties of the Investor. The Investor hereby represents and warrants to the Selling Stockholder and the Company that the statements contained in this Section 5 are complete and accurate:

5.1. Organization, Good Standing and Qualification. The Investor is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation and has all requisite corporate power and authority to enter into and consummate the transactions contemplated by this Agreement and to carry out its obligations hereunder and thereunder.

5.2. Authorization. The Investor has the requisite corporate power and authority and has taken all requisite corporate action necessary for, and no further action on the part of the Investor, its officers, directors and stockholders is necessary for (i) the authorization, execution and delivery of this Agreement and (ii) the authorization of the performance of all obligations of the Investor hereunder.

5.3. Due Execution; Enforceability. This Agreement has been duly executed and delivered by the Investor and constitutes a valid and legally binding obligation of the Investor, enforceable against the Investor in accordance with its terms, subject to (i) applicable bankruptcy, insolvency, fraudulent transfer, moratorium, reorganization or other similar laws of general application relating to or affecting the enforcement of creditors' rights generally and (ii) general principles of equity.

5.4. Consents; No Conflict, Breach, Violation or Default. The execution, delivery and performance by the Investor of its obligations under this Agreement require no consent of, action by or in respect of, or filing with, any Person, governmental body, agency or official. The execution, delivery and performance of this Agreement by the Investor will not conflict with or result in a breach or violation of any of the terms and provisions of, or constitute a default under, the Investor's organizational documents or any applicable statute, rule, regulation or order of any governmental agency or body or any court, domestic or foreign, having jurisdiction over the Investor, or any of its assets or properties.

5.5. Acquisition Entirely for Own Account. The Shares are being acquired for the Investor's own account, not as nominee or agent, and not with a view to the resale or distribution of any part thereof in violation of the 1933 Act, and the Investor has no present

intention of selling, granting any participation in, or otherwise distributing the same in violation of the 1933 Act without prejudice, however, to the Investor's right at all times to sell or otherwise dispose of all or any part of the Shares in compliance with applicable federal and state securities laws. Nothing contained herein shall be deemed a representation or warranty by the Investor to hold the Shares for any period of time. The Investor is not a broker-dealer registered with the SEC under the 1934 Act or an entity engaged in a business that would require it to be so registered.

5.6. Investment Experience. The Investor acknowledges that it can bear the economic risk and complete loss of its investment in the Shares and has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment contemplated hereby.

5.7. Restricted Securities. The Investor understands that the Shares are characterized as "restricted securities" under the U.S. federal securities laws and that under such laws and applicable regulations such securities may be sold without registration under the 1933 Act only in certain limited circumstances.

5.8. Accredited Investor. The Investor is an "accredited investor" within the meaning of Rule 501 under the 1933 Act. The Investor has determined based on its own independent review and such professional advice as it deems appropriate that its acquisition of the Shares and participation in the transactions contemplated by this Agreement (i) comply and are consistent with all investment policies, guidelines and other restrictions applicable to the Investor and (ii) do not and will not violate or constitute a default under the Investor's charter, by-laws or other constituent document or under any law, rule, regulation, agreement or other obligation by which the Investor is bound.

5.9. Legends. It is understood that, except as provided below, certificates or book entry positions evidencing the Shares may bear the following or any similar legend:

> "The securities represented hereby have not been registered with the Securities and Exchange Commission or the securities commission of any state in reliance upon an exemption from registration under the Securities Act of 1933, as amended, and, accordingly, may not be transferred unless (i) such securities have been registered for sale pursuant to the Securities Act of 1933, as amended, (ii) such securities may be sold pursuant to Rule 144 or other applicable exemption from applicable securities laws. The Company may require an opinion of counsel to the holder of these securities, reasonably satisfactory to the Company, that such transfer may lawfully be made without registration under the Securities Act of 1933, as amended."

6. Further Covenants and Agreements.

6.1. Exchange Listing. Until such time as the Shares have been disposed of by the Company and its Affiliates, the Company will use its best efforts to continue the listing and trading of its Common Stock on the Pink Open Market of the OTC Markets Group (or in lieu thereof, any other exchange of the OTC Markets Group or any national securities exchange) and,

in accordance, therewith, will use its best efforts to comply in all respects with the Company's reporting, filing and other obligations under the bylaws or rules of such market or exchange, as applicable.

6.2. Current Public Information. With a view to making available to the Investor the benefits of Rule 144 (or its successor rule) and any other rule or regulation of the SEC that may at any time permit the Investor or its Affiliates to sell shares of Common Stock to the public without registration, the Company covenants and agrees to: (i) make and keep adequate current public information available, as such term is used in Rule 144, (ii) file with the SEC in a timely manner all reports and other documents that would be required of the Company under the 1934 Act if it were a Public Reporting Company and (iii) furnish to the Investor upon request (A) a written statement by the Company that it has complied with the reporting requirements of the 1934 Act that would be applicable to it if it were a Public Reporting Company, (B) a copy of the Company's most recent Annual Report on Form 10-K or Quarterly Report on Form 10-Q and (C) such other information as may be reasonably requested in order to avail the Investor and its Affiliates of any rule or regulation of the SEC that permits the selling of any of the Shares without registration. The covenant set forth in this Section 6.2 shall terminate as of the earlier of such time as the Shares (i) have been sold or transferred pursuant to an effective registration statement, (ii) have been sold pursuant to Rule 144 or (iii) are eligible for resale without restriction pursuant to paragraph (b)(1) of Rule 144 or any similar successor provision.

