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, 2018

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)

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 Section 15(d) of the Act. Yes [ ] No [X]

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 every Interactive Data File required to be submitted 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 such files). Yes [X] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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, a smaller reporting company, or emerging growth company. See definition of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates on June 30, 2018, based upon the closing price of Common Stock on such date as reported on OTC Pink Marketplace, was approximately $25.3 million. Shares of voting stock held by each officer and director have been excluded in that such persons may be deemed to be affiliates. This assumption regarding affiliate status is not necessarily a conclusive determination for other purposes.

The number of outstanding shares of the registrant's common stock as of March 15, 2019, was 35,272,626.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of our definitive proxy statement for our 2019 annual meeting of stockholders, which we intend to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after our fiscal year ended December 31, 2018, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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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. 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 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 obtain adequate financing to fund our business operations in the future;
- 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 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.

In this Form 10-K, "we," "us", "our", "Processa" and "the Company" refer to Processa Pharmaceuticals, Inc. and its subsidiary.

Part I

Item 1. Business

General

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 multiple 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, including published case studies or clinical experience, 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.

While time to develop a drug from finding/designing a molecule (i.e., the discovery stage) to FDA approval typically takes between 10-15 years, our business model is to identify drugs that are in the clinical stage of drug development where (i) a pivotal study can be completed in 2 to 4 years or (ii) enough clinical data can be obtained to demonstrate the value of the asset to a future licensing partner. The FDA approval of the drug would then occur after the preparation of the NDA documents and the FDA review process.

In order to add significant value to in-licensed drugs within 2 to 4 years, the drugs must be in the clinical development stage or minimally in the Pre-Investigation New Drug ("IND") toxicology stage of development. During these 2 to 4 years, we must be able to obtain clinical data to support the use of the drug for the desired indication in order to increase the value of the drug. The additional clinical data could range from clinical proof-of-concept data to demonstrate that the proposed pharmacology occurs clinically in the targeted patient population to pivotal well-designed randomized controlled trial(s).

To be able to complete the clinical studies within 2 to 4 years, these drugs must (i) already have clinical proof-of-concept data demonstrating the desired pharmacological activity in humans or, minimally, clinical evidence in the form of case studies or clinical experience demonstrating the drug or a similar drug pharmacologically can successfully treat patients with the targeted indication, (ii) target indications for which the FDA suggests that a single positive pivotal study might be able to demonstrate efficacy, provide enough evidence that the clinical benefits of the drug and of approval outweigh the risks associated with the drug or the present standard of care (e.g., many serious life-threatening conditions, some serious quality of life conditions), and/or (iii) target indications where the prevalence of the condition and the likelihood of patients enrolling in a study meet the desired time-frame to demonstrate at some level that the drug can treat or potentially can treat patients with the condition.

Our Drug in Clinical Development

Processa's lead product, PCS-499, is an oral tablet that is a deuterated analog (i.e., a compound having a structure similar to that of the original molecule but differing from it in respect to deuterium replaces hydrogen at certain positions in the molecule) of an active metabolite of an already approved drug called pentoxifylline (PTX). PTX (Trental®) was approved by the FDA on August 30, 1984 for the treatment of patients with intermittent claudication on the basis of chronic occlusive arterial disease of the limbs. In the body, PCS-499 is broken down into multiple metabolites some of which are exactly the same as PTX metabolites and others that differ by deuterium replacing hydrogen at specific sites on the molecule. In addition, PCS-499 is reversibly metabolized to a deuterated form of PTX. PCS-499 and its metabolites have the same basic pharmacological properties as PTX and its metabolites regardless of the molecule having deuterium or hydrogen in animal and healthy human volunteer studies, the systemic exposure to PCS-499 and certain key active metabolites after PCS-499 administration is two times greater than the exposure to the non-deuterated equivalents after the same dose of PTX. Despite the greater exposure to these pharmacologically active molecules, a dose of PCS-499 50% greater than the highest administered safely tolerated PTX dose is well tolerated in animal toxicology and human volunteer safety studies.

Based on our findings in the literature that PTX has some activity in a number of conditions, PCS-499 may potentially provide clinical benefit over other on-label or off-label products used for the various conditions. These conditions include Necrobiosis Lipoidica (NL). 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. Other conditions such as radiation induced fibrosis (RIF), Type 1 diabetes, venous leg ulcers, psychopathological symptoms in patients with cerebrovascular insufficiency, acute pancreatitis, and numerous other conditions have been treated with PTX with some efficacy reported in case studies or small clinical studies.

For example, just as in NL, the dose limiting toxicity of PTX appears to prevent more widespread use in patients with RIF. RIF is a condition that occurs after radiation exposure causes multiple pathophysiological changes in the head and neck area. RIF can significantly affect the quality of life of these patients causing symptoms such as dry mouth, oral mucositis, muscular atrophy, swallowing dysfunction, vascular damage, and neural damage. A drug that attacks the multiple pathophysiological changes in RIF may increase the probability of positively treating patients with this condition. The complex mechanism of action of PCS-499 (e.g., enhanced inhibition of cytokines such as TNF-α, and IFN-γ that induce inflammation and granuloma formation, effect on red blood cell deformability and promotion of platelet deaggregation resulting in an improvement of microcirculatory flow) and the ability to administer a greater yet safer dose than PTX could provide a much-needed treatment for these patients.

Our team had a successful Pre-IND meeting with the FDA on NL in October 2017, defining the next steps to move PCS-499 into Phase 2 studies and the path to eventual approval. We have also entered into an agreement with Integrium, LLC ("Integrium"), a contract research organization (CRO), to conduct our Phase 2a clinical study to further evaluate PCS-499 for the treatment of NL. Integrium is a full-service Clinical Proof of Concept firm based in Tustin, California, that specializes in a wide range of therapeutic areas including cardiovascular, metabolic disease and dermatology research. The budget agreed to with Integrium for the completion of the Phase 2 Clinical study is approximately $1.6 to $1.8 million, which PoC Capital has committed to funding up to $1.8 million.

The FDA has cleared the IND for PCS-499 in NL such that we are able to move directly into a Phase 2 trial based on the pre-clinical and clinical trials when the compound was developed by CoNCERT Pharmaceuticals for a different indication (i.e. diabetic nephropathy) and a Processa Phase 1 single dose - multiple dose study. When we licensed PCS-499 from CoNCERT in March 2018, all the previous preclinical, Phase 1 and Phase 2 clinical data was also acquired. Based on the development program and pre-IND meeting with FDA, Processa was able to show sufficient pharmacological, toxicological, pharmacokinetic and safety data to support the Phase 2 program in NL without having to repeat pre-clinical and Phase 1 work that had been previously conducted and submitted for the PCS-499 by CoNCERT. Pharmacologically, PCS-499 is believed to have a complex mechanism of action including anti-inflammatory, immunomodulatory, hemorheological and antifibrotic effects. PCS-499 may benefit NL patients based on its enhanced inhibition of cytokines (TNF-α, IFN-γ) that induce inflammation and granuloma formation as well as its effect on red blood cell deformability and promotion of platelet deaggregation, which can improve microcirculatory flow. From a safety perspective, six clinical trials with PCS-499 including four studies in healthy volunteers and two studies in patients with chronic kidney disease have been completed. Since PCS-499 is an analog (i.e., a compound having a structure similar to that of the approved drug, but differing from it in respect to a certain component of the molecule which may cause it to have similar or different effects on the body) of an active metabolite of an already approved drug called pentoxifylline (PTX), we were able to define a development and regulatory strategy for PCS-499 based on the previous PCS-499 data and our findings in the literature that PTX has some pharmacological effects and clinical evidence that could be relevant to the treatment of NL.

The development program to date has included five Phase 1 studies, which were conducted to support the clinical pharmacology program for PCS-499, and one Phase 2 study in patients with chronic kidney disease (CKD) with Type 2 diabetes. Of the five Phase 1 studies, four were conducted by CoNCERT (CP505.1001, CP.505.1002, CP505.1003 and CP505.1004) and one by Processa (PCS499.1005). Four of the Phase 1 studies were conducted in healthy volunteers and one Phase 1 study was performed in patients with chronic kidney disease (CKD). Each of the Phase 1 studies was conducted to assess the safety, tolerability and pharmacokinetics of PCS-499 oral tablets. No serious adverse events related to PCS-499 have been experienced during the conduct of these studies.

The initial Phase 1 clinical trial (CP505.1002) evaluated the safety and pharmacokinetics in 16 healthy volunteers after administration of single doses of 400 mg of three different tablet formulations of PCS-499 (slow, medium, fast release), with comparison to Trental® (pentoxifylline) 400 mg extended-release tablets. A formulation was chosen from this study and was used in subsequent studies. The second Phase 1 trial (CP505.1001) assessed the safety and pharmacokinetics in 6 healthy volunteers after single ascending doses from 600 mg to 2400 mg of the modified release formulation tablets of PCS-499 as well as a single dose of PCS-499 immediate-release (IR) capsules. Doses of PCS-499 up to 1800 mg were well tolerated. The third study (CP505.1003) was designed to evaluate the safety and pharmacokinetics of 4 weeks of treatment with PCS-499 compared to placebo in non-dialysis patients associated with moderate CKD. Doses of PCS-499 administered in this study started with 600 mg once daily for 2 weeks, followed by 600 mg twice daily for 2 weeks. Four weeks of treatment with PCS-499 was found to be safe and well tolerated in the patients with moderate CKD in this study. The fourth study (CP505.1004) was designed to assess the effect of food on the bioavailability of single 600 mg doses of PCS-499 in 14 healthy volunteers. Based on the results of this study, the product appears to be better tolerated when administered with food. A fifth study (PCS499.1005) conducted by Processa, was a Phase 1 study to evaluate the safety and pharmacokinetics of single and optional multiple dosing regimens of modified release formulations of PCS-499 compared to Trental® (pentoxifylline) administered to healthy subjects under fed conditions. Part 1 was a single-dose administration of three modified release formulations of PCS-499 and Trental® to 12 healthy volunteers. Part 2 of the study was an open-label, 3-period crossover comparison in 6 healthy volunteers administration of two different dosage regimens of PCS-499 (900 mg twice daily or 600 mg three times a day) and Trental® after multiple dosing over 4 days. Administration of PCS-499 produced higher concentrations/exposures of the parent and primary metabolite (PCS-499 and D-PTX) on a per mg basis as compared to the concentrations/exposures of the parent and primary metabolite (PTX and PTX-M1) following PTX administration with no increase in frequency or severity of adverse events. From this study, a new modified release formulation was chosen based on the pharmacokinetics results and both dosage regimens of PCS-499 were shown to be well tolerated.

In addition to the Phase 1 studies, CoNCERT had previously conducted a Phase 2 study (CP505.2001) which was a randomized, double-blind, placebo-controlled multicenter study designed to assess the safety and efficacy of treatment with PCS-499 600 mg tablets orally, twice daily, in CKD patients with Type 2 diabetes receiving concomitant angiotensin-converting enzyme inhibitor (ACEi) and/or angiotensin II receptor blocker (ARB) therapy. This study included a 48-week double-blind, randomized, placebo-controlled period to evaluate the safety and efficacy of 600 mg PCS-499 twice daily in which 177 patients were enrolled. Of the patients that completed the double-blind period of the study, 102 patients chose to enroll in a 48-week open-label period (in which all patients received PCS-499). The primary endpoint of this Phase 2 study was the change after 24 weeks in urinary albumin to creatinine ratio (UACR), a marker of kidney tissue damage. The UACR outcomes at 24 weeks of treatment resulted in no significant differences between the PCS-499 and placebo groups. However, at 48 weeks, UACR in patients receiving PCS-499 increased 24 mg/g from baseline compared to 223 mg/g increase in patients receiving placebo ($p = 0.097$). While not statistically significant, the longer-term treatment duration suggests a favorable trend in UACR for patients receiving PCS-499 as compared to placebo.

At 48 weeks, a measurable impact on serum creatinine, a key secondary endpoint, was also observed. The mean serum creatinine level in patients receiving PCS-499 increased by 0.13 mg/dL compared to an increase of 0.21 mg/dL in patients receiving placebo through the 48 weeks of treatment ($p = 0.057$), reflecting 38% lower levels in the PCS-499 treatment group. Furthermore, 10.3% of patients receiving placebo experienced a 50% or greater increase in serum creatinine levels after 48 weeks compared with 1.5% of patients receiving PCS-499 ($p = 0.026$). In this Phase 2 study, the overall incidence of serious adverse events was consistent with what might be expected, given the target population studied and the underlying medical histories and characteristics of the patients. Of the patients enrolled in the double-blind phase of the study, a total of 33 patients experienced at least one serious adverse event (SAE) with no meaningful differences between treatment groups (18 (20.2%) of the PCS-499 patients and 15 (17.0%) of the placebo patients). Cardiac disorders were the most frequently reported SAEs, with 4 (4.5%) PCS-499 and 7 (8.0%) placebo patients experiencing at least one event in this system organ class. Infections and infestations (6 (6.7%) PCS-499 patients and 4 (4.5%) placebo patients) and vascular disorders (4 (4.5%) PCS-499 patients and 6 (6.8%) placebo patients) were the system organ classes with the next highest incidence of SAEs. Twelve (11.8%) of the 102 patients that entered the open-label treatment phase experienced at least one SAE during the open-label treatment phase, of which, infections and infestations (5 (4.9%) patients), cardiac disorders (3 (2.9%) patients), and renal and urinary disorders (3 (2.9%) patients), were the most frequently reported SAEs by the system organ class. All SAEs that occurred during the study (in both the double-blind and open-label periods) were judged to be not related to PCS-499. The most common adverse events associated with PCS-499 were gastrointestinal effects such as nausea, diarrhea and vomiting.

On June 22, 2018, the FDA granted orphan-drug designation to our leading clinical compound PCS-499 for treatment of NL. On September 28, 2018, the FDA cleared our IND for PCS-499 in NL to permit our Phase 2 study. Our first patient in this dose tolerance Phase 2a study received the first dose of PCS-499 on January 29, 2019. As of March 15, 2019, four additional patients have been enrolled in the study and have received at least one dose of PCS-499. All these patients have tolerated PCS-499 to date and are continuing in the study. Our trial is taking place at two sites: The University of Pennsylvania and University of Pittsburgh Medical Center (UPMC). Our hope is that all 12 patients planned for this study will be enrolled by June 2019.