6.3. Removal of Legends. In connection with any sale or disposition of any Shares by the Investor pursuant to Rule 144 or pursuant to any other exemption under the 1933 Act, the Company shall use its best efforts to cause the transfer agent for the Common Stock to remove any restrictive legends related to the certificate evidencing, or the book entry account holding, such Shares and issue a new, unlegended certificate or book entry position for the Shares sold or disposed of within two trading days of the request of the Investor and receipt by the Company from the Investor of customary representations and other documentation reasonably acceptable to the Company in connection therewith. Subject to receipt by the Company of customary representations and other documentation reasonably acceptable to the Company in connection therewith, upon the earlier of such time as the Shares (i) have been sold or transferred pursuant to an effective registration statement, (ii) have been sold pursuant to Rule 144 or (iii) are eligible for resale without restriction pursuant to paragraph (b)(1) of Rule 144 or any similar successor provision, the Company shall (A) deliver to the transfer agent for the Common Stock irrevocable instructions that such transfer agent shall issue a new, unlegended certificate or book entry position for the Shares and (B) cause its counsel to deliver to the transfer agent for the Common Stock one or more opinions to the effect that the removal of such legends in such circumstances may be effected under the 1933 Act. The Company shall be responsible for the fees of the transfer agent for the Common Stock and all fees of The Depository Trust Company associated with such issuance.

6.4. Right of First Offer. Subject to the terms and conditions of this Section 6.4, if the Company proposes to offer or sell any New Securities, the Company shall first provide the Investor with the opportunity to purchase the portion of such New Securities specified in this Section 6.4. The Investor shall be entitled to apportion the right of first offer hereby granted to it in such proportions as it deems appropriate among itself and its Affiliates.

(a) Prior to any proposed offering of New Securities, the Company shall give notice (the "Offer Notice") to the Investor, stating (i) the Company's bona fide intention to offer such New Securities, (ii) the number of such New Securities to be offered and (iii) the price and terms, if any, upon which the Company proposes to offer such New Securities.

(b) By notification to the Company within fifteen (15) Business Days after the Offer Notice is given (the "ROFO Period"), the Investor may elect to purchase or otherwise acquire, at the price and on the terms specified in the Offer Notice, up to that portion of such New Securities that equals the proportion that the Common Stock then held by the Investor and its Affiliates (including all shares of Common Stock then issuable (directly or indirectly) upon conversion and/or exercise, as applicable, of any Derivative Securities then held by the Investor and its Affiliates) bears to the total Common Stock of the Company then outstanding (assuming full conversion and/or exercise, as applicable, of all Derivative Securities). The closing of any sale of New Securities that the Investor elects to purchase or otherwise acquire pursuant to this Section 6.4(b) shall occur concurrently with the earliest closing for the other New Securities offered by the Company.

(c) The Company may, during the sixty (60) days following the expiration of the ROFO Period, offer and sell the New Securities that the Investor (and its Affiliates) have not elected to purchase in such offering at a price not less than, and upon terms no more favorable to the offeree than, those specified in the Offer Notice. If the Company does not consummate the sale of such securities within such 30-day period, the right of first offer under this Section 6.4 shall be deemed to be revived and such New Securities shall not be offered unless the Investor shall have again been provided with a right of first offer with respect thereto in accordance with this Section 6.4.

(d) The right of first offer set forth in this Section 6.4 shall not be applicable to offers or sales of equity securities that are registered by the Company on Form S-8 under the 1933 Act.

(e) The right of first offer set forth in this Section 6.4 shall remain in effect as long as Investor and its Affiliates collectively own two percent (2%) or more of the outstanding Common Stock, with any shares of Common Stock that are issuable upon the exercise, conversion or exchange of any securities held by Investor or any of its Affiliates being considered to be outstanding shares of Common Stock for purposes of this sentence.

6.5. Leak-Out. Notwithstanding any other provision in this Agreement, the Investor will not, directly or indirectly:

(i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of any Shares or any securities convertible into or exercisable or exchangeable for Shares, owned by the Investor or with respect to which the Investor has the power of disposition, or

(ii) enter into any swap or other agreement, arrangement or transaction that transfers to another, in whole or in part, directly or indirectly, any of the

economic consequence of ownership of any Shares or any securities convertible into or exercisable or exchangeable for any Shares,

whether any transaction described in clause (i) or (ii) above is to be settled by delivery of Shares, other securities, in cash or otherwise, prior to July 2, 2018 unless: (a) the transaction price is in excess of $4.08 per share (subject to appropriate adjustment for any stock split, stock dividend, reclassification, recapitalization or other similar transaction affecting the Common Stock after the execution of this Agreement) of Common Stock and the number of Shares so sold prior to July 1, 2018 does not exceed 15% of the Shares; or (b) the transaction price is in excess of $5.10 per share (subject to appropriate adjustment for any stock split, stock dividend, reclassification, recapitalization or other similar transaction affecting the Common Stock after the execution of this Agreement) of Common Stock and the number of Shares so sold prior to July 2, 2018 does not exceed 40% of the Shares. In addition, Investor agrees that prior to July 2, 2018, Shares may only be sold at or above the lowest "offer" or "ask" prices stated by the relevant market maker for the Common Stock on the OTC Markets or any nationally recognized exchange on which the Common Stock is publicly traded. Investor further agrees that (a) no sales will be made at the "bid" prices for the Common Stock and that (b) it will not engage in any short selling of the Common Stock prior to July 2, 2018.

7. Survival, Indemnification and Remedies.

7.1. Survival. The representations, warranties, covenants, indemnities and agreements contained in this Agreement shall survive the Closing for the applicable statute of limitations.

7.2. Indemnification.

(a) Company and Selling Stockholder Indemnification of the Investor. In consideration of the Investor's execution and delivery of this Agreement and acquiring the Shares hereunder and in addition to all of the Company's and the Selling Stockholder's other obligations under this Agreement, subject to the provisions of this Section 7.2(a) and Section 7.3, the Company and the Selling Stockholder shall, severally and not jointly, indemnify and hold harmless the Investor, each of its directors, officers, shareholders, members, partners, employees, representatives, agents and advisors (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding the lack of such title or any other title), each Person, if any, who controls the Investor (within the meaning of Section 15 of the 1933 Act or Section 20(a) of the 1934 Act), and the respective directors, officers, shareholders, members, partners, employees, representatives, agents and advisors (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding the lack of such title or any other title) of such controlling Persons (each, an "Investor Party"), from and against all losses, liabilities, obligations, claims, damages, costs and expenses (including all judgments, amounts paid in settlement, court costs, reasonable attorneys' fees and costs of defense and investigation) (collectively, "Damages") that such Investor Party may suffer or incur as a result of or relating to any breach of any of the representations, warranties, covenants or agreements made by the Company or the Selling Stockholder in this Agreement; provided, however, that the foregoing indemnity shall not apply to any Damages to the extent, but only to the extent, that such

Damages resulted directly and primarily from a breach of any of the Investor's representations, warranties, covenants or agreements contained in this Agreement.

An Investor Party's right to indemnification or other remedies based upon the representations, warranties, covenants and agreements of the Company or the Selling Stockholder set forth in this Agreement shall not in any way be affected by any investigation or knowledge of such Investor Party. Such representations, warranties, covenants and agreements shall not be affected or deemed waived by reason of the fact that an Investor Party knew or should have known that any representation or warranty might be inaccurate or that the Company or the Selling Stockholder failed to comply with any agreement or covenant. Any investigation by such Investor Party shall be for its own protection only and shall not affect or impair any right or remedy hereunder.

To the extent that the foregoing undertakings by the Company and the Selling Stockholder set forth in this Section 7.2(a) may be unenforceable for any reason, the Company and the Selling Stockholder shall make the maximum contribution to the payment and satisfaction of each of the Damages which is permissible under applicable law.

(b) Investor Indemnification of the Company and the Selling Stockholder. In consideration of the Company's and the Selling Stockholder's execution and delivery of this Agreement and disposition of the Shares hereunder and in addition to all of the Investor's other obligations under this Agreement, subject to the provisions of this Section 7.2(b) and Section 7.3, the Investor shall indemnify and hold harmless the Company and the Selling Stockholder, each of their respective directors, officers, stockholders, employees, representatives, agents and advisors (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding the lack of such title or any other title), each Person, if any, who controls the Company or the Selling Stockholder (within the meaning of Section 15 of the 1933 Act or Section 20(a) of the 1934 Act), and the respective directors, officers, shareholders, members, partners, employees, representatives, agents and advisors (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding the lack of such title or any other title) of such controlling Persons (each, a "Company Party"), from and against all Damages that such Company Party may suffer or incur as a result of or relating to any breach of any of the representations, warranties, covenants or agreements made by the Investor in this Agreement; provided, however, that the foregoing indemnity shall not apply to any Damages to the extent, but only to the extent, that such Damages resulted directly and primarily from a breach of any of the representations, warranties, covenants or agreements of the Company or the Selling Stockholder contained in this Agreement.

A Company Party's right to indemnification or other remedies based upon the representations, warranties, covenants and agreements of the Investor set forth in this Agreement shall not in any way be affected by any investigation or knowledge of such Company Party. Such representations, warranties, covenants and agreements shall not be affected or deemed waived by reason of the fact that a Company Party knew or should have known that any representation or warranty might be inaccurate or that the Investor failed to comply with any agreement or covenant. Any investigation by such Company Party shall be for its own protection only and shall not affect or impair any right or remedy hereunder.

To the extent that the foregoing undertakings by the Investor set forth in this Section 7.2(b) may be unenforceable for any reason, the Investor shall make the maximum contribution to the payment and satisfaction of each of the Damages which is permissible under applicable law.

7.3. Conduct of Indemnification Proceedings. Any person entitled to indemnification hereunder shall (i) give prompt notice to the indemnifying party of any claim with respect to which it seeks indemnification and (ii) permit such indemnifying party to assume the defense of such claim with counsel reasonably satisfactory to the indemnified party; provided that any person entitled to indemnification hereunder shall have the right to employ separate counsel and to participate in the defense of such claim, but the fees and expenses of such counsel shall be at the expense of such person, unless (a) the indemnifying party has agreed to pay such fees or expenses, (b) the indemnifying party shall have failed to assume the defense of such claim and employ counsel reasonably satisfactory to such person or (c) in the reasonable judgment of any such person, based upon written advice of its counsel, a conflict of interest exists between such person and the indemnifying party with respect to such claims (in which case, if the person notifies the indemnifying party in writing that such person elects to employ separate counsel at the expense of the indemnifying party, the indemnifying party shall not have the right to assume the defense of such claim on behalf of such person); and provided, further, that the failure of any indemnified party to give notice as provided herein shall not relieve the indemnifying party of its obligations hereunder, except to the extent that such failure to give notice shall materially adversely affect the indemnifying party in the defense of any such claim or litigation. It is understood and agreed that the indemnifying party shall not, in connection with any proceeding in the same jurisdiction, be liable for fees or expenses of more than one separate firm of attorneys at any time for all such indemnified parties. No indemnifying party will, except with the consent of the indemnified party, consent to entry of any judgment or enter into any settlement that (i) does not include as an unconditional term thereof the giving by the claimant or plaintiff to such indemnified party of a release from all liability in respect of such claim or litigation or (ii) that includes the granting of any equitable relief or the admission by the indemnified party of its officers, directors, managers, partners or Affiliates of any legal, regulatory or ethical violations.