In April 2018, we had an FDA Pre-IND meeting to better define the potential development program for PCS-499 in the treatment of RIF in head and neck cancer. With the FDA, we defined a development program, but have decided not to immediately pursue this indication until other potentially acquired drugs and PCS-499 indications could be evaluated. Our goal is to diversify the Processa portfolio by adding a second indication for PCS-499 and/or acquire additional drugs.

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 IND enabling studies to NDA submission. Our team'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. Although we believe that the skills and experience of our team in drug development and commercialization is an important indicator of our future success, the past successes of our team do not guarantee successful development and commercialization of our drugs. In addition, while our executive officers and directors previously served in companies that experienced substantial revenue growth, the growth was due to many factors. There is no guarantee that they will successfully operate or manage us or that we will experience similar growth in revenues, even if they continue to serve as executive officers and/or directors.

Current treatments for NL

The Necrobiosis Lipoidica condition is an idiopathic disease of the dermis, characterized by collagen degeneration, granuloma formation, fat deposition, and endothelial wall thickening. It is a chronic, disfiguring skin condition that develops on the pretibial region of the lower extremities but can also occur on other areas including the face, scalp, forearm, and trunk. NL usually presents initially as red papules that enlarge to form patches or plaques with an atrophic yellow center and is more common in women than in men.

Although more commonly found in diabetic patients, non-diabetic patients can also develop NL and the progression of the disease is not correlated with glycemic control. The disease is encountered in 0.3% - 1.2 % of the diabetic patients which represent 11% - 65% of the overall NL patient population. An association between underlying autoimmunity and the development of NL has been suggested based on the higher-than-expected prevalence of the disease in patients with Type 1 diabetes (as compared to Type 2 diabetes), as well as cases in patients with rheumatoid arthritis, Graves's disease, Hashimoto's thyroiditis, inflammatory bowel disease, and sarcoidosis. Ulceration occurs in approximately 30% of NL patients, which can lead to more severe complications, such as deep tissue infections and osteonecrosis that can threaten life of the limb. Rare cases of squamous cell carcinoma in the NL region have also been reported.

Although the pathogenesis of NL remains unclear, various potential mechanisms for development and progression of NL have been proposed. Firstly, the formation of granulomas possibly from impaired neutrophil migration, and antibody-mediated vasculitis, as well as the higher incidence of NL in several chronic inflammatory and autoimmune diseases suggest that inflammation and autoimmunity may be a significant contributor to this disease. Secondly, tissue hypoxia has been suggested to play an important role in the pathogenesis of NL based on the presence of angiopathy characterized by glycoprotein (particularly in diabetic patients) and immune complex deposition in blood vessels and lowered O2 tensions within NL lesions. Thirdly, enhanced platelet aggregation and coagulation has been speculated. Lastly, collagen abnormalities including fibrosis and increased collagen crosslinking in the basement membrane have also been hypothesized. Although these hypotheses have been postulated for decades, they have not yet been examined in a relevant disease model due to unavailability of such models.

No approved therapies exist for NL and current treatment approaches are based on empirical evidence. Potent topical steroids are often prescribed as first-line therapy, but use can lead to skin atrophy and scarring. Although intralesional steroids are also utilized, concern exists regarding the trauma of injection leading to exacerbation of existing wounds or new ulcerations. Other treatment regimens, including systemic corticosteroids, topical calcineurin inhibitors, anti-platelet agents, various immunosuppressants (chloroquine, thalidomide, TNF-alpha blockers, etc.), UV phototherapy, and skin grafting have been reported, but results have been inconsistent. For ulcerated lesions, proper wound care involving moisture control, infection control, conservative debridement, and compression therapy is also employed. Nonetheless, NL remains difficult to treat, especially in patients with ulcerations, and spontaneous resolution has been reported in only 13-19% of NL patients after 6-12 years.

Multiple clinical case reports have been published demonstrating the benefit of PTX in NL patients with and without ulceration, although PTX dose limiting side effects limits its use. In Phase 1 clinical studies, administration of PCS-499 produced higher concentrations/exposures of the parent and primary metabolite (PCS-499 and D-PTX) on a per mg basis as compared to the concentrations/exposures of the parent and primary metabolite (PTX and PTX-M1) following PTX administration with no increase in adverse events. Both the parents (PCS-499 and PTX) and primary metabolites (D-PTX and PTX-M1) similarly inhibit the secretion of pro-inflammatory cytokines (i.e., TNF-α, IFN-γ), as well as increase red blood cell flexibility and platelet deaggregation. Furthermore, concentrations of M5, which is associated with the hemorheological activity of PTX, was only slightly lower following PCS-499 administration than after PTX administration. Based on the pharmacological activity of PCS-499 and its metabolite profile, enhanced activity versus PTX may be seen with PCS-499 in NL. Thus, PCS-499 may benefit NL patients based on its enhanced inhibition of cytokines (TNF-α, IFN-γ) that induce inflammation and granuloma formation, as well as its effect on red blood cell deformability and promotion of platelet deaggregation, which can improve microcirculatory flow.

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 us with the third-party contractors providing the hands-on services to perform the studies. We purchase materials 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.

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

Our current patent portfolio consists of patents licensed from CoNCERT Pharmaceuticals for PCS-499 and related compounds. The portfolio includes approximately 26 issued patents (of which 8 are in the United States), that are directed to claims for composition of matter, methods of use and certain chemical processes. Of these, 3 issued patents in the U.S., as well as 2 in each of Europe, Australia, Canada, China, Japan and Mexico and 1 in each of Taiwan, Hong Kong, Russia, South Korea, the Philippines and South Africa cover the composition of matter of PCS-499. There are also approximately 4 pending patent applications for PCS-499 and related compounds directed to claims for composition of matter and methods of use, including 2 in the United States and 1 in each of Europe and Brazil. The issued U.S. and European patents are expected to expire in 2029 and 2030, excluding any extension or adjustment of patent term that may be available.

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

License Agreement with CoNCERT Pharmaceuticals, Inc.

On October 4, 2017, Promet entered into the CoNCERT Agreement with CoNCERT. On March 19, 2018, we, Promet, and CoNCERT entered into an Amended Option Licensing Agreement ("March Amendment") that, among other things, assigned the CoNCERT Agreement from Promet to us and we exercised the exclusive commercial license option for the PCS-499 compound from CoNCERT.

The CoNCERT Agreement provides us with an exclusive (including to CoNCERT) royalty-bearing license to CoNCERT's patent rights and know-how to develop, manufacture, use, sub-license and commercialize compounds (PCS-499 and each metabolite thereof) and pharmaceutical products with such compounds worldwide. We are required to pay CoNCERT royalties, on a product by product basis, on worldwide net sales, as follows:

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

We will incur royalty obligations to CoNCERT on a country-by-country and product-by-product basis that expire on a country-by-country and product-by-product basis on the later of (i) expiration or invalidation of the last patent rights covering such product in such country or (ii) the tenth anniversary of the date of the first commercial sale to a non-sublicensee third party of such product in such country. The March Amendment provides that if we sublicense any of the intellectual property licensed to us by CoNCERT to a third party prior to the earliest date that (a) we raise gross proceeds of at least $8.0 million in one or more equity offerings and (b) CoNCERT can sell the shares of common stock released to it by Promet upon execution of the March Amendment without restriction under Rule 144(b)(1), then we must pay CoNCERT 15% of such revenue.

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

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

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:

(i) Preclinical studies;
(ii) Submission of an Investigational New Drug Application or IND, for clinical trials;
(iii) Adequate and well-controlled human clinical trials to establish safety and efficacy of the product;
(iv) Review of a New Drug Application, or NDA; and
(v) Inspection of facilities used in the manufacturing of the drug to access 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 healthy human volunteers 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. An 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 an 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 Regulations

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 March 15, 2019, we had 15 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, or do not have a class of securities registered under the Exchange Act) are required to comply with such new or revised financial accounting standards. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. 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.

Tax-Free Combination with Heatwurx

On October 2, 2017, Heatwurx, Inc. ("Heatwurx") entered into a tax-free transaction pursuant to the Asset Purchase Agreement with Promet Therapeutics, LLC, a Delaware limited liability company ("Promet") pursuant to which, on October 4, 2017, Heatwurx acquired all the net assets of Promet, including the rights to the CoNCERT Agreement in exchange for issuing Promet (and CoNCERT) 31,745,242 shares of its common stock. Immediately following the transaction, Promet owned approximately 84% of our common stock and, as part of the Section 351 transaction, held approximately 6% of our common stock for the benefit of CoNCERT, until the CoNCERT transaction had been concluded whereupon CoNCERT took title to their shares. Following the closing, we changed our name from "Heatwurx Inc." to "Processa Pharmaceuticals Inc." and abandoned Heatwurx's prior business plan. We are now pursuing Promet's historical and proposed business.

We accounted for the net asset acquisition transaction as a reverse acquisition in accordance with U.S. GAAP, Financial Accounting Standards Board ("FASB"), Accounting Standards Codification ("ASC") 805-40-45, *Business Combinations – Reverse Acquisitions,* where Promet was considered the accounting acquirer, and as a tax-free contribution for tax purposes under Internal Revenue Code Section 351. Accordingly, Promet's historical results of operations replaced our historical results of operations for all periods prior to the Merger. Unless otherwise stated, all comparisons in this Management's Discussion and Analysis to prior year periods are to the results of Promet for such period on a stand-alone basis. Prior to the acquisition, we had nominal net liabilities and operations. It was considered a non-operating public shell corporation.

In December 2017, we effected a one-for-seven reverse split of our shares of common stock. The accompanying consolidated financial statements and notes give retroactive effect to this one-for-seven reverse stock split.

Business Segments

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

Corporate Information

Processa (formerly Heatwurx) was incorporated under the laws of the State of Delaware on March 29, 2011. Our principal executive offices are located at 7380 Coca Cola Drive, Suite 106, Hanover, Maryland 21076, and our telephone number at that address is (443) 776-3133.

We make available free of charge on or through our Internet website (*http://www.processapharmaceuticals.com*) our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (SEC). The SEC also maintains a website which provides on-line access to reports and other information regarding registrants that file electronically with the SEC at: www.sec.gov.

The information contained on our website and social media channels is not included as a part of, or incorporated by reference into, this report.

Directors and Executive Officers

The table below sets forth, as of March 15, 2019, certain information concerning our current directors and executive officers. No family relationships exist among any of our directors or executive officers

Name	Age	Position with Processa
David Young, Pharm.D., Ph.D	66	Director and Chief Executive Officer
Sian Bigora, Pharm.D.	58	Chief Development Officer
Wendy Guy	54	Chief Administrative Officer
Patrick Lin	53	Director and Chief Business & Strategy Officer
James Stanker	61	Chief Financial Officer
Justin Yorke	52	Director
Virgil Thompson	79	Director

David Young, Pharm.D., Ph.D. - 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. He served as our interim CFO from October 4, 2017 to September 1, 2018. From 2006 to 2009, prior to joining the Questcor executive management team, Dr. Young served as an independent Director on the Questcor Board of Directors. During this time, the Board mandated a change in the business model from a sales force driven specialty pharmaceutical company to an orphan disease specialty pharmaceutical company. As an independent director, Dr. Young, representing Questcor, worked with the FDA in developing a process to obtain approval for Acthar (the only commercial product owned by Questcor) in Infantile Spasms (IS), a deadly and debilitating very rare orphan indication. In 2009, Dr. Young joined the Questcor executive management team as Chief Scientific Officer (CSO) in order to obtain IS FDA approval and market exclusivity by completing the New Drug Application (NDA) process, working with FDA on modernizing the label, and leading all aspects of approval including the Advisory Committee Meeting that voted to approve the NDA for IS. During the eight years that Dr. Young was involved with Questcor as an independent director and as its CSO, Questcor transitioned to an orphan drug specialty pharmaceutical company, moving from an outdated Acthar label and near bankruptcy in 2007 to a modernized Acthar label that helped it to achieve sales greater than $750M per year and the ultimate sale of the company for approximately $5.6 billion in 2014. While serving on Questcor's Board of Directors, Dr. Young was Executive Director & President, U.S. Operations of AGI Therapeutics plc. Dr. Young has also served as the Executive Vice President of the Strategic Drug Development Division of ICON plc, an international CRO, and was the Founder and CEO of GloboMax LLC, a CRO specializing in FDA drug development, purchased by ICON plc in 2003. Prior to forming GloboMax, Dr. Young was a Tenured Associate Professor at the School of Pharmacy, University of Maryland, 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 Guidances, 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.

Sian Bigora, Pharm.D. - 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 - 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.

Patrick Lin - 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 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.

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

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

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

Item 1A. Risk Factors

An investment in our securities involves a high degree of risk. If any of the following risks actually occur, our business, financial condition, or results of operations could be materially adversely affected, the trading price of our common stock could decline, and you may lose all or part of your investment. You should also refer to the other information contained in this Form 10-K, including our consolidated financial statements and the notes to those statements, and the information set forth under the caption "Cautionary Note Regarding Forward-Looking Statements." The risks described below and contained in our other periodic reports are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also adversely affect our business operations.

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 $3.3 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 approximately $7.6 million at December 31, 2018. We 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 have limited cash resources and will require additional financing.

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

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

We 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 our ability to continue as a going concern as of the date of the filing of this annual report on Form 10-K and our auditors have included a going concern paragraph in their Report of Independent Registered Public Accounting Firm. The accompanying consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of recorded assets, or the amounts and classification of liabilities that might be different should we be unable to continue as a going concern based on the outcome of these uncertainties described above.

Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to our technology or product candidates.

We may seek additional capital through a combination of private and public equity offerings, debt financings, receivables or royalty financings, strategic partnerships and alliances and licensing arrangements. We do not currently have any committed external source of funds other than the $1.8 million committed by PoC Capital. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt, receivables and royalty financings may be coupled with an equity component, such as warrants to purchase stock, which could also result in dilution of our existing stockholders' ownership. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business and may result in liens being placed on our assets and intellectual property. If we were to default on such indebtedness, we could lose such assets and intellectual property. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us.

Risks Relating to Clinical Development and Commercialization of Our Product Candidates

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

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

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

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

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

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

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

We are not permitted to market our product candidates as prescription pharmaceutical products in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries. 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, European Medicines Agency ("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 little corporate history of conducting clinical trials. Our planned clinical trials or those of our collaborators may reveal significant adverse events, toxicities or other side effects not seen in our preclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.