7.4. Remedies.

(a) The Investor shall have all rights and remedies set forth in this Agreement and all rights and remedies that the Investor has been granted at any time under any other agreement or contract and all of the rights that the Investor has under any law. The Company and the Selling Stockholder recognize that in the event that either of them fails to perform, observe or discharge any or all of its obligations under this Agreement, any remedy at law may prove to be inadequate relief to the Investor. The Company and the Selling Stockholder therefore each agree that the Investor shall be entitled to seek specific performance and/or temporary, preliminary and permanent injunctive or other equitable relief from any court of competent jurisdiction in any such case without the necessity of proving actual damages and without posting a bond or other security.

(b) The Company and the Selling Stockholder shall have all rights and remedies set forth in this Agreement and all rights and remedies that the Company and the

Selling Stockholder, respectively, have been granted at any time under any other agreement or contract and all of the rights which the Company and the Selling Stockholder, respectively, have under any law. The Investor recognizes that in the event that it fails to perform, observe or discharge any or all of its obligations under this Agreement, any remedy at law may prove to be inadequate relief to the Company or the Selling Stockholder. The Investor therefore agrees that the Company and the Selling Stockholder shall be entitled to seek specific performance and/or temporary, preliminary and permanent injunctive or other equitable relief from any court of competent jurisdiction in any such case without the necessity of proving actual damages and without posting a bond or other security.

8. Miscellaneous.

8.1. Successors and Assigns. This Agreement may not be assigned by a party hereto without the prior written consent of each other party hereto, provided, however, that, the Investor may, without the prior written consent of the Company or the Selling Stockholder, assign its rights and delegate its duties hereunder in whole or in part by operation of law, to an Affiliate or to a third party acquiring all or substantially all of its assets or securities in a transaction complying with applicable securities laws. The provisions of this Agreement shall inure to the benefit of and be binding upon the respective permitted successors and assigns of the parties. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective permitted successors and assigns any rights, remedies, obligations, or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement.

8.2. Counterparts; Faxes; E-mail. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may also be executed via facsimile or e-mail, which shall be deemed an original.

8.3. Titles and Subtitles. The titles and subtitles used in this Agreement are used for convenience only and are not to be considered in construing or interpreting this Agreement.

8.4. Notices. Unless otherwise provided, any notice required or permitted under this Agreement shall be given in writing and shall be deemed effectively given as hereinafter described (i) if given by personal delivery, then such notice shall be deemed given upon such delivery, (ii) if sent by electronic mail during normal business hours of the recipient, then notice shall be deemed given when sent, and if not sent during normal business hours, then notice shall be deemed given on the recipient's next Business Day, (iii) if given by facsimile, then such notice shall be deemed given upon receipt of confirmation of complete transmittal, (iv) if given by mail, then such notice shall be deemed given upon the earlier of (A) receipt of such notice by the recipient or (B) three days after such notice is deposited in first class mail, postage prepaid, and (v) if given by an internationally recognized overnight air courier, then such notice shall be deemed given one Business Day after delivery to such carrier. All notices shall be addressed to the party to be notified at the address as follows, or at such other address as such party may designate by ten days' advance written notice to the other party:

If to the Company or the Selling Stockholder:

Processa Pharmaceuticals, Inc.
7380 Coca Cola Drive, Suite 106,
Hanover, Maryland 21076
Attention: David Young, CEO
Fax: (443) 288-4420
E-mail: dyoung@processapharmaceuticals.com

With a copy to:

Foley & Lardner LLP
One Independent Drive
Suite 1300
Jacksonville, Florida 32202
Attention: John Wolfel
Fax: (904) 359-8700
E-mail: jwolfel@foley.com

If to the Investor:

CoNCERT Pharmaceuticals, Inc.
99 Hayden Avenue, Suite 500
Lexington, Massachusetts 02421
Attention: General Counsel
Fax: (781) 674-5310
E-mail: lherscha@concertpharma.com

With a copy to:

Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, Massachusetts 02109
Attention: Steven D. Barrett
Fax: (617) 526-5000
E-mail: steven.barrett@wilmerhale.com

8.5. Amendments and Waivers. Any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively), only with the written consent of each of the parties hereto.

8.6. Publicity. No public release or announcement concerning the transactions contemplated hereby shall be issued by any party hereto without the prior consent of each of the other parties hereto, except as such release or announcement may be required by law or the applicable rules or regulations of any securities exchange or securities market, in which case the releasing or announcing party shall allow each other party hereto, to the extent

reasonably practicable in the circumstances, reasonable time to comment on such release or announcement in advance of such issuance.

8.7. Severability. Any provision of this Agreement that is prohibited or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof but shall be interpreted as if it were written so as to be enforceable to the maximum extent permitted by applicable law, and any such prohibition or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction. To the extent permitted by applicable law, the parties hereby waive any provision of law which renders any provision hereof prohibited or unenforceable in any respect.

8.8. Entire Agreement. This Agreement and the License Agreement constitute the entire agreement among the parties hereof with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, both oral and written, between the parties with respect to the subject matter hereof and thereof.

8.9. Further Assurances. The parties shall execute and deliver all such further instruments and documents and take all such other actions as may reasonably be required to carry out the transactions contemplated hereby and to evidence the fulfillment of the agreements herein contained.

8.10. Governing Law; Consent to Jurisdiction. This Agreement shall be governed by, and construed in accordance with, the internal laws of the Commonwealth of Massachusetts without regard to the choice of law principles thereof. Each of the parties hereto irrevocably submits to the exclusive jurisdiction of the courts of the Commonwealth of Massachusetts located in Suffolk County and the United States District Court for the District of Massachusetts for the purpose of any suit, action, proceeding or judgment relating to or arising out of this Agreement and the transactions contemplated hereby. Service of process in connection with any such suit, action or proceeding may be served on each party hereto anywhere in the world by the same methods as are specified for the giving of notices under this Agreement. Each of the parties hereto irrevocably consents to the jurisdiction of any such court in any such suit, action or proceeding and to the laying of venue in such court. Each party hereto irrevocably waives any objection to the laying of venue of any such suit, action or proceeding brought in such courts and irrevocably waives any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum.

[remainder of page intentionally left blank]

IN WITNESS WHEREOF, the parties have executed this Agreement or caused their duly authorized officers to execute this Agreement as of the date first above written.

COMPANY:

PROCESSA PHARMACEUTICALS, INC.

By: _____
Name: David Young
Title: CEO

SELLING STOCKHOLDER:

PROMET THERAPEUTICS, LLC

By: _____
Name: David Young
Title: CEO

INVESTOR:

CONCERT PHARMACEUTICALS, INC.

By: _____
Name: Davy Stout
Title: COO

CONVERTIBLE NOTE

NEITHER THIS SECURITY NOR THE SECURITIES INTO WHICH THIS SECURITY IS CONVERTIBLE HAVE BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS. THIS SECURITY AND THE SECURITIES ISSUABLE UPON CONVERSION OF THIS SECURITY MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT OR OTHER LOAN SECURED BY SUCH SECURITIES.

Original Issue Date: As of October_____, 2017

$_____

PROCESSA PHARMACEUTICALS, INC.
8.0% SENIOR CONVERTIBLE NOTE

THIS NOTE is a duly authorized and validly issued Senior Convertible Note of Processa Pharmaceuticals, Inc., a Delaware corporation, and its subsidiaries (the "Company"), having its principal place of business at 7380 Coca Cola Drive, Suite 106, Hanover, MD 21076, designated as a 8.0% Senior Secured Convertible Note (this "Note" or the "Senior Note").

FOR VALUE RECEIVED, and in consideration of the principal amount of _____, (hereinafter "Principal Amount") as _____(the "Holder") has made hereunder, to the Company, the Company promises to pay to the Holder, or its permitted assigns, the aggregate unpaid Principal Amount under this Note, on the earlier of on the earlier of: 1) Mandatory and automatic conversion of the Note into the next PIPE financing for the Company provided such PIPE financing yields gross proceeds to the Company of at least $4 million at the pre-money valuation stated below under "Mandatory Conversion" ("Qualified Financing") or, 2) payable no later than the One (1) Year Anniversary of this Note (the "Maturity Date"), and to pay interest to the Holder on the aggregate unconverted and then outstanding Principal Amount of this Note in accordance with the provisions hereof.

This Note is subject to the following additional provisions:

Section 1. Definitions. For the purposes hereof, in addition to the terms defined elsewhere in this Note (a) capitalized terms not otherwise defined herein shall have the meanings set forth in the Subscription Agreement and (b) the following terms shall have the following meanings:

"Bankruptcy Event" means any of the following events: (a) the Company or any Significant Subsidiary (as such term is defined in Rule 1-02(w) of Regulation S-X) thereof

commences a case or other proceeding under any bankruptcy, reorganization, arrangement, adjustment of debt, relief of debtors, dissolution, insolvency or liquidation or similar law of any jurisdiction relating to the Company or any Significant Subsidiary thereof; (b) there is commenced against the Company or any Significant Subsidiary thereof any such case or proceeding that is not dismissed within sixty (60) days after commencement; (c) the Company or any Significant Subsidiary thereof is adjudicated insolvent or bankrupt or any order of relief or other order approving any such case or proceeding is entered; (d) the Company or any Significant Subsidiary thereof suffers any appointment of any custodian or the like for it or any substantial part of its property that is not discharged or stayed within sixty (60) calendar days after such appointment; (e) the Company or any Significant Subsidiary thereof makes a general assignment for the benefit of creditors; (f) the Company or any Significant Subsidiary thereof calls a meeting of its creditors with a view to arranging a composition, adjustment or restructuring of its debts; or (g) the Company or any Significant Subsidiary thereof, by any act or failure to act, expressly indicates its consent to, approval of or acquiescence in any of the foregoing or takes any corporate or other action for the purpose of effecting any of the foregoing.

"Business Day" means any day except any Saturday, any Sunday, any day which shall be a federal legal holiday in the United States or any day on which banking institutions in the State of Delaware are authorized or required by law or other governmental action to close.

"Common Stock Equivalents" means any securities of the Company or its subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, rights, options, warrants or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock. "Event of Default" shall have the meaning set forth in Section 5(a).

"Delaware Courts" shall have the meaning set forth in Section 6(d).

"Original Issue Date" means the date of the first issuance of this Note, regardless of any transfers of this Note and regardless of the number of instruments which may be issued to evidence this Note.

"Permitted Indebtedness" means (a) the indebtedness evidenced by this Note, (b) the indebtedness existing on the Closing Date, (c) lease obligations and purchase money indebtedness incurred in connection with the acquisition of capital assets and lease obligations with respect to newly acquired or leased assets, (d) loans previously provided to Promet Therapeutics, LLC by the Small Business Administration and assumed by Heatwurx or its subsidiary, and (e) indebtedness that is expressly subordinate to this Note pursuant to a written subordination agreement with the Holder that is acceptable to the Holder in its sole and absolute discretion.

"Permitted Lien" means the individual and collective reference to the following: (a) Liens existing on the Closing Date, (b) Liens for taxes, assessments and other

governmental charges or levies not yet due or Liens for taxes, assessments and other governmental charges or levies being contested in good faith and by appropriate proceedings for which adequate reserves (in the good faith judgment of the management of the Company) have been established in accordance with GAAP; (c) Liens imposed by law which were incurred in the ordinary course of the Company's business, such as carriers', warehousemen's and mechanics' Liens, statutory landlords' Liens, and other similar Liens arising in the ordinary course of the Company's business, and which (x) do not individually or in the aggregate materially detract from the value of such property or assets or materially impair the use thereof in the operation of the business of the Company and its consolidated Subsidiaries or (y) are being contested in good faith by appropriate proceedings, which proceedings have the effect of preventing for the foreseeable future the forfeiture or sale of the property or asset subject to such Lien; and (d) Liens incurred in connection with Permitted Indebtedness.