Our operations to date have been limited to financing and staffing, conducting research and developing our core technologies, identifying and optimizing our lead product clinical candidates, performing due diligence on other potential drug in-licensing opportunities, receiving FDA orphan designation on PCS-499 in Necrobiosis Lipoidica (NL), improving the manufacturing of PCS-499 final product, receiving FDA IND clearance on one indication, conducting one healthy human volunteer trial and presently conducting a Phase 2 PCS-499 clinical trial in patients with NL. Although we have recruited a team that has experience with clinical trials in the United States and outside the United States, as a company, we have only conducted two clinical trials in any jurisdiction and have not had previous experience commercializing product candidates through the FDA or similar submissions to initiate clinical trials or obtain marketing authorization to foreign regulatory authorities. We cannot be certain that other planned clinical trials will begin or be completed on time, if at all; that our development program and studies would be acceptable to the FDA or other regulatory authorities; or that, if regulatory approval is obtained, our product candidates can be successfully commercialized. Clinical trials and commercializing our product candidates will require significant additional financial and management resources, and reliance on third-party clinical investigators, contract research organizations ("CROs"), consultants and collaborators. Relying on third-party clinical investigators, CROs or collaborators may result in delays that are outside of our control.

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

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.

Through our IND, we are conducting a Phase 2 safety tolerability evaluation of PCS-499 in patients with NL. We and the FDA have assumed that the drug will be tolerated and safe at 900 mg b.i.d. (twice daily) or 600 mg t.i.d. (thrice daily) based on our past experience with the drug in a healthy human volunteer study, the experience of CoNCERT Pharmaceuticals in healthy human volunteers and patients with diabetic nephropathy studies, and the preclinical toxicology data and studies involving diabetic nephropathy patients. However, we do not know if the drug dosed at the 1,800 mg per day dose (900 mg b.i.d. or 600 mg t.i.d.) will be safe and tolerated in patients with NL. Given NL patients are mainly women and multiple pathophysiological changes have occurred in their body from the NL, the NL patients could be more sensitive to the drug, thus decreasing their ability to tolerate PCS-499. If this occurs, there may not be any way to differentiate PCS-499 from PTX thus making development and commercialization of PCS-499 in NL not worth pursuing.

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

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

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

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

- demonstration of clinical safety and efficacy;
- relative convenience, dosing burden and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe our product candidates, and the target patient population to try new therapies;
- efficacy of our product candidates compared to competing products;
- the introduction of any new products that may in the future become available targeting indications for which our product candidates may be approved;
- new procedures or therapies that may reduce the incidences of any of the indications in which our product candidates may show utility;
- pricing and cost-effectiveness;
- the inclusion or omission of our product candidates in 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.

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.

To date, we are using PCS-499 originally manufactured for CoNCERT Pharmaceuticals. Since PCS-499 is a deuterated molecule requiring special facilities and chemicals for manufacturing, the manufacturing costs for PCS-499 could result in the cost of goods being too high for the commercial price to be obtainable or even too high to even manufacture the amount of drug needed to run the clinical studies prior to approval.

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

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or comparable foreign regulatory authorities pursuant to inspections that will be conducted after we submit an NDA or biologics license application to the FDA or their equivalents to other relevant regulatory authorities. We will not control the manufacturing process of, and will be completely dependent on, our contract manufacturing partners for compliance with cGMPs 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.

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, 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, 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 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, regulatory review or approval process.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Relating to Our Intellectual Property Rights

We depend on rights to certain pharmaceutical compounds that are or will be licensed to us. We do not 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 current patent portfolio consists of patents licensed from CoNCERT Pharmaceuticals for PCS-499 and related compounds that are directed to claims for composition of matter, methods of use, and certain processes. This includes approximately 26 issued patents (including 8 in the United States, 2 in Europe, and 2 in Japan) and approximately 7 pending patent applications (including 3 in the United States and 2 in Europe). The issued U.S., European, and Japanese patents are expected to expire in 2029 and 2030, excluding any extension or adjustment of patent term that may be available.

In addition, we do not own any intellectual property rights, including any patents that underlie our drug candidates. These drugs are in-licensed from other biotech or pharmaceutical companies and our rights to develop and commercialize the product candidates we license are subject to the validity of the owner's intellectual property rights. All of our product candidates are either in the early stages of clinical development or late stages of preclinical development and we have only recently initiated a clinical trial and 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 our drug candidates. 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.

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. Our license agreements with CoNCERT Pharmaceuticals include provisions that allow the licensor to terminate the license if (i) we breach any payment obligation or other material provision under the agreement and fail to cure the breach within a fixed time following written notice of termination, (ii) we or any of our affiliates, licensees or sublicensees directly or indirectly challenge the validity, enforceability, or extension of any of the licensed patents, or (iii) we declare bankruptcy or dissolve. 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 also 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 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 total of 15-20 full-time or part-time employees or consultants. As our development and commercialization plans and strategies develop, we may need to expand the size of our employee and consultant/contractor base. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

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

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

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 U.S., 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 have obtained 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.

Because we do not currently have an audit committee, compensation committee or any other form of corporate governance committee, stockholders will have to rely on our directors, a majority of which are not independent, to perform these functions.

We currently do not have an audit committee, compensation committee or any form of corporate governance committees. The Board, a majority of which is not independent, performs these functions as a whole. Our Board is in the process of establishing certain committees; however, until such committees and controls are formally established, there is a potential conflict in that board members who are also part of management will participate in discussions concerning management compensation and audit issues that may affect management decisions.

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 us 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.

We identified a material weakness in our internal control over financial reporting. The specific material weakness and our remediation efforts are described in Item 9A, "Controls and Procedures" of this Annual Report on Form 10-K in "Disclosure Controls and Procedures." A "material weakness" is a deficiency, or a combination of deficiencies, in internal controls, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements would not be prevented or detected. We cannot assure you that additional material weaknesses in our internal controls will not be identified in the future. Any failure to maintain or implement required new or improved controls, or any difficulties we encounter in their implementation, could result in additional material weaknesses, or could result in material misstatements in our financial statements. These misstatements could result in restatements of our financial statements, cause us to fail to meet our reporting obligations or cause investors to lose confidence in our reported financial information.

Our assessment has indicated we have material weaknesses related to certain entity level controls; inadequate segregations of duties throughout the entire year; and our formal documentation of certain policies and procedures, their related controls, and the operation thereof. We recently expanded our finance team, hiring a Director of Finance and Accounting in July 2018 and our CFO in September 2018. We are developing remediation steps to our material weakness and to improve our internal controls and are in the process of implementing more fully documented formal policies and procedures. For more information relating to our internal controls and disclosure controls and procedures, and the remediation plan undertaken by us, see Item 9A, "Controls and Procedures" of this Annual Report on Form 10-K. 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 are exposed to cyber-attacks and data breaches, including the risks and costs associated with protecting our systems and maintaining integrity and security of our business information, as well as personal data of our guests, employees and business partners.

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

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

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

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

Risks Related to Ownership of Our Common Stock

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;
- negative 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 OTCQB 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 OTCQB. The OTCQB is viewed by investors as a 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 may 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 March 15, 2019, our directors, executive officers and their respective affiliates beneficially owned or controlled approximately 84% of our outstanding shares of common stock (and have owned such approximately 84% since the combination of Promet and Heatwurx). As a result, these stockholders and our officers and directors, collectively, 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; therefore, you may find it difficult to sell shares of our common stock.

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.

Sales of substantial amounts of our common stock under Rule 144 in the public markets could cause the market price of our common stock to decline.

Substantial amounts of our common stock may be sold under Rule 144 into the public market which may adversely affect prevailing market prices for the common stock and could impair our ability to raise capital in the future through the sale of equity securities. Rule 144 permits a person who presently is not and who has not been an affiliate of ours for at least three months immediately preceding the sale and who has beneficially owned the shares of common stock for at least six months to sell such shares without restriction other than the requirement that there be current public information as set forth in Rule 144. If a non-affiliate has held the shares for more than one year, such person may make unlimited sales pursuant to Rule 144 without restriction. Shares held by directors, executive officers, and other affiliates will also be subject to volume limitations under Rule 144 under the Securities Act.

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

We have never 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 our valuation will appreciate in value or even maintain the valuation at which our stockholders have purchased their shares.

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

Our Amended and Restated Certificate of Incorporation allow our Board of Directors to issue up to 10,000,000 shares of preferred stock. Currently, no shares of preferred stock are issued and outstanding. However, we can issue shares of our preferred stock in one or more series and can set the terms of the preferred stock without seeking any further approval from the holders of our common stock. Any preferred stock that we issue may rank ahead of our common stock in terms of dividend priority or liquidation premiums and may have greater voting rights than our common stock. In addition, such preferred stock may contain provisions allowing it to be converted into shares of common stock, which could dilute the value of our common stock to then current stockholders and could adversely affect the market price, if any, of our common stock.

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

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

Item 1B. Unresolved Staff Comments

None

Item 2. Properties.

Our principal executive office is located at 7380 Coca Cola Drive, Suite 106, Hanover, MD 21076. We currently lease approximately 6,500 square feet of office space at this location under a three-year lease agreement. In January 2019, we extended our current lease which was scheduled to expire in September 2019 for an additional three-year term at a cost comparable to our current lease.

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 common stock commenced trading on the OTCQB on December 8, 2018 under the symbol "PCSA." Prior to December 8, 2018, we traded on the OTC Pink Marketplace. The following table shows the high and low prices of our common shares as quoted by the OTCQB or the OTC Pink Marketplace, as applicable, for each calendar quarter during 2018 and 2017. The quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions:

Quarter Ended	High	Low
December 31, 2018	$ 4.35	$ 1.70
September 30, 2018	$ 4.78	$ 2.50
June 30, 2018	$ 4.70	$ 3.25
March 31, 2018	$ 5.00	$ 2.60
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

The market price of our common stock, like that of other emerging pharmaceutical companies focusing on clinical development, is highly volatile and is subject to fluctuations in response to variations in operating results, announcements of technological innovations or new products, or other events or factors. Our stock price may also be affected by broader market trends unrelated to our performance.

Holders

As of March 15, 2019, there were 38,674,265 shares of common stock outstanding and 195 shareholders of record.

Transfer Agent and Registrar

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

Dividend Policy

We have not previously declared or paid any dividends on our common stock and do not intend to do so in the near future. We intend to retain any future earnings to fund ongoing operations and future capital requirements of our business. Any future determination to pay cash dividends will be at the discretion of the Board of Directors and will be dependent upon our financial condition, results of operations, capital requirements and such other factors as the Board of Directors deems relevant.

Securities Authorized for Issuance under Equity Compensation Plans

The table below provides information as to our Amended and Restated 2011 Equity Incentive Plan as of December 31, 2018.

	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	50,000	$ 3.47	207,143
Equity compensation plans not approved by security holders	334,400	$ 2.84	-
Total	384,400		207,143(1)

(1) Consists of shares available for issuance under the Amended and Restated 2011 Equity Incentive Plan.

Recent Sales of Unregistered Securities

We did not sell any unregistered securities during the fourth quarter of 2018.

Repurchases of Equity Securities

We did not repurchase any shares of our common stock during the fourth quarter of 2018.

Item 6. Selected Financial Data

Not applicable.

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

Overview

We are 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 multiple indications (i.e., the use of a drug to treat a particular disease) and searching for additional products for our portfolio.

On October 4, 2017, we acquired all the net assets of Promet Therapeutics, LLC ("Promet) a private Delaware limited liability company, including the rights to the CoNCERT Agreement in exchange for 31,745,242 shares of our common stock. Immediately following the transaction, the former equity holders of Promet owned approximately 84% and held approximately 6% of the shares for the benefit of CoNCERT in relation to the CoNCERT contribution of the license to Processa as part of the Section 351 transaction, and our stockholders immediately prior to the transaction owned approximately 10% of our common stock. Following the completion of the transaction, we changed our corporate name from "Heatwurx Inc." to "Processa Pharmaceuticals Inc." and changed our common stock's trading symbol from "HUWX" to "PCSA." We traded on the OTC Pink Marketplace until December 8, 2018 when we listed our common stock on the OTCQB.

We accounted for the net asset acquisition transaction as a "reverse acquisition" merger under the acquisition method for GAAP, where Promet was considered the accounting acquirer; and for tax purposes, as a tax-free contribution under Internal Revenue Code Section 351. Accordingly, Promet's historical results of operations replaced our historical results of operations for all periods prior to the merger. Unless otherwise stated, all comparisons in this Management's Discussion and Analysis to periods prior to the merger are to the results of Promet for such period on a stand-alone basis. Prior to the acquisition, we had nominal net liabilities and operations. It was considered a non-operating public shell corporation.

In December 2017, we effected a one-for-seven reverse split of our shares of common stock. The accompanying 2017 consolidated financial statements and notes give retroactive effect to this one-for-seven reverse stock split.

We have a limited operating history as we were formed on March 29, 2011. Since that date, our operations have focused on acquiring the rights to PCS-499, organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and conducting clinical trials. We do not have any drug candidates approved for sale and have not yet generated any revenue from drug sales. We have funded our operations through the private sale of equity and equity-linked securities to accredited investors. Since inception, we have incurred operating losses. As of December 31, 2018, we had an accumulated deficit of $7.6 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- continue to invest in the development of PCS-499 for the treatment of NL;
- manufacture our drug candidate;
- hire additional research and development and general and administrative personnel;
- maintain, expand and protect our intellectual property portfolio;
- evaluate opportunities for the development of additional drug candidates; and
- incur additional costs associated with operating as a newly formed public company.

Going Concern and Management's Plan

Our consolidated financial statements are prepared using U.S. GAAP and are based on the assumption that we will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. We face certain risks and uncertainties 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 raised substantial doubt about our ability to continue as a going concern as of the date of the filing of this annual report on Form 10-K for the year ended December 31, 2018.

We have relied exclusively on private placements with a small group of accredited investors to finance our business and operations. We do not have any credit facilities as a source of future funds. We have not had any revenue since our inception on August 31, 2015 and we do not currently have any revenue under contract or any immediate sales prospects. As of December 31, 2018, we had an accumulated deficit of approximately $7.6 million. For the year ended December 31, 2018, we incurred a net loss from continuing operations of approximately $3.8 million and used approximately $3.7 million in net cash from operating activities. We expect our operating costs to be substantial as we incur costs related to the clinical trials for our product candidates and that we will operate at a loss for the foreseeable future.