"Subscription Agreement" means the Subscription Agreement, dated as of October __, 2017, among the Company and the original Holder, as amended, modified or supplemented from time to time in accordance with its terms.

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Subsidiary" shall have the meaning set forth in the Subscription Agreement.

"Transaction Documents" shall have the meaning set forth in the Subscription Agreement.

Section 2. Interest; No Prepayment.

a) Interest Rate. Interest shall accrue daily on the outstanding principal amount of this Note at a rate per annum equal to 8.0%, and is Payable-In-Kind ("PIK") based upon a pre-market valuation discount defined below.

b) Payment of Interest. On the Maturity Date, the Company shall pay to the Holder any accrued but unpaid and unconverted interest hereunder on the aggregate unconverted and then outstanding principal amount of this Note. The amount of interest that has accrued on the principal hereof as of any date may be added to and included with the principal amount being so converted on any date on which a conversion is effected under Section 3 below.

c) Interest Calculations. Interest shall be calculated on the basis of a three hundred sixty (360)-day year, consisting of twelve (12) thirty (30) calendar day periods, and shall accrue daily commencing on the Original Issue Date until payment in full of the outstanding principal, together with all accrued and unpaid interest and other amounts which may become due hereunder, has been made. Interest hereunder will be paid to the Person in whose name this Note is registered on the records of the Company regarding registration and transfers of this Note.

d) Prepayment. This Note may be prepaid by the Company at any time following the Original Issuance Date on seven (7) day's prior written to the Holder.

Section 3. Conversion.

a) Mandatory Conversion on Qualified Financing. Each Holder will be required to convert a Senior Note into the Qualified Financing at a conversion price per share equal to the lower of (i) $72 million **or** (ii) a 10% discount to the pre-money valuation for said Qualified Financing. (The parties contemplate a Qualified Financing at an $80 million pre-money valuation, resulting in a $72 million valuation based on the 10% discount for Senior Note Holders as noted above.) This mandatory conversion shall be automatic and the Company will provide notice to Holder at least seven (7) days prior to the closing of a Qualified Financing as to the number of shares, Holder would receive based on applying the discounted pricing described above for principal and PIK shares. In conjunction with any conversion, Holder will become a party to and will execute appropriate subscription agreements for the Qualified Financing. The intent of the Qualified Financing is to add gross proceeds to the Company of $8,000,000 or more.

b). Other Mandatory Conversion. If the Senior Note not been paid or converted prior to the Maturity Date, the outstanding Principal Amount of the Senior Note will be automatically converted into shares of common stock of the Company equal to the lesser of (i) $72 million pre-money valuation or (ii) any adjusted price resulting from the application of the "Most Favored Nations Provision" set forth below. In such event the Anti-Dilution period, as defined below, will be extended for a further 12 months.

c). Payment on Change of Control. If prior to the Maturity Date, there is a Change of Control and the Senior Note has not previously been converted, a Holder may elect to have the Senior Note together with any accrued interest repaid in full at that time plus an additional 10% on the principal amount of the Senior Note.

d). Most Favored Nations Provision. If the Senior Note has not been paid or converted prior to the Maturity Date, and if at any time or from time to time prior to December 31, 2018 (the "Anti-Dilution Period") the Company/HUWX issues any additional securities (a "New Issuance") (including, but not limited to, any class of shares, preferred stock, warrants, rights to subscribe for shares, convertible debt or other securities convertible into any share class, referred to below collectively as "Securities") for a consideration per share, after giving effect to, and net of, commissions, fees and other expenses (collectively "offering costs"), that is less, or which on conversion or exercise of the underlying security is less, than the conversion price of the Holder (as adjusted for changes resulting from any forward or reverse share splits, stock dividends and similar events) (a "Down Round Price"), the Company shall issue additional Securities to Holder at no additional cost in an amount that it would have received at the Down Round Price, rounded up to the next whole share, on a full ratchet basis at no additional consideration ("Holder's Down Round Issuances"). In the event that a New Issuance is made at a Down Round Price and includes both equity securities and rights to acquire additional securities (whether in the form of warrants, options or other rights) (the "Rights"), then as part of any full ratchet adjustment the Company shall also include, within the Holder's Down Round

Issuances, that number of Rights which Holder would have acquired had it participated in the New Issuance.

Section 4. Negative Covenants. As long as any portion of this Note remains outstanding, unless the Holder shall have otherwise given prior written consent, the Company shall not, and shall not permit any of its subsidiaries (whether or not a Subsidiary on any Closing Date) to, directly or indirectly:

a) other than Permitted Indebtedness, enter into, create, incur, assume, guarantee or suffer to exist any indebtedness for borrowed money of any kind, including but not limited to, a guarantee, on or with respect to any of its property or assets now owned or hereafter acquired or any interest therein or any income or profits therefrom;

b) other than Permitted Liens, enter into, create, incur, assume or suffer to exist any Liens of any kind, on or with respect to any of its property or assets now owned or hereafter acquired or any interest therein or any income or profits therefrom;

c) repay, repurchase or offer to repay, repurchase or otherwise acquire more than a de minimis number of shares of its Common Stock or Common Stock Equivalents other than repurchases of Common Stock or Common Stock Equivalents of departing employees of the Company, provided that such repurchases shall not exceed an aggregate of $150,000 for all employees during the term of this Note;

d) pay cash dividends or distributions on Common Stock of the Company;

e) enter into any transaction with any Affiliate of the Company which would be required to be disclosed in any public filing with the Commission, unless such transaction is expressly approved by a majority of the disinterested directors of the Company (even if less than a quorum otherwise required for board approval); or

f) enter into any agreement with respect to any of the foregoing.

Section 5. Events of Default.

a) "Event of Default" means, wherever used herein, any of the following events (whatever the reason for such event and whether such event shall be voluntary or involuntary or effected by operation of law or pursuant to any judgment, decree or order of any court, or any order, rule or regulation of any administrative or governmental body), provided that an event specified in item i, ii, iii, or vii below will not become an Event of Default unless and until it is not cured, if possible to cure, within the earlier to occur of (i) five (5) Business Days after notice of such failure sent by the Holder or by any other Holder and (ii) ten (10) Business Days after the Company has become or should have become aware of such failure:

i. any default in the payment of (A) the principal amount of this Note or (B) interest, and other amounts owing to the Holder of this Note, as and when the same shall become due and payable;

ii. the Company shall fail to observe or perform any other covenant or agreement contained in this Note;

iii. a default or event of default shall occur under any of the Transaction Documents (subject to any grace or cure period provided in the applicable Transaction Document);

iv. any representation or warranty made in the Transaction Documents shall be untrue or incorrect in any material respect as of the date when made or deemed made;

v. the Company or any Significant Subsidiary shall be subject to a Bankruptcy Event;

vi. the Company or any Subsidiary shall default on any of its obligations under any mortgage, credit agreement or other facility, indenture agreement, factoring agreement or other instrument under which there may be issued, or by which there may be secured or evidenced, any indebtedness for borrowed money or money due under any long term leasing or factoring arrangement that (A) involves an obligation greater than $100,000, whether such indebtedness now exists or shall hereafter be created, (B) results in such indebtedness becoming or being declared due and payable prior to the date on which it would otherwise become due and payable, and (C) is not listed on Schedule I to this Note;

vii. if at any time commencing six months from the date hereof the Company is not subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act or has failed to file all reports required to be filed thereunder during the then preceding twelve (12) months;

viii. if Dr. David Young ceases to serve full time as the President and Chief Executive Officer of the Company and perform the duties consistent with such positions for similarly situated companies, provided that if such cessation is due to death, permanent disability, voluntary termination or termination by the Company for cause, then an Event of Default shall not be deemed to have occurred unless and until the Company shall have failed to retain a full-time replacement reasonably acceptable to the Holder within ninety (90) days following such death, permanent disability, voluntary termination or termination by the Company for cause; or

ix. any monetary judgment, writ or similar final process shall be entered or filed against the Company, any subsidiary or any of their respective property or other assets for more than $100,000, and such judgment, writ or similar final process shall remain unvacated, unbonded or unstayed for a period of forty-five (45) calendar days; provided, however, that any judgment which is covered by

insurance or an indemnity from a creditworthy party (such creditworthiness as reasonably determined by the Holder) shall not be included in calculating the amount of such judgment, writ or final process so long as the Company provides the Holder a written statement from such insurer or indemnity provider (which written statement shall be reasonably satisfactory to the Holder) to the effect that such judgment is covered by insurance or an indemnity and the Company will receive the proceeds of such insurance or indemnity within forty-five (45) calendar days of the issuance of such judgment.

b) Acceleration Upon Event of Default. If any Event of Default occurs, the outstanding principal amount of this Note, plus accrued but unpaid interest and other amounts owing in respect thereof through the date of acceleration, shall become, at the Holder's election (which the Holder shall not make more than the later of thirty (30) calendar days after the date (a) such Event of Default is cured or otherwise resolved and (b) the Holder is aware of such cure or resolution), immediately due and payable in cash. If there is such an acceleration, then upon the payment in full of the amounts due hereunder, the Holder shall promptly surrender this Note to or as directed by the Company. In connection with such acceleration described herein, the Holder need not provide, and the Company hereby waives, any presentment, demand, protest or other notice of any kind, and the Holder may immediately and without expiration of any grace period enforce any and all of its rights and remedies hereunder and all other remedies available to it under applicable law. Such acceleration may be rescinded and annulled by Holder at any time prior to payment hereunder and the Holder shall have all rights as a holder of the Note until such time, if any, as the Holder receives full payment pursuant to this Section 5(b). No such rescission or annulment shall affect any subsequent Event of Default or impair any right consequent thereon.

Section 6. Miscellaneous.

a) Notices. Any and all notices or other communications or deliveries to be provided by the Holder hereunder, including, without limitation, any Notice of Conversion, shall be in writing and delivered personally, by facsimile, or sent by a nationally recognized overnight courier service, addressed to the Company, at the address set forth above, or such other facsimile number or address as the Company may specify for such purpose by notice to the Holder delivered in accordance with this Section 6. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by facsimile, or sent by a nationally recognized overnight courier service addressed to each Holder at the facsimile number or address of the Holder appearing on the books of the Company, or if no such facsimile number or address appears, at the principal place of business of the Holder. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the date of transmission or delivery, if such notice or communication is delivered via facsimile at the facsimile number, or delivered by such courier service to the address, specified in this Section 6 prior to 5:30 p.m. (New York City time), (ii) the date immediately following the date of transmission or delivery, if such notice or communication is delivered via facsimile at the facsimile number, or delivered by such courier to the address, specified in this

Section 6 between 5:30 p.m. (New York City time) and 11:59 p.m. (New York City time) on any date, or (iii) upon actual receipt by the party to whom such notice is required to be given. The address for such notices and communications shall be as set forth on the signature pages attached to the Subscription Agreement.

b) Absolute Obligation. Except as expressly provided herein, no provision of this Note shall alter or impair the obligation of the Company, which is absolute and unconditional, to pay the principal of, and accrued interest, as applicable, on this Note at the time, place, and rate, and in the coin or currency, herein prescribed. This Note is a direct debt obligation of the Company.