As further described under Recent Developments, since December 31, 2017 we have received proceeds of approximately $3.2 million dollars from the sale of 1,402,442 shares of our common stock and warrants to purchase the same number of shares of common stock exercisable at $2.724 per share. We also entered into an agreement with an investor for a commitment to fund up to $1.8 million of clinical trial expenses in exchange for 792,952 shares of our common stock and warrants to purchase the same number of shares of common stock exercisable at $2.724 per share. We will use these committed funds for our Phase 2a clinical trial of PCS-499 in patients with NL. Payment under this commitment will be made directly to the CRO based on their invoicing and not to us. Finally, on May 25, 2018, we converted approximately $2.35 million of our 8.0% Convertible Notes into 1,206,245 shares of our common stock and 1,206,245 warrants to purchase common stock.

We are looking at ways to add an additional revenue stream to offset some of our expenses. We are planning on raising additional funds in the first half of 2019. In addition, we are seeking alternative options to add additional cash. However, no assurance can be given that we will be successful in securing adequate funds that may be required. 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.

As a result, substantial doubt existed about our ability to continue as a going concern as of the date of the filing of our annual report on Form 10-K for the year ended December 31, 2018. 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.

Recent Developments

Phase 2a Study and Orphan Drug Designation. On June 22, 2018, the FDA granted orphan-drug designation to our leading clinical compound PCS-499 for the treatment of NL. On September 28, 2018, the FDA cleared our IND for PCS-499 in NL such that we could move forward with the Phase 2 study. Our first patient in this dose tolerance Phase 2a study received their first dose of PCS-499 on January 29, 2019. As of March 15, 2019, four additional patients have been enrolled in the study and have received at least one dose of PCS-499. All these patients have tolerated PCS-499 to date and are continuing in the study. Our trial is taking place at two sites: The University of Pennsylvania and University of Pittsburgh Medical Center (UPMC). Our hope is that all 12 patients planned for this study will be enrolled by June 2019, which we believe is on track to occur.

CoNCERT License Agreement. On October 4, 2017, Promet entered into an option and license agreement (the "CoNCERT Agreement") with CoNCERT Pharmaceuticals, Inc. ("CoNCERT"), which was thereafter transferred, contributed, and assigned to Processa. On March 19, 2018, we, Promet, and CoNCERT entered into an agreement (the "March Amendment") that, among other things, completed the assignment of the CoNCERT Agreement from Promet to us allowing us to exercise the exclusive commercial license option for the PCS-499 compound from CoNCERT. Our agreement with CoNCERT, along with raising additional financing, was contemplated as part of the reverse acquisition of Heatwurx by Promet. The March Amendment also amended the CoNCERT Agreement to provide: (i) for the immediate transfer and release of $8.0 million of our common stock that was held for the benefit of CoNCERT by Promet (2,090,301 shares) to CoNCERT and (ii) that if we sublicense any of the intellectual property licensed to us by CoNCERT to a third party prior to the earliest date that (a) we raise gross proceeds of at least $8.0 million in one or more equity offerings and (b) CoNCERT can sell the shares of common stock released to it by Promet without restriction under Rule 144(b)(1), then we must pay CoNCERT 15% of such revenue. All other terms of the CoNCERT Agreement, including the royalty amounts that would be due to Concert on the sale of products remain unchanged. As a result, we recognized an intangible asset of approximately $11.0 million, additional paid-in capital of $8.0 million resulting from Promet releasing the earmarked shares to CoNCERT in satisfaction of our obligation to CoNCERT, along with a $3.0 million deferred tax liability related to the acquired temporary difference for an asset purchased that is not a business combination and has a nominal tax basis.

PIPE Transactions. On May 15, 2018, and June 29, 2018, we entered into Subscription and Purchase Agreements with certain accredited investors and conducted closings pursuant to which we sold 1,402,442 shares of common stock at a purchase price of $2.27 per share. In addition, each investor received a warrant to purchase one share of common stock for each share of common stock purchased by such investor at an exercise price equal to $2.724, subject to adjustment thereunder. We received total gross proceeds of approximately $3.2 million prior to deducting placement agent fees and estimated expenses payable by us. We currently intend to use the proceeds of the transaction to fund research and development of our lead product candidate, PCS-499, including clinical trial activities, and for general corporate purposes. Our placement agent received $167,526 and a warrant to purchase up to 84,146 shares of common stock at an exercise price equal to $2.724. We also incurred costs totaling $141,304 related to this transaction and our contractual obligations to file a resale registration statement related to the PIPE transaction with the SEC.

Clinical Trial Funding. On May 25, 2018, we entered into an agreement with an accredited investor to whom we sold 792,952 shares of common stock at a purchase price of $2.27 per share for a clinical funding commitment of $1.8 million. We will use these committed funds for our Phase 2a clinical trial of PCS-499 in patients with NL. The investor will typically make payments not to us, but rather directly to the CRO conducting our Phase 2 Necrobiosis Lipoidica Trial based on their invoicing. The investor also received warrants to purchase one share of common stock for each share of common stock purchased at an exercise price equal to $2.724 per share. As of December 31, 2018, we have made payments totaling approximately $239,000 to our CRO. Subsequent to December 31, 2018, our Clinical Trial Funding investor has made payments to our CRO totaling $115,000 for amounts being currently invoiced. We expect the investor to repay us within the next year, as well as continue to make payments to our CRO for outstanding and future invoices related to our Phase 2a trial. Our placement agent received $108,000 and a warrant to purchase up to 47,578 shares of common stock at an exercise price equal to $2.724. We also incurred costs totaling $60,457 related to this transaction and our contractual obligations to file a resale registration statement related to the Clinical Trial Funding commitment transaction with the SEC.

We accounted for payments we made to our CRO in 2018 as either a prepaid expense or a research and development expense depending on whether the related service has been provided. Since the amount of the Clinical Trial Funding commitment has not changed, we continue to show the full amount of that commitment, $1.8 million, as a subscription receivable. We will reduce the subscription receivable in the period the investor makes payment to our CRO or us.

Note Conversion. On May 25, 2018, we converted approximately $2.35 million of our mandatory convertible 8.0% Senior Notes and accrued interest of $109,472 into 1,206,245 shares of common stock, at a price of $2.043 per share. The noteholders also received warrants to purchase one share of common stock for each share of common stock purchased at an exercise price equal to $2.452. Our placement agent received a warrant to purchase 72,375 shares of common stock at an exercise price of $2.452. We also incurred costs totaling $82,502 related to this transaction and our contractual obligations to file a resale registration statement related to transaction with the SEC.

The common stock, but not the warrants, issued in the PIPE Transactions, the clinical trial funding and the note conversion have, subject to certain customary exceptions, full ratchet anti-dilution protection. Until we have issued equity securities or securities convertible into equity securities for a total of an additional $20.0 million in cash or assets, including the proceeds from the exercise of the warrants issued above, in the event we issue additional equity securities or securities convertible into equity securities at a purchase price less than $2.27 per share of common stock, the above purchase prices shall be adjusted and new shares of common stock issued as if the purchase price was such lower amount (or, if such additional securities are issued without consideration, to a price equal to $0.01 per share).

Results of Operations

Comparison of the year ended December 31, 2018 and 2017

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

	Year Ended December 31,		
	2018	2017	Change
Operating Expenses			
Research and development costs	$ 3,085,317	$ 964,164	$ 2,121,153
General and administrative expenses	1,439,623	838,269	601,354
Total operating expenses	4,524,940	1,802,433	2,722,507
Other Income (Expense)			
Interest expense	(161,205)	(59,063)	(102,142)
Interest income	18,297	5,181	13,116
Total other income (expense)	(142,908)	(53,882)	(89,026)
Net Operating Loss Before Income Tax Benefit	(4,677,848)	(1,856,315)	(2,811,533)
Income Tax Benefit	902,801	-	902,801
Net Loss	$ (3,765,047)	$ (1,856,315)	$ (1,908,732)

Revenues.

We do not currently have any revenue under contract or any immediate sales prospects.

Research and Development Expenses.

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

During the years ended December 31, 2018 and 2017, we incurred total research and development expenses of $3,085,317 and $964,164, respectively, for the continued development and testing of our lead product, PCS-499. A majority of costs incurred in 2017 and all the costs incurred in 2018 relate to the development of PCS-499.

On March 19, 2018, we exercised the License and Option Agreement with CoNCERT for PCS-499 that we entered into on October 4, 2017.

Costs for the years ended December 31, 2018 and 2017 were as follows.

	Year ended December 31, 2018	Year ended December 31, 2017
Amortization of intangible assets	$ 621,647	$ -
Research and development salaries and benefits	650,702	520,734
Preclinical, clinical trial and other costs	1,812,968	443,430
Total	$ 3,085,317	$ 964,164

During the year ended December 31, 2018, our research and development costs increased by $2,121,153 to $3,085,317 from $964,164 for year ended December 31, 2017.

As we noted above, 2018 was a year of significant events related to our continued development of PCS-499, including:

- in March 2018, exercising the CoNCERT license and option agreement for PCS-499;
- in June 2018, the FDA granting us orphan-drug designation to our leading clinical compound PCS-499 for the treatment in NL;
- in August 2018, completing a healthy human volunteer study demonstrating that PCS-499 was well tolerated and had the potential to be more beneficial in NL than existing drugs used off-label;
- in December 2018, began recruiting and screening patients for our 12-patient Phase 2 study “A Study to Evaluate the Safety and Tolerability of PCS-499 for the Treatment of Necrobiosis Lipoidica”; and
- in January 2019, we began dosing our patients with PCS-499.

As a result of exercising the CoNCERT license and option agreement for PCS-499 in March 2018, and the purchase of a software license, we recognized $621,647 of amortization expense during the year ended December 31, 2018. We had no similar expense in 2017. During 2018, we completed a Phase 1 study to evaluate the safety and pharmacokinetics of single and optional multiple dosing regimens of modified release formulations of PCS-499 compared to Trental® (pentoxifylline) administered to healthy subjects. We also incurred costs to establish a new site to contract manufacture the tablets of PCS-499 needed for our clinical trial since the original CoNCERT tablet manufacturing site could no longer be used. Our research and development salaries and benefits increased by $129,968 for the year ended December 31, 2018 when compared to the same period in 2017 related to an increase in full-time equivalent staff and related staff costs. We recognized higher research and development expenses for preclinical, clinical trial and other costs of $1,369,538 during the year ended December 31, 2018 when compared to the same period in 2017 due to the completion of our Phase 1 pharmacokinetics study described above, the scaling up of the manufacture of clinical trial material we will need for the Phase 2a clinical trial for NL, beginning our Phase 2a clinical study in fourth quarter of 2018, and for other research and development costs that we incurred. We anticipate most of the research and development costs going forward into 2019 will be related to our current Phase 2a clinical trial for NL. We will also incur additional costs when we need to manufacture additional clinical material as we currently do not have enough to complete our Phase 2a clinical trial.

During the early part of 2017, we were finalizing a contract we had with Drexel University that officially terminated in June 2017. We incurred nominal costs in 2017 in connection with the contract we had with Drexel University. Most of the research and development costs incurred in 2017 related to PCS-499.

We anticipate our research and development costs to increase in the future as we continue our Phase 2a clinical trial activities for NL in 2019. We anticipate the cost of our current Phase 2a trial to be approximately $1.6 to $1.8 million. We incurred $519,531 of costs related to this trial in 2018, and anticipate $481,200 will be incurred in 2019 with the remainder in 2020. We believe the Clinical Trial Funding commitment of $1.8 million dollars we executed in March 2018 will be sufficient to fund the costs of this trial. The funding necessary to bring a drug candidate to market is however subject to numerous uncertainties. Once a drug candidate is identified, the further development of that drug candidate can be halted or abandoned at any time due to a number of factors. These factors include, but are not limited to, funding constraints, safety or a change in market demand. For each of our drug candidate programs, we periodically assess the scientific progress and merits of the programs to determine if continued research and development is economically viable. Certain of our programs may be terminated due to the lack of scientific progress and lack of prospects for ultimate commercialization.

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.

During the year ended December 31, 2018, we made payments related to our Phase 2a trial totaling approximately $239,000 to our CRO. Our Clinical Trial Funding investor has, subsequent to year end, made payments to our CRO totaling $115,000 for amounts being currently invoiced. We expect the investor to repay us, as well as continue to make payments to our CRO for outstanding and future invoices related to our Phase 2a trial. We have accounted for payments we made to our CRO in 2018 as either a prepaid expense or a research and development expense depending on whether the related service has been provided. Since the amount of the Clinical Trial Funding commitment has not changed, we continue to show the full amount of that commitment, $1.8 million, as a subscription receivable. We will reduce the subscription receivable in the period the investor makes payment to our CRO or us.

General and Administrative Expenses.

Our general and administrative expenses for the year ended December 31, 2018 increased by $601,354 to $1,439,623 from $838,269 for the year ended December 31, 2017. The increase related primarily to professional fees for legal, accounting, advisory and consulting costs of approximately $223,000 related to our operations and compliance and other costs of operating as a public company. During 2018, we experienced increased payroll, and related costs of approximately $199,000 as we build our finance team, including hiring a Chief Financial Officer and a Director of Finance and Accounting to support our growth and public company reporting and compliance requirements. Included in this amount is stock-based compensation of $74,063. During 2018, we also incurred a cybersecurity fraud loss of approximately $144,000 for which we did not have insurance coverage. The remaining increase in our general and administrative expense was due to additional administrative costs such as insurance, office expenses, continuing education, and travel. Reimbursements from CorLyst of $107,402 for rent and other costs during the year ended December 31, 2018 were approximately $4,000 less than reimbursements for the same period in 2017.

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

Interest Expense.

Interest expense was $161,205 and $59,063 for the years ended December 31, 2018 and 2017, respectively related to our $2.58 million of 8% Senior Notes sold in 2017. In March 2018, $2.35 million of these Senior Convertible Notes were converted into shares of our common stock and stock purchase warrants. Included in interest expense is the amortization of debt issuance costs totaling $67,069 and $23,370 for the years ended December 31, 2018 and 2017, respectively.

Interest Income.

Interest income was $18,297 and $5,181 for the years ended December 31, 2018 and 2017, respectively. Interest income represents interest earned on money market funds and certificates of deposit.

Income Tax Benefit.