c) Lost or Mutilated Note. If this Note shall be mutilated, lost, stolen or destroyed, the Company shall execute and deliver, in exchange and substitution for and upon cancellation of a mutilated Note, or in lieu of or in substitution for a lost, stolen or destroyed Note, a new Note for the principal amount of this Note so mutilated, lost, stolen or destroyed, but only upon receipt of evidence of such loss, theft or destruction of such Note, and of the ownership hereof, reasonably satisfactory to the Company.

d) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Note shall be governed by and construed and enforced in accordance with the internal laws of the State of Delaware, without regard to the principles of conflict of laws thereof. Each party agrees that all legal proceedings concerning the interpretation, enforcement and defense of the transactions contemplated by any of the Transaction Documents (whether brought against a party hereto or its respective Affiliates, directors, officers, shareholders, employees or agents) shall be commenced in the state and federal courts sitting in Delaware (the "Delaware Courts"). Each party hereto hereby irrevocably submits to the exclusive jurisdiction of the Delaware Courts for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of such Delaware Courts, or such Delaware Courts are improper or inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Note and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by applicable law. Each party hereto hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Note or the transactions contemplated hereby. If either party shall commence an action or proceeding to enforce any provisions of this Note, then the prevailing party in such action or proceeding shall be reimbursed by the other party for its attorney's fees and other costs and expenses reasonably incurred in the investigation, preparation and prosecution of such action or proceeding.

e) Waiver. Any waiver by the Company or the Holder of a breach of any provision of this Note shall not operate as or be construed to be a waiver of any other breach of such provision or of any breach of any other provision of this Note. The failure of the Company or the Holder to insist upon strict adherence to any term of this Note on one or more occasions shall not be considered a waiver or deprive that party of the right thereafter to insist upon strict adherence to that term or any other term of this Note. Any waiver by the Company or the Holder must be in writing.

f) Severability. If any provision of this Note is invalid, illegal or unenforceable, the balance of this Note shall remain in effect, and if any provision is inapplicable to any Person or circumstance, it shall nevertheless remain applicable to all other Persons and circumstances. If it shall be found that any interest or other amount deemed interest due hereunder violates the applicable law governing usury, the applicable rate of interest due hereunder shall automatically be lowered to equal the maximum rate of interest permitted under applicable law. The Company covenants (to the extent that itmay lawfully do so) that it shall not at any time insist upon, plead, or in any manner whatsoever claim or take the benefit or advantage of, any stay, extension or usury law or other law which would prohibit or forgive the Company from paying all or any portion of the principal of or interest on this Note as contemplated herein, wherever enacted, now or at any time hereafter in force, or which may affect the covenants or the performance of this indenture, and the Company (to the extent it may lawfully do so) hereby expressly waives all benefits or advantage of any such law, and covenants that it will not, by resort to any such law, hinder, delay or impeded the execution of any power herein granted to the Holder, but will suffer and permit the execution of every such as though no such law has been enacted.

g) Next Business Day. Whenever any payment or other obligation hereunder shall be due on a day other than a Business Day, such payment shall be made on the next succeeding Business Day.

h) Headings. The headings contained herein are for convenience only, do not constitute a part of this Note and shall not be deemed to limit or affect any of the provisions hereof.

i) Right to Participate in Future Offerings. The Holder shall be permitted a pro rata right to participate in any future offerings made by the Company which occur prior to December 31, 2018.

****

IN WITNESS WHEREOF, the Company has caused this Note to be duly executed by a duly authorized officer as of the date first above indicated.

PROCESSA PHARMACEUTICALS, INC.

By:_____
Name: Dr. David Young
Title: Chief Executive Officer
Facsimile No. for delivery of Notices:

EXHIBIT 21.1

SUBSIDIARIES OF
PROCESSA PHARMACEUTICALS, INC.

NAME	STATE OF FORMATION	PERCENTAGE OWNERSHIP
Processa Therapeutics, LLC.	Delaware	100%

BD&CO. INC.
CERTIFIED PUBLIC ACCOUNTANTS
MANAGEMENT CONSULTANTS

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement Number 333-190697 on Form S-8 of Processa Pharmaceuticals, Inc. of our report, dated April 16, 2018, relating to our audits of the consolidated financial statements as of and for the years ended December 31, 2017 and 2016 appearing in this Annual Report on Form 10-K of Processa Pharmaceuticals, Inc.

BD & Company, Inc.

Owings Mills, MD
April 16, 2018

EXHIBIT 31.1

CERTIFICATIONS

I, David Young, Chief Executive Officer and Acting Chief Financial Officer of PROCESSA PHARMACEUTICALS, INC., certify that:

1. I have reviewed this annual report on Form 10-K of PROCESSA PHARMACEUTICALS, INC.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. Responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. Disclosed based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 16, 2018

By: */s/ David Young*
David Young
Chief Executive Officer and Acting Chief Financial Officer
(Principal Executive Officer, Principal Financial Officer and
Principal Accounting Officer)

EXHIBIT 32.1

Written Statement of the Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. §1350

Solely for the purposes of complying with 18 U.S.C. §1350, I, the undersigned Chief Executive Officer and Acting Chief Financial Officer of PROCESSA PHARMACEUTICALS, INC. (the "Company"), hereby certify, to the best of my knowledge, that the annual report on Form 10-K of the Company for the year ended December 31, 2017 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This certification is being furnished solely to accompany this Report pursuant to 18 U.S.C. 1350 and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and is not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Date: April 16, 2018

By: */s/ David Young*
David Young
Chief Executive Officer and Acting Chief Financial Officer
(Principal Executive Officer, Principal Financial Officer and
Principal Accounting Officer)