An income tax benefit of $902,801 was recognized for the year ended December 31, 2018 as a result of our recording and amortizing the deferred tax liability created in connection with our acquisition of CoNCERT's license and "Know-How" in exchange for Processa stock that had been issued in the Internal Revenue Code Section 351 transaction on March 19, 2018. The Section 351 transaction treated the acquisition of the Know-How for stock as a tax-free exchange. As a result, under ASC 740-10-25-51 *Income Taxes*, Processa recorded a deferred tax liability of $3,037,147 for the acquired temporary difference between the financial reporting basis of $11,038,929 and the tax basis of $1,782. The deferred tax liability may be offset by the deferred tax assets resulting from 2017 and 2018 net operating losses. This offset results in the recognition of a deferred tax benefit shown in the consolidated statements of operations for 2018. There was no income tax benefit in 2017 since the tax benefit of the net loss was offset by a full valuation allowance.

Prior to the asset purchase transaction on October 4, 2017, 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/benefit or liability for income taxes was included in the consolidated financial statements through October 4, 2017.

Financial Condition

At December 31, 2018, we had $1,740,961 in cash and a $1.8 million commitment for PoC Capital to fund our Phase 2a clinical trial for NL. Net cash used in our operating activities during the year ended December 31, 2018 totaled $3,707,914 compared to $1,654,617 for the year ended December 31, 2017.

Our total assets increased by approximately $10.2 million to $13.2 million at December 31, 2018 compared to $3.0 million at December 31, 2017. Our assets increased by $11 million when we exercised our option to acquire the exclusive license from CoNCERT related to patent rights and know-how to develop and commercialize compounds and products for PCS-499 and each metabolite thereof in exchange for $8 million of our common stock (2,090,301 shares), and the related income tax effects resulting from the temporary difference between the book and tax basis of the intangible asset and transaction costs. The intangible asset is used in research and development activities and management believes it has alternative future uses (in research and development projects or otherwise). As a result, the acquisition cost of approximately $11 million was capitalized and is being amortized over the intangible asset's useful life in accordance with Topic 350, Intangibles – *Goodwill and Other.* In May and June of 2018, we sold 1,402,442 common stock units for approximately $3.2 million and are using these proceeds to fund our operating activities. Lastly, we made prepayments totaling $239,000 to our CRO related to our Phase 2a clinical trial for NL we expect to be reimbursed for by our Clinical Trial Funding investor. Subsequent to December 31, 2018, the investor has made payments to our CRO totaling $115,000 for amounts being currently invoiced.

At December 31, 2018, our total liabilities, not including the impact of deferred income taxes, decreased almost $2 million to $645,704 when compared to $2.6 million at December 31, 2017. This reduction is due primarily to the conversion in May 2018 of $2,350,000 of our senior convertible notes into 1,206,245 shares of our common stock. This left $230,000 of senior convertible notes outstanding at December 31, 2018. These notes are held by Canadian investors and will be automatically converted into approximately 119,000 shares of our common stock once certain Canadian regulatory matters have been resolved. We anticipate this will occur in 2019. In connection with exercising the option agreement with CoNCERT, we recognized a $3,037,147 deferred income tax liability since the intangible assets purchased had only a nominal tax basis. We also experienced an increase in our accounts payable and accrued expenses related to the continued development of PCS-499, costs related to beginning our Phase 2 clinical trial and other operating costs.

The following transactions, some of which are mentioned above, had a direct impact on our stockholders' equity.

- the 2,090,301 shares of our common stock valued at $8 million paid by Processa to CoNCERT to acquire the exclusive license intangible asset recorded along the related tax effect;
- the conversion of $2.46 million in senior convertible notes, including accrued interest into 1,206,245 shares of common stock;
- completing private placement transactions with gross proceeds totaling $3.2 million for 1,402,442 shares of our common stock;
- receipt of a future clinical trial funding commitment of $1.8 million in exchange for 792,952 shares of common stock; and
- the results of our operations, including stock-based compensation of $74,063.

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, 2018, we had $1.7 million in cash and cash equivalents compared to $2.8 million at December 31, 2017. We also received a Clinical Trial Funding commitment of $1.8 million to fund clinical trial expenses. We believe the clinical trial committed funds will be sufficient to fund our current Phase 2a clinical trial of PCS-499 in patients with NL. 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 our ability to continue as a going concern within one year after the date that this Form 10-K is filed with the SEC.

In May and June of 2018, we received proceeds of approximately $3.2 million dollars from the sale of 1,402,442 shares of our common stock and warrants to purchase a similar number of shares of common stock exercisable at $2.724 per share. On May 25, 2018, we also entered into an agreement with an investor (PoC Capital) for a commitment to fund up to $1.8 million of clinical trial expenses in exchange for 792,952 shares of our common stock and warrants to purchase a similar number of shares of common stock exercisable at $2.27 per share. This investor will typically make payments not to us, but rather directly to the CRO conducting our Phase 2a trial based on the CRO's invoicing. As of December 31, 2018, we have made payment totaling approximately $239,000 to our CRO and subsequent to December 31, 2018 the investor has made payments to our CRO totaling $115,000 for amounts currently invoiced. We expect this investor to repay us for payments we have made in 2019 and to continue to make payments to our CRO for current and future invoices. Finally, on May 25, 2018, we converted $2.35 million of our 8% convertible debt and related accrued interest into 1,206,245 shares of our common stock. Senior Notes totaling $230,000 held by Canadian individuals cannot be converted until we complete certain regulatory matters and filings in Canada. Once these regulatory matters and filings have been met, the Senior Notes held by these individuals will automatically convert on the same terms as the other noteholders, which includes additional accrued interest until conversion.

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 PCS-499 and our other product candidates;
- the scope, rate of progress, results and cost of our clinical trials, preclinical testing and other related activities;
- the time and costs involved in obtaining regulatory and marketing approvals in multiple jurisdictions for our product candidates that successfully complete clinical trials;
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the emergence of competing technologies or other adverse market developments;
- the introduction of new product candidates and the number and characteristics of product candidates that we pursue; and
- the potential acquisition and in-licensing of other technologies, products or assets.

Based on our current plan and our available resources (including the Clinical Trial Funding commitment of $1.8 million from PoC Capital), we will need to raise additional capital before the end of the second quarter of 2019 in order to fund our future operations. While we believe our current resources are adequate to complete our upcoming Phase 2a trial, we do not currently have resources to conduct other future trials without raising additional capital. As noted above, the timing and extent of our spending will depend on the cost associated with, and the results of our upcoming Phase 2a trial. Our anticipated spending and our cash flow needs could change significantly as the trial progresses. There may be costs we incur during our trial that we do not currently anticipate requiring us to need additional capital sooner than currently expected.

When additional funding is required, it 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 our sources and uses of cash and cash equivalents for the years ended December 31, 2018 and 2017:

	For the years ended December 31,	
	2018	2017
Net cash provided by (used in):		
Operating activities	$ (3,707,914)	$ (1,654,617)
Investing activities	(22,282)	1,004,952
Financing activities	2,623,728	2,425,200
Net increase in cash and cash equivalents	$ (1,106,468)	$ 1,775,535

Net cash used in operating activities

We used net cash in our operating activities of $3,707,914 and $1,654,617 during the years ended December 31, 2018 and 2017, respectively. The increase in cash used in operating activities in 2018 compared to 2017 is primarily related to the increased spending on research and development activities for PCS-499 licensing, program and testing costs, including internal staff costs and increased general and administrative costs related to internal staff growth, professional fees (primarily for legal and accounting), and other costs of being a public company. In addition, we incurred a cybersecurity fraud loss of approximately $144,000 in January 2018, which was recognized in general and administrative expenses.

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

Net cash used in investing activities

We used net cash in our investing activities of $22,282 during the year ended December 30, 2018 for transaction costs related to the exercise of the option agreement with CoNCERT and for the purchase a software license. We obtained the exclusive commercial license for the PCS-499 compound from CoNCERT in a non-cash transaction through the release to CoNCERT of $8.0 million of our common stock that was held for the benefit of CoNCERT by Promet (2,090,301 shares). We incurred nominal actual cash transaction costs. Investing inflows in 2017 of $1,004,952 were from proceeds we received when certificates of deposits matured.

Net cash provided by (used in) financing activities

During the year ended December 31, 2018, we sold 1,402,442 common stock units (each unit consisted of one share of common stock and a warrant to purchase one share of common stock) for gross proceeds of $3.2 million. Also during 2018, we converted approximately $2.35 million of our mandatory convertible 8.0% Senior Notes and accrued interest of $109,472 into 1,206,245 shares of common stock, at a price of $2.043 per share and a warrant to purchase one share of common stock for each share of common stock purchased at an exercise price equal to $2.452. In connection with our capital raising and debt conversion transactions in 2018, we incurred $559,789 of placement agent and other professional fees. During the year ended December 31, 2017, we received net proceeds of $2.43 million from the issuance of $2.58 million of 8.0% Senior Convertible Notes, partially offset by approximately $155,000 of debt issuance costs.

Contractual Obligations and Commitments

At December 31, 2018, our contractual obligations were $35,000 compared to $896,000 at December 31, 2017. See Note 12 included in the consolidated financial statements in this Form 10-K. Due to the contingent nature of the amounts and timing of the payments, we have excluded our agreement with the CRO with whom we have contracted to conduct our Phase 2a clinical trial for NL. We were contractually obligated for up to approximately $1.8 million of future services under the agreement, but our actual contractual obligations will vary depending on the progress and results of the clinical trial which will be funded through our Clinical Trial Funding Commitment we have with an investor.

Off Balance Sheet Arrangements

At December 31, 2018 and 2017, we did not have any off-balance sheet arrangements.

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 consolidated 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.

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

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

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

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

We file U.S. federal income and 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 years ended December 31, 2018 and 2017, we incurred net operating losses of $4,667,848 and $606,113, respectively. We did not record any income tax benefit for the $1,356,840 ($373,368 tax effected) and $347,530 ($95,504 tax effected) of general and administrative expenses treated as deferred start-up expenditures for tax purposes for the years ended December 31, 2018 and 2017, respectively. Additionally, we did not record any income tax benefit for the $258,583 ($71,283 tax effected) of tax losses incurred in 2017 which resulted in tax loss carryforwards. The 2017 net operating loss carry forwards are available for application against future taxable income for 20 years expiring in 2037. Tax losses incurred after December 31, 2017 have an indefinite carry forward period. However, the tax loss incurred after December 31, 2017 and carried forward can only offset 80 percent of future taxable income in any one year, with any excess losses being carried forward indefinitely. We have recorded the benefit of our 2018 and 2017 net operating losses in our consolidated financial statements as a reduction in the deferred tax liability created by the future financial statement amortization of the intangible asset from the acquired Know-How. The benefit associated with the net operating loss carry forward will more-likely-than-not go unrealized unless future operations are successful except for their offset against the deferred tax liability created by the acquired CoNCERT license and “Know-How.”

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

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.

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

We expense research and development costs as they are incurred.

Valuation of Intangible Assets. Our intangible assets consist of the capitalized costs of $20,500 for a software license and $11,038,929 associated with the exercise of the option to acquire the exclusive license from CoNCERT related to patent rights and know-how to develop and commercialize compounds and products for PCS-499 and each metabolite thereof and the related income tax effects. The capitalized costs for the license rights to PCS-499 include $1,782 in transaction costs and $3,037,147 associated with the initial recognition of an offsetting deferred tax liability related to the acquired temporary difference for an asset purchased that is not a business combination and has a nominal tax basis in accordance with ASC 740-10-25-51 *Income Taxes.* In accordance with ASC Topic 730, *Research and Development*, we capitalized the costs of acquiring the exclusive license rights to PCS-499 as the exclusive license rights represent intangible assets to be used in research and development activities that have future alternative uses. We had no recorded intangible assets as of December 31, 2017.

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

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

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

Non-employee share-based compensation awards 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 estimate the fair value of stock option grants using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. All stock-based compensation costs are recorded in general and administrative or research and development costs in the statements of operations based upon the underlying individual's role.

Recently Issued Accounting Pronouncements

See Note 3 of our consolidated financial statements for new accounting pronouncements or changes to the recent accounting pronouncements during the year ended December 31, 2018.

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, or do not have a class of securities registered under the Exchange Act) are required to comply with such new or revised financial accounting standards. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. 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.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Item 7A is not applicable to us as a smaller reporting company and has been omitted.

Item 8. Financial Statements and Supplementary Data

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Processa Pharmaceuticals, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Processa Pharmaceuticals, Inc. (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations, stockholders' equity, and cash flows, for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its 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 Note 2 to the financial statements, the Company has suffered recurring losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BD & Company

Owings Mills, MD
March 28, 2019

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

Processa Pharmaceuticals, Inc.
Consolidated Balance Sheets

	December 31, 2018	December 31, 2017
ASSETS		
Current Assets		
Cash and cash equivalents	$ 1,740,961	$ 2,847,429
Due from related party	21,583	62,709
Prepaid expenses and other	257,832	41,446
Total Current Assets	2,020,376	2,951,584
Property and equipment, net	17,375	25,821
Intangible assets, net	10,437,782	-
Security deposit	5,535	5,535
Total Assets	$ 13,214,629	$ 2,982,940
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Senior convertible notes, net of debt issuance costs	$ 230,000	$ 2,448,570
Accrued interest	20,343	35,693
Accounts payable	292,102	50,686
Due to related parties	-	436
Accrued expenses	103,259	64,428
Total Current Liabilities	645,704	2,599,813
Non-current Liabilities		
Accrued rent liability	-	9,963
Net deferred tax liability	2,134,346	-
Total Liabilities	3,513,611	2,609,776
Commitments and Contingencies	-	-
Stockholders' Equity		
Preferred stock, par value $0.0001, 10,000,000 shares authorized; no shares issued and outstanding	-	-
Common stock, par value $0.0001, 350,000,000 and 43,261,049 shares authorized; 38,674,265 and 35,272,626 issued and outstanding at December 31, 2018 and 2017, respectively	3,867	3,527
Additional paid-in capital	19,121,285	4,228,723
Stock subscription receivable	(1,800,000)	-
Accumulated deficit	(7,624,134)	(3,859,086)
Total Stockholders' Equity	9,701,018	373,164
Total Liabilities and Stockholders' Equity	$ 13,214,629	$ 2,982,940

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

Processa Pharmaceuticals, Inc.
Consolidated Statements of Operations
Years Ended December 31, 2018 and 2017

	2018	2017
Operating Expenses:		
Research and development	$ 3,085,317	$ 964,164
General and administrative	1,439,623	838,269
Operating Loss	(4,524,940)	(1,802,433)
Other Income (Expense):		
Interest expense	(161,205)	(59,063)
Interest income	18,297	5,181
Net Operating Loss Before Income Tax Benefit	(4,667,848)	(1,856,315)
Income Tax Benefit	902,801	-
Net Loss	$ (3,765,047)	$ (1,856,315)
Net Loss Per Common Share - Basic and Diluted	$ (0.10)	$ (0.06)
Weighted Average Common Shares Used to Compute Net Loss Per Common Shares - Basic and Diluted	37,324,267	32,595,680

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

Processa Pharmaceuticals, Inc.
Consolidated Statement of Changes in Stockholders' Equity

	Common Stock		Preferred Stock		Additional Paid-In	Subscription	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Receivable	Deficit	Total
Balance at January 1, 2017	31,745,242	$ 3,175	-	$ -	$ 4,266,825	$ -	$ (2,002,772)	$ (2,267,229)
Fair value of Heatwurx net liabilities obtained in a reverse merger	3,527,284	352	-	-	(38,102)	-	-	(37,750)
Net loss	-	-	-	-	-	-	(1,856,315)	(1,856,315)
Balance, December 31, 2017	35,272,626	3,527	-	-	4,228,723	-	(3,859,087)	373,163
Recognize the fair value of the license acquired from CoNCERT in exchange for 2,090,301 common shares of Processa	-	-	-	-	8,000,000	-	-	8,000,000
Conversion of senior convertible notes and accrued interest for common stock and stock purchase warrants, net of costs of $82,502	1,206,245	121	-	-	2,312,488	-	-	2,312,609
Issuance of common stock units for cash, net of costs of $308,830	1,402,442	140	-		2,874,547	-	-	2,874,687
Issuance of common stock units for a clinical trial funding commitment, net of costs of $168,457	792,952	79	-	-	1,631,464	(1,800,000)	-	(168,457)
Stock-based compensation	-	-	-	-	74,063	-	-	74,063
Net loss	-	-	-	-	-	-	(3,765,047)	(3,765,047)
Balance, December 31, 2018	38,674,265	$ 3,867	-	$ -	$ 19,121,285	$ (1,800,000)	$ (7,624,134)	$ 9,701,018

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

Processa Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows
Years Ended December 31, 2018 and 2017

	2018	2017
Cash Flows From Operating Activities		
Net loss	$ (3,765,047)	$ (1,856,315)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	8,445	1,865
Amortization of debt issuance costs	67,069	23,370
Amortization of intangible asset	621,647	-
Impairment of software costs	-	15,330
Deferred income tax benefit	(902,801)	-
Stock-based compensation	74,063	-
Net changes in operating assets and liabilities:		
Prepaid expenses	(216,386)	(23,299)
Vendor deposit	-	227,657
Accrued interest	94,122	35,693
Accounts payable	241,416	9,995
Due to related parties	40,690	(62,368)
Accrued rent liability	-	13,284
Accrued liabilities	28,868	(39,829)
Net cash used in operating activities	(3,707,914)	(1,654,617)
Cash Flows From Investing Activities		
Proceeds from the redemption of certificates of deposit	-	1,019,294
Purchase of property and equipment	-	(20,622)
Purchase of intangible asset	(20,500)	-
Acquisition costs related to the CoNCERT intangible asset	(1,782)	-
Cash received in a reverse acquisition transaction	-	6,280
Net cash provided by (used in) investing activities	(22,282)	1,004,952
Cash Flows From Financing Activities		
Proceeds from issuance of common stock, net of issuance costs of $308,830	2,874,687	-
Proceeds from issuance of senior convertible notes	-	2,580,000
Costs related to the Clinical Trial Funding Commitment	(168,457)	-
Costs related to the conversion of the Senior Notes and in 2017, payment of debt issuance costs	(82,502)	(154,800)
Net cash provided by financing activities	2,623,728	2,425,200
Net Increase in Cash	(1,106,468)	1,775,535
Cash and Cash Equivalents – Beginning of Year	2,847,429	1,071,894
Cash and Cash Equivalents – End of Year	$ 1,740,961	$ 2,847,429

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

Processa Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows (continued)
Years Ended December 31, 2018 and 2017

	2018	2017
Supplemental Cash Flow Information:		
Cash paid for interest	$ -	$ -
Cash Paid for income taxes	$ -	$ -
Non-Cash Investing and Financing Activities:		
Recognize the exclusive license intangible asset acquired from CoNCERT	$ (11,037,147)	$ -
Recognize deferred tax liability for basis difference of Intangible asset	3,037,147	-
Recognize additional paid-in-capital for consideration paid from the transfer of 2,090,301 common shares of Processa released by Promet to CoNCERT for Processa	8,000,000	-
Cash paid for intangible license asset acquired from CoNCERT	$ -	$ -
Conversion of $2,350,000 of Senior Convertible Debt and related accrued interest of $109,472 into 1,206,245 shares of common stock and stock purchase warrants	$ 2,395,111	$ -
Common stock and stock purchase warrants issued in connection with a clinical trial funding commitment	$ 1,800,000	$ -
Assumption of liabilities related to the reverse merger transaction	$ -	$ 44,030
Less: issuance of common stock related to the reverse merger transaction	-	(37,750)
Cash received related to the net liabilities assumed in the reverse merger transaction	$ -	$ 6,280

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

Note 1 – Organization and Description of the Business

Processa Pharmaceuticals, Inc. ("Processa" or "the Company") is an emerging clinical stage biopharmaceutical company focused on the development of drug products that are intended to provide treatment for and improve the survival and/or quality of life of patients who have a high unmet medical need condition or who have no alternative treatment. Within this group of pharmaceutical products, we currently are developing one product for multiple indications (i.e., the use of a drug to treat a particular disease) and searching for additional products for our portfolio.

Our lead product, PCS-499 is an oral tablet that is an analog of an active metabolite of an already approved FDA drug. The advantage of PCS-499 is that it potentially may work in many conditions because it has multiple pharmacological targets it affects that are important in the treatment of these conditions. Based on its pharmacological activity, we have identified multiple unmet medical need conditions where the use of PCS-499 may result in clinical efficacy. The lead indication currently under development for PCS-499 is Necrobiosis Lipoidica (NL). We started our Phase 2a clinical trial in NL patients in the fourth quarter of 2018, and on January 29, 2019 our first patient received the first dose of PCS-499. As of March 15, 2019, four additional patients have been enrolled in the study and have received at least one dose of PCS-499. All these patients have tolerated PCS-499 to date and are continuing in the study. Our trial is taking place at two sites: The University of Pennsylvania and University of Pittsburgh Medical Center (UPMC). We anticipate all 12 patients planned for this study will be enrolled by June 2019.

We continue to evaluate other unmet need conditions for PCS-499, as well as other potential assets and develop strategies including the regulatory pathway and commercialization plans for product(s) for these unmet medical conditions.

On October 4, 2017, we (formerly known as Heatwurx, Inc. or "Heatwurx") and our wholly-owned subsidiary, Processa Therapeutics LLC, ("Processa LLC") a Delaware limited liability company, acquired all the net assets of Promet Therapeutics, LLC ("Promet") a private Delaware limited liability company, including the rights to the CoNCERT Agreement (see Note 5) in exchange for 31,745,242 shares of our common stock, which at closing, constituted approximately 90% of our issued and outstanding common stock on a fully diluted basis (approximately 84% of which was beneficially owned by Promet and approximately 6% of which was held for the benefit of CoNCERT until released to CoNCERT on behalf of Processa at the conclusion of the CoNCERT transaction).

We accounted for the net asset acquisition transaction as a "reverse acquisition" merger using the acquisition method of accounting in accordance with Accounting Standards Codification ("ASC") 805-40-45, *Business Combinations – Reverse Acquisitions*, where Promet was considered the accounting acquirer. For tax purposes, the transaction was accounted for as a tax-free contribution under Internal Revenue Code Section 351. Accordingly, Promet's historical results of operations replaced our historical results of operations for all periods prior to the merger. Prior to the merger, we had nominal net liabilities and operations and were considered a non-operating public shell corporation.

On March 19, 2018, along with Promet and CoNCERT Pharmaceuticals Inc. ("CoNCERT"), the Option and License Agreement (the "Agreement") executed with CoNCERT in October 2017 was amended. The Agreement was assigned to us and we exercised the exclusive option for the PCS-499 compound. The option was exercised in exchange for CoNCERT receiving (i) $8 million of our common stock that was held by Promet for the benefit of CoNCERT (2,090,301 shares which represented a 5.93% interest in our common stock outstanding on that date), and (ii) 15% of any sublicense revenue earned by us for a period equivalent to the royalty term (as defined in the Agreement) until the earliest of (a) our raising $8 million of gross proceeds; and (b) CoNCERT being able to sell its shares of our common stock without restrictions pursuant to the terms of the amended Agreement. All other terms of the Agreement remain unchanged. As a result, we recognized an intangible asset and additional paid-in capital in the amount of $8 million resulting from Promet releasing the shares to CoNCERT on our behalf in satisfaction of our obligation under the Agreement to CoNCERT (see Note 5 - Intangible Asset for income tax effect of this transaction). There was no change in the total shares issued and outstanding, and after Promet LLC released CoNCERT's shares it held for CoNCERT, Promet's percentage beneficial interest held in us remained at 84%.

In December 2017, we effected a one-for-seven reverse split of our shares of common stock. The accompanying consolidated financial statements and notes give retroactive effect to this one-for-seven reverse stock split.

Note 2 – Going Concern and Management's Plans

Our consolidated financial statements have been prepared using U.S. GAAP and are based on the assumption that we will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. We face certain risks and uncertainties that are present in many emerging 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.

We have relied exclusively on private placements with a small group of accredited investors to finance our business and operations. We do not have any prospective arrangements or credit facilities as a source of future funds. We have not had any revenue since our inception as Promet on August 31, 2015. We are looking at ways to add a revenue stream to offset some of our expenses but do not currently have any revenue under contract or any immediate sales prospects. As of December 31, 2018, we had an accumulated deficit of approximately $7.6 million, incurred a net loss of approximately $3.8 million and used approximately $3.7 million in net cash from operating activities from continuing operations for the year ended December 31, 2018. At December 31, 2018, we had total cash and cash equivalents of approximately $1.7 million and a Clinical Trial Funding commitment from an investor (PoC Capital) of $1.8 million.

Based on our current plan and our available resources (including the Clinical Trial Funding commitment of $1.8 million from PoC Capital), we will need to raise additional capital before the end of the second quarter of 2019 in order to fund our future operations. While we believe our current resources are adequate to complete our upcoming Phase 2a trial for NL, we do not currently have resources to conduct other future trials without raising additional capital. As noted above, the timing and extent of our spending will depend on the cost associated with, and the results of our upcoming Phase 2a trial for NL. Our anticipated spending and our cash flow needs could change significantly as the trial progresses. There may be costs we incur during our trial that we do not currently anticipate requiring us to need additional capital sooner than currently expected.

When additional funding is required, it 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 raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Uncertainty concerning our ability to continue as a going concern may hinder our ability to obtain future financing. Continued operations and our ability to continue as a going concern are dependent on our ability to obtain additional funding in future and thereafter, and no assurances can be given that such funding will be available at all, in a sufficient amount, or on reasonable terms. Without additional funds from debt or equity financing, sales of assets, sales or out-licenses of intellectual property or technologies, or other transactions providing funds, we will rapidly exhaust our resources and be unable to continue operations. Absent additional funding, we believe that our cash and cash equivalents will not be sufficient to fund our operations for a period of one year or more after the date that these consolidated financial statements are available to be issued based on the timing and amount of our projected net loss from continuing operations and cash to be used in operating activities during that period of time.

As a result, substantial doubt exists about our ability to continue as a going concern within one year after the date that these 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 we be unable to continue as a going concern based on the outcome of these uncertainties described above.

Note 3 – Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and pursuant to the rules and regulations of the United States Securities and Exchange Commission (the "SEC"), and reflect all of our activities, including those of our wholly-owned subsidiary. All material intercompany accounts and transactions have been eliminated in consolidation.

We have reclassified certain immaterial prior year amounts to conform to our current year presentation. The reclassification of prior period amounts had no effect on previously reported net income, stockholders' equity or cash flows.

Use of Estimates

In preparing our consolidated financial statements and related disclosures in conformity with GAAP and pursuant to the rules and regulations of the SEC, we make estimates and judgments that affect the amounts reported in the consolidated financial statements and accompanying notes. Estimates are used for, but not limited to: stock-based compensation, determining the fair value of acquired assets and assumed liabilities, intangible assets, and income taxes. These estimates and assumptions are continuously evaluated and are based on management's experience and knowledge of the relevant facts and circumstances. While we believe the estimates to be reasonable, actual results could differ materially from those estimates and could impact future results of operations and cash flows.

Cash and Cash Equivalents

Cash and cash equivalents include cash on hand and money market funds. We consider all highly liquid investments with a maturity at the date of purchase of three months or less to be cash equivalents. Money market funds totaled $1,328,049 and $1,300,815 at December 31, 2018 and 2017, respectively.

Property and Equipment

Property is stated at cost, less accumulated depreciation. Costs of renewals and improvements that extend the useful lives of the assets are capitalized. Expenditures for maintenance and routine repairs are charged to expense as incurred. Depreciation is recognized on a straight-line basis over the estimated useful lives of the assets, which generally range from 3 to 5 years. We amortize leasehold improvements over the shorter of the estimated useful life of the asset or the term of the related lease. Upon retirement or disposition of assets, the costs and related accumulated depreciation are removed from the accounts with the resulting net gain or loss, if any, reflected in the statement of operations.

Intangible Assets

Intangible assets acquired individually or with a group of other assets from others (other than in a business combination) are recognized at cost, including transaction costs, and allocated to the individual assets acquired based on relative fair values and no goodwill is recognized. Cost is measured based on cash consideration paid. If consideration given is in the form of non-cash assets, liabilities incurred, or equity interests issued, measurement of cost is based on either the fair value of the consideration given or the fair value of the assets (or net assets) acquired, whichever is more clearly evident and more reliably measurable. Costs of internally developing, maintaining or restoring intangible assets that are not specifically identifiable, have indeterminate lives or are inherent in a continuing business are expensed as incurred.

Intangible assets purchased from others for use in research and development activities and that have alternative future uses (in research and development projects or otherwise) are capitalized in accordance with ASC Topic 350, *Intangibles – Goodwill and Other.* Those that have no alternative future uses (in research and development projects or otherwise) and therefore no separate economic value are considered research and development costs and are expensed as incurred. Amortization of intangibles used in research and development activities is a research and development cost.

Intangibles with a finite useful life are amortized using the straight-line method unless the pattern in which the economic benefits of the intangible assets are consumed or used up are reliably determinable. The useful life is the best estimate of the period over which the asset is expected to contribute directly or indirectly to our future cash flows. The useful life is based on the duration of the expected use of the asset by us and the legal, regulatory or contractual provisions that constrain the useful life and future cash flows of the asset, including regulatory acceptance and approval, obsolescence, demand, competition and other economic factors. We evaluate the remaining useful life of intangible assets each reporting period to determine whether any revision to the remaining useful life is required. If the remaining useful life is changed, the remaining carrying amount of the intangible asset will be amortized prospectively over the revised remaining useful life. If an income approach is used to measure the fair value of an intangible asset, we consider the period of expected cash flows used to measure the fair value of the intangible asset, adjusted as appropriate for company-specific factors discussed above, to determine the useful life for amortization purposes.

If no regulatory, contractual, competitive, economic or other factors limit the useful life of the intangible to us, the useful life is considered indefinite. Intangibles with an indefinite useful life are not amortized until its useful life is determined to be no longer indefinite. If the useful life is determined to be finite, the intangible is tested for impairment and the carrying amount is amortized over the remaining useful life in accordance with intangibles subject to amortization. Indefinite-lived intangibles are tested for impairment annually and more frequently if events or circumstances indicate that it is more-likely-than-not that the asset is impaired.

Impairment of Long-Lived Assets and Intangibles Other Than Goodwill

We account for the impairment of long-lived assets in accordance with ASC 360, *Property, Plant and Equipment* and ASC 350, *Intangibles – Goodwill and Other* which requires that long-lived assets and certain identifiable intangibles be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to its expected future undiscounted net cash flows generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amounts of the assets exceed the fair value of the assets based on the present value of the expected future cash flows associated with the use of the asset. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. Based on management's evaluation, there was no impairment loss recorded during the year ended December 31, 2018.

Fair Value Measurements and Disclosure

We apply ASC 820, *Fair Value Measurements and Disclosures*, which expands disclosures for assets and liabilities that are measured and reported at fair value on a recurring basis. Fair value is defined as an exit price, representing the amount that would be received upon the sale of an asset or payment to transfer a liability in an orderly transaction between market participants.

Fair value is a market-based measurement that is determined based on assumptions that market participants would use in pricing an asset or liability. A three-tier fair value hierarchy is used to prioritize the inputs in measuring fair value as follows:

Level 1 – Quoted market prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2 – Quoted market prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable, either directly or indirectly. Fair value determined through the use of models or other valuation methodologies.

Level 3 – Significant unobservable inputs for assets or liabilities that cannot be corroborated by market data. Fair value is determined by the reporting entity's own assumptions utilizing the best information available and includes situations where there is little market activity for the asset or liability.

The asset's or liability's fair value measurement within the fair value hierarchy is based upon the lowest level of any input that is significant to the fair value measurement. Our policy is to recognize transfers between levels of the fair value hierarchy in the period the event or change in circumstances that caused the transfer. There were no transfers into or out of Level 1, 2, or 3 during the periods presented.

Stock-based Compensation

Stock-based compensation expense is based on the grant-date fair value estimated in accordance with the provisions of ASC 718,*Compensation-Stock Compensation.* We expense stock-based compensation to employees over the requisite service period based on the estimated grant-date fair value of the awards. Stock-based awards with graded-vesting schedules are recognized on a straight-line basis over the requisite service period for each separately vesting portion of the award. We estimate the fair value of stock option grants using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. Stock-based compensation costs are recorded as general and administrative or research and development costs in the statements of operations based upon the underlying individual's role.

Net Loss Per Share

Basic loss per share is computed by dividing our net loss available to common shareholders by the weighted average number of shares of common stock outstanding during the year. Diluted loss per share is computed by dividing our net loss available to common shareholders by the diluted weighted average number of shares of common stock during the period. Since we experienced a net loss for each of the years presented, basic and diluted net loss per share are the same.

Our diluted net loss per share for the years ended December 31, 2018 and 2017 excluded 3,898,219 and 1,262,849 of potentially dilutive common shares, respectively, related to the conversion of our Senior Notes and outstanding stock options and warrants since those shares would have had an anti-dilutive effect on loss per share during the years then ended.

Segments

We operate in one segment. Management uses one measurement of profitability and does not segregate its business for internal reporting. During 2018 and 2017 all our long-lived assets were located within the United States.

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable and the senior convertible notes approximate fair value because of the short-term maturity of these instruments, including the mandatory conversion of the Senior Notes into our common stock upon meeting certain conditions.

Debt Issuance Costs

We recognized the debt issuance costs incurred related to our 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.

Research and development

Research and development costs are expensed as incurred and consisted of direct and overhead-related expenses. Research and development costs totaled $3,085,317 and $964,164 for the years ended December 31, 2018 and 2017, respectively. Expenditures to acquire technologies, including licenses, which are utilized in research and development and that have no alternative future use are expensed when incurred. Technology we develop for use in our products is expensed as incurred until technological feasibility has been established after which it is capitalized and depreciated. No costs have been capitalized during the years ended December 31, 2018 and 2017.

Income Taxes

As a result of the reverse acquisition merger (see Notes 1 and 4), we experienced a change in control on October 4, 2017. Prior to the closing of the merger, 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 significantly limited following an ownership change as defined by Internal Revenue Code Section 382 and were fully reserved with a valuation allowance. 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.*

Subsequent to the closing of the combination of Heatwurx and the assets of Promet, we 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. We account 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 our deferred tax assets at December 31, 2018 and 2017.

With respect to uncertain tax positions, we 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 unrecognized tax benefits or uncertain tax positions at December 31, 2018 or 2017.

Recent Accounting Pronouncements

From time to time, the Financial Accounting Standards Board (“FASB”) or other standard setting bodies issue new accounting pronouncements. Updates to the FASB Accounting Standards Codification are communicated through issuance of an Accounting Standards Update (“ASU”). We have implemented all new accounting pronouncements that are in effect and that may impact its financial statements. We have evaluated recently issued accounting pronouncements and determined that there is no material impact on our financial position or results of operations.

Recently issued accounting pronouncements not yet adopted

In February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2016-02 (Topic 842) - *Leases*. Topic 842 supersedes the lease requirements in Accounting Standards Codification (ASC) Topic 840, "Leases." Under Topic 842, lessees are required to recognize assets and liabilities on the balance sheet for most leases and provide enhanced disclosures. Leases will continue to be classified as either finance or operating. We will adopt Topic 842 effective January 1, 2019 using a modified retrospective method and will not restate comparative periods. As permitted under the transition guidance, we will carry forward the assessment of whether our contracts contain or are leases, classification of our leases and remaining lease terms. Based on our portfolio of leases as of December 31, 2018, approximately $318,000 of lease assets and liabilities will be recognized on our consolidated balance sheet upon adoption. We are substantially complete with our implementation efforts.

In June 2016, the FASB issued Accounting Standards Update No. 2016-13 (ASU 2016-13) -*Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model which requires the use of forward-looking information to calculate credit loss estimates. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. These changes will result in earlier recognition of credit losses. We will adopt ASU 2016-13 effective January 1, 2020. We are currently evaluating the effect of the adoption of ASU 2016-13 on our consolidated financial statements. The effect will largely depend on the composition and credit quality of our investment portfolio and the economic conditions at the time of adoption.

Recently adopted accounting pronouncements

From May 2014 through December 31, 2018, the FASB issued several ASUs related to ASU 2014-09,*Revenue from Contracts with Customers.* 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. We are currently in the pre-revenue stages of operations. As such, the adoption of this standard did not have a material impact on our results of operations, financial condition or cash flows.

In July 2017, the FASB issued Accounting Standards Update 2017-11 (ASU 2017-11), which allows companies to exclude a down round feature when determining whether a financial instrument is considered indexed to the entity's own stock. As a result, financial instruments with down round features are no longer classified as liabilities and embedded conversion options with down round features are no longer bifurcated. For equity-classified freestanding financial instruments, such as warrants, an entity will treat the value of the effect of the down round, when triggered, as a dividend and a reduction of income available to common shareholders in computing basic earnings per share. For convertible instruments with embedded conversion options that have down round features, an entity will recognize the intrinsic value of the feature only when the feature becomes beneficial. The guidance in ASU 2017-11 is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. We early adopted ASU 2017-11 effective January 1, 2018 without a material impact on our consolidated financial statements.

The SEC staff issued Staff Accounting Bulletin ("SAB") 118, which provides guidance on accounting for the tax effects of the U.S. tax reform announced on December 22, 2017 by the U.S. Government commonly referred to as the Tax Cuts and Jobs Act. SAB 118 provides a measurement period that should not extend beyond one year from the U.S. tax reform enactment date for companies to complete the accounting under Accounting Standards Codification ("ASC") 740. In accordance with SAB 118, a company must reflect the income tax effects of those aspects of the U.S. tax reform for which the accounting under ASC 740 is complete.

Specifically, we were required to revalue our U.S. deferred tax assets and liabilities due to the federal income tax rate reduction from 35 percent to 21 percent. Since we have provided a full valuation allowance against our deferred tax assets, the revaluation of the deferred tax assets did not have a material impact on any period presented.

Note 4 – Acquisition

On October 4, 2017, in exchange for 90 percent or 31,745,242 shares of our common stock, we acquired the net assets of Promet, totaling $1,017,342, in a transaction that was accounted for as a reverse acquisition in accordance with ASC 805-40-45, *Business Combinations - Reverse Acquisitions*. We completed this transaction to provide improved access to the capital markets in order to obtain the resources necessary to continue the development of PCS-499 and build a clinical development drug company. Immediately following the transaction, we had 35,272,626 shares of common stock issued and outstanding, which represented our total legal capital. Promet owned approximately 84% of our common stock, and as part of the Section 351 transaction, held approximately 6% for the benefit of CoNCERT until the CoNCERT transaction had been concluded, whereupon CoNCERT took title to their shares. Together, Promet's pre-transaction owners and CoNCERT held a 90% economic and voting interest in the combined company immediately following completion of the transaction and as such, Promet was considered the acquirer for accounting purposes. Subsequent to the Merger, we changed our name from "Heatwurx, Inc." to "Processa Pharmaceuticals, Inc." and our ticker symbol was changed from "HWRX" to "PCSA."

The transaction was considered a capital transaction in substance. Accordingly, for accounting purposes, it was assumed that Promet issued shares to Heatwurx at fair value, net of the assets and liabilities assumed from Heatwurx as shown below, which were recognized as a reduction of additional paid-in-capital at closing of the reverse merger. The net recognized value of Heatwurx identifiable assets and liabilities included the following:

Cash	$	6,280
Accounts payable		(26,098)
Accrued expenses		(17,932)
Net liabilities assumed	$	(37,750)

Our financial statements present the financial position (with a retrospective adjustment to Promet's legal capital to reflect our pre-merger capital structure) and operations of Promet prior to October 4, 2017, and of the combined company from October 4, 2017 forward. The assets and liabilities of Promet are recognized and measured at their historical carrying amounts. The accumulated deficit and other equity balances of Promet have been carried forward and adjusted to reflect our legal shares and par value with the difference allocated to additional paid-in capital.

Promet incurred acquisition-related transaction costs of $58,763, which are included in general and administrative expense, a component of operating expenses in the consolidated statements of operations.

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

Note 5 – Intangible Assets

Intangible assets at December 31, 2018 consisted of the capitalized costs of $20,500 for a purchased software license and $11,038,929 associated with our exercise of the option to acquire the exclusive license from CoNCERT related to patent rights and know-how to develop and commercialize compounds and products for PCS-499 and each metabolite thereof and the related income tax effects (See Note 1). The capitalized costs for the license rights to PCS-499 include $8 million purchase price, $1,782 in transaction costs and $3,037,147 associated with the initial recognition of an offsetting deferred tax liability related to the acquired temporary difference for an asset purchased that is not a business combination and has a tax basis of $1,782 in accordance with ASC 740-10-25-51 *Income Taxes*. In accordance with ASC Topic 730, *Research and Development*, we capitalized the costs of acquiring the exclusive license rights to PCS-499 as the exclusive license rights represent intangible assets to be used in research and development activities that have future alternative uses.

Acquisition of the CoNCERT License

On March 19, 2018, Promet, Processa and CoNCERT amended the Agreement executed in October 2017. The Agreement was assigned to Processa and Processa exercised the exclusive option for the PCS-499 compound in exchange for CoNCERT receiving, in part, $8 million of our common stock that was held by Promet (2,090,301 shares at $3.83 per share) and to be released to CoNCERT for the benefit of Processa in satisfaction of the obligation due for the exclusive license for PCS-499 acquired by us. There was no change in the total shares issued and outstanding of 35,272,626, however, Promet released to CoNCERT the approximately 6% of the shares acquired in the Promet/Heatwurx combination, which were reserved for CoNCERT in respect of the license as part of the overall transaction leaving Promet with approximately 84% controlling interest and CoNCERT with approximately 6%. Promet contributed the payment of the obligation due for the exclusive license to us without consideration paid to them. As a result of the transaction, we recognized an exclusive license intangible asset with a fair value of $8 million and an offsetting increase in additional paid-in capital resulting from Promet releasing the shares reserved for CoNCERT in respect of CoNCERT's contributed license on behalf of Processa, and thereby satisfying Processa's liability to CoNCERT.

The negotiation of the modification to the Agreement was in process as of October 4, 2017 and was finalized in mid-February 2018 and the legal documents were thereafter executed and the option was exercised on March 19, 2018 in exchange for CoNCERT receiving: (i) $8 million of our common stock that was held by Promet LLC for the benefit of CoNCERT; (ii) 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; and (iii) 15% of any sublicense revenue earned by us for a period equivalent to the royalty term (as defined in the Agreement) until the earliest of (a) our raising $8 million of gross proceeds and (b) CoNCERT being able to sell its shares of our common stock without restrictions pursuant to the terms of the amended Agreement. All other terms of the Agreement remained unchanged. The license agreement was assigned to and exercised by us. As a result of the transaction, we recognized an intangible asset for the fair value of the common stock consideration paid of $8 million with an offsetting amount in additional paid-in capital resulting from Promet releasing the shares to CoNCERT in satisfaction of our obligation to CoNCERT under the Agreement.

We estimated the fair value of the common stock issued based on the market approach and CoNCERT's requirement to receive shares valued at $8 million. The market approach was based on the final negotiated number of shares of stock determined on a volume weighted average price of our common stock quoted on the OTC Pink Marketplace over a 45 day period preceding the mid-February 2018 finalized negotiation of the modification to the option and license agreement with CoNCERT, an unrelated third party, for the exclusive license rights to PCS-499. However, we have less than 300 shareholders, the volume of shares trading for our common stock is not significant and the OTC Pink Marketplace is not a national exchange; therefore, the volume weighted average price quotes for our common stock are from markets that are not active and consequently are Level 2 inputs. The total cost recognized for the exclusive license acquired represents the allocated fair value related to the stock transferred to CoNCERT plus the recognition of the deferred tax liability related to the acquired temporary difference and the transaction costs incurred to complete the transaction as discussed above.

Our intangible assets consist of the following at December 31, 2018:

	License Rights to PCS-499	Software License	December 31, 2018
Gross intangible asset	$ 11,038,929	$ 20,500	$ 11,059,429
Less: accumulated amortization	(616,807)	(4,840)	(621,647)
Total intangible asset, net	$ 10,422,122	$ 15,660	$ 10,437,782

Amortization expense was $621,647 for the year ended December 31, 2018 and is included within research and development expense in the accompanying consolidated statements of operations. We had no intangible assets at December 31, 2017. As of December 31, 2018, estimated amortization expense for the next two years amounts will be approximately $795,000 per year and for annual periods thereafter approximately $788,000 per year.

Note 6 – Notes Payable

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 1,850,625 shares of common stock. As of December 31, 2017, there were no Heatwurx notes payable outstanding.

Senior Convertible Notes

The balance of our Senior Convertible Notes ("Senior Notes") at December 31, 2018 and 2017 was as follows:

	2018	2017
Senior Notes	$ 230,000	$ 2,580,000
Less: Debt issuance costs	-	(131,430)
Balance	230,000	2,448,570
Current portion	(230,000)	(2,448,570)
Long term portion	$ -	$ -

Interest expense totaled $161,205 and $59,063 for the years ended December 31, 2018 and 2017. Included in interest expense is the amortization of the related debt issuance costs of $67,069 and $23,370 for the years ended December 31, 2018 and 2017, respectively. The Senior Notes and related accrued interest are classified as current liabilities in our consolidated balance sheets.

Issuance of the Senior Notes

As of 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. On May 25, 2018, $2,350,000 of Senior Notes were converted, as described below, leaving $230,000 of Senior Notes outstanding at December 31, 2018.

The Senior Notes bear interest at 8% per year and are payable in kind (in common stock).

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

We retained a placement agent and agreed to pay the placement agent (i) six percent (6%) of gross proceeds received by us 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 upon their conversion. As a result of the Senior Notes conversion, warrants to purchase a total of 72,375 shares of common stock were issued, with a three-year term, at an exercise price equal to $2.452.

We incurred $154,800 in debt issuance costs on the Senior Notes in connection with a payment to the placement agent, which was reported as a reduction of the carrying amount of the Senior Convertible Notes on the face of the consolidated balance sheets. The debt issuance costs are amortized to interest expense using the effective interest rate method over the term of the Senior Convertible Notes. The effective interest rate on the Senior Notes was 7.72% before debt issuance costs, since no payments of interest are due until maturity and 13.96% including the debt issuance costs based on the repayment terms of the Senior Notes.

Conversion of Our Senior Notes

On May 25, 2018, pursuant to the mandatory and automatic conversion provisions of the Senior Notes, we converted $2,350,000 of the $2,580,000 outstanding Senior Notes, along with any accrued interest into 1,206,245 shares of common stock (at a conversion price of $2.043 per share) and a warrant to purchase one share of common stock for three years, at an exercise price of $2.452. We also incurred costs totaling $82,502 related to our contractual obligations to file a resale registration statement related to this transaction with the SEC

Senior Notes totaling $230,000 held by Canadian individuals cannot be converted until we complete certain regulatory matters and filings in Canada. Once these regulatory matters and filings have been met, the Senior Notes held by these individuals will automatically convert on the same terms as the other noteholders, which includes additional accrued interest until conversion.

We evaluated the warrants issued in this transaction and determined they should be classified as equity.

Note 7 – Stockholders' Equity

Preferred Stock

As of December 31, 2018, we have 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 shareholders converted 178,924 shares of Series D Preferred Stock and all accrued dividends in the amount of $118,658 into 102,789 shares of common stock.

Common Stock

As of December 31, 2018, we have authorized 350,000,000 of common stock with a $0.0001 par value.

2018 Private Placement Transactions

Between May 15, 2018 and June 29, 2018, we sold an aggregate of 1,402,442 units in a private placement transaction at a purchase price equal to $2.27 per unit for gross proceeds of approximately $3.2 million. Each unit consisted of one share of our common stock and a warrant to purchase one share of our common stock for $2.724, subject to adjustment thereunder for a period of three years. We paid $167,526 to our placement agent and issued placement agent warrants to purchase up to 84,146 shares of common stock, with a three-year term, at an exercise price equal to $2.724. We also incurred costs totaling $141,304 related to this transaction and our contractual obligation to file a resale registration statement related to the PIPE transaction with the SEC. The issuance costs were charged against additional paid in capital.

On May 25, 2018, we entered into an Agreement with PoC Capital, LLC ("PoC"), where PoC has agreed to finance $1,800,000 in study costs associated with certain clinical studies, including our Phase 2a study to evaluate the safety, tolerability, efficacy and pharmacodynamics of PCS 499 in patients with Necrosis Lipoidica in exchange for 792,952 shares of our common stock and a warrant for the purchase of 792,952 shares of common stock with an exercise price of $2.724, expiring on July 29, 2021. Any study costs in excess of that amount will be our responsibility. PoC will typically not make payments to us, but directly to the contract research organization based on their invoices. We paid $108,000 to our placement agent and issued our placement agent warrants to purchase 47,578 shares of common stock, with a three-year term, at an exercise price equal to $2.724. We also incurred costs totaling $60,457, related to this transaction and our contractual obligation to file a resale registration statement related to this transaction with the SEC. The issuance costs were charged against additional paid in capital.

We also entered into a pledge agreement with PoC, under which we received a security interest for 396,476 shares, or half the shares we issued them, to hold as collateral. These shares will be released in two tranches of 198,238 shares each, with each tranche released upon PoC making payments totaling $720,000. During the year ended December 31, 2018, we have made payments to our CRO of $239,129, including the prepayment of certain amounts, all of which will be repaid to us by PoC in the next year. We have accounted for payments we made to our CRO in 2018 as either a prepaid expense or a research and development expense depending on whether the related service has been provided. Since the amount of the Clinical Trial Funding commitment has not changed, we continue to show the full amount of that commitment, $1.8 million, as a subscription receivable. We will reduce the subscription receivable in the period the investor makes payment to our CRO or us.

The common stock, but not the warrants, issued for the 2018 Private Placement Transactions and the conversion of the Senior Convertible Notes have, subject to certain customary exceptions, full ratchet anti-dilution protection. Until we have issued equity securities or securities convertible into equity securities for a total of an additional $20 million in cash or assets, including the proceeds from the exercise of the warrants issued above, in the event we issue additional equity securities or securities convertible into equity securities at a purchase price less than $2.27 per share of common stock, the above purchase prices shall be adjusted and new shares of common stock issued as if the purchase price was such lower amount (or, if such additional securities are issued without consideration, to a price equal to $0.01 per share).

We evaluated the warrants issued in the 2018 Private Placement Transactions and determined they should be classified as equity.

Note 8 – Income Taxes

The historical information presented in our consolidated financial statements prior to October 4, 2017 was that of Promet. As described in Note 4, 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 was not subject to income tax at the entity level. Therefore, no provision or liability for income taxes has been included in these consolidated financial statements through the date of the asset purchase on October 4, 2017.

We account for income taxes in accordance with ASC Topic 740, *Income Taxes.* Deferred income taxes are recorded for the expected tax consequences of temporary differences between the tax basis of assets and liabilities for financial reporting purposes and amounts recognized for income tax purposes. We record a valuation allowance to reduce our deferred tax assets to the amount of future tax benefit that is more likely than not to be realized.

As described more fully in Note 1, Promet and Processa entered into an Asset Purchase Agreement pursuant to which Processa acquired, in an IRC Section 351 tax-free contribution of assets solely for over 80% of the voting stock of Processa (the "Section 351 Transaction") by Promet, for properties, rights and assets, including liabilities and commitments, owned by Promet (the "Contributed Assets"). Contemplated in the Contributed Assets were rights, title and interest under a certain option and license agreement with CoNCERT with respect to certain know-how, patent rights and compounds developed or obtained by CoNCERT (the "CoNCERT Assets") for which voting securities of Processa were expressly contemplated to be issued as part and parcel with, and integrated into, the Section 351 Transaction to CoNCERT because all Contributed Assets including the CoNCERT Assets were contemplated to be integral to each other and were considered to be an integrated undertaking as the primary target, purpose and reason for the overall transaction itself.

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 approximate 6% of shares issued in the Section 351 transaction for CoNCERT and held by Promet for the benefit of CoNCERT until the CoNCERT transaction could be concluded). The overall transaction resulted in an ownership change as defined by Internal Revenue Code Section 382. Promet also determined that it was not required to record a liability related to any uncertain tax positions as a result of the requirements of ASC 740-10-25 *Income Taxes.* The net deferred tax assets of Heatwurx were principally federal and state net operating loss carry forwards, which are significantly limited following an ownership change as defined by Internal Revenue Code Section 382.

A deferred tax liability was recorded when Processa exercised its option and received CoNCERT's license and "Know-How" in exchange for Processa stock that had been issued in the Internal Revenue Code Section 351 Transaction on March 19, 2018. The Section 351 Transaction treats the acquisition of the license and Know-How for stock as a tax-free exchange. As a result, under ASC 740-10-25-51 *Income Taxes*, Processa recorded a deferred tax liability of $3,037,147 for the acquired temporary difference between the financial reporting basis of approximately $11,038,929 and the tax basis of approximately $1,782. The deferred tax liability will be reduced for the effect of non-deductibility of the amortization of the intangible asset and may be offset by the deferred tax assets resulting from 2017, 2018 and subsequent net operating losses.

For the year ended December 31, 2018, we recorded a federal income tax benefit of $902,801 as a result of offsetting our deferred tax liability by the deferred tax assets resulting from 2017 and 2018 net operating losses and the income tax effect of the intangible asset amortization for financial statement purposes. We did not record any current federal or state tax provision in our 2017 consolidated financial statements.

Our provision (benefit) for income taxes for the years ended December 31, 2018 and 2017 was as follows:

	Year Ended December 31,	
	2018	2017
Current:		
Federal	$ -	$ -
State	-	-
Total deferred tax benefit	-	-
Deferred:		
Federal	(940,510)	(116,783)
State	(292,047)	(50,004)
Total deferred tax benefit	(1,232,557)	(166,787)
Valuation allowance	329,756	166,787
Net deferred tax benefit	(902,801)	-
Total tax provision (benefit)	$ (902,801)	$ -

A reconciliation of our effective income tax rate and statutory income tax rate for the years ended December 31, 2018 and 2017 is as follows:

	Year Ended December 31,	
	2018	2017
Federal statutory income tax rate	21.00%	34.00%
State tax rate, net	4.58%	5.45%
Permanent differences	(0.90)%	(0.02)%
Impact of change in federal income tax rates	-	(11.92)%
Deferred tax asset valuation allowance	(5.33)%	(27.51)%
Effective income tax rate	(19.35)%	-

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 ("TCJA") was signed into law. Among its provisions, the TCJA reduces the statutory U.S. Corporate income tax rate from 34% to 21% effective January 1, 2018. The TCJA includes provisions that, in certain instances, impose U.S. income tax liabilities on future earnings of foreign subsidiaries and limit the deductibility of future interest expenses. The TCJA also provides for accelerated deductions of certain capital expenditures made after September 27, 2017 through bonus depreciation and an indefinite tax loss carryforward period for losses incurred after December 31, 2017. However, these tax-loss carry forwards can only offset 80 percent of future taxable income in any one year, with respect to any excess continuing to be carried forward indefinitely. Losses incurred prior to January 1, 2018 continue to carry forward for twenty years. The application of the TCJA may change due to regulations subsequently issued by the U.S. Treasury Department.

We applied the guidance in SAB 118 when accounting for the enactment-date effects of the TCJA in 2017 and throughout 2018. As of December 31, 2017, we remeasured certain deferred tax assets and liabilities based on the rates at which they were expected to reverse in the future (which is generally 21%), by recording a provisional amount of $72,300, which was fully offset by the valuation allowance. Upon further analysis of certain aspects of the Act and refinement of our calculations during the year ended December 31, 2018, we determined that no adjustment was necessary to the provisional amount.

At December 31, 2018 and 2017, we had available federal net operating loss carryforwards of approximately $2.7 million and $259,000, respectively. The net operating loss generated in 2018 of $2.4 million will carry forward indefinitely and be available to offset up to 80% of future taxable income each year. Net operating losses generated prior to 2018 will expire from 2019 through 2037. We are evaluating our qualified research expenditures for the federal orphan drug credit and the federal and state credit for increasing research activities to offset potential future tax liabilities. The federal research and development tax credits have a 20-year carryforward period. The Maryland research and development tax credits have a 7-year carryforward period. We have not recognized any deferred tax assets related to research and development tax credits as of December 31, 2018 or 2017. We also have available state net operating loss carryforwards of approximately $2.7 million and $259,000 as of December 31, 2018 and 2017, respectively, which expire from 2028 to 2037. All federal and state net operating loss and credit carryforwards listed above are reflected after the reduction for amounts effectively eliminated under Section 382.

We do not recognize other deferred income tax assets at this time because the realization of the assets is not more-likely-than-not that they will go unrealized. As of December 31, 2018 and 2017, we had deferred start-up expenditures and net operating losses for both federal and state income tax purposes of $4,369,700 and $606,113, respectively. The benefit associated with the amortization of the deferred start-up expenditures will more-likely-than-not go unrealized unless future operations are successful. Since the success of future operations is indeterminable, the potential benefits resulting from these deferred tax assets have not been recorded in our consolidated financial statements.

The significant components of our deferred tax assets and liabilities for Federal and state income taxes consisted of the following:

	December 31,	
	2018	2017
Deferred tax assets:		
Non-current:		
Net operating loss carry forward – Federal	$ 559,817	$ 49,822
Net operating loss carry forward – State	173,743	21,333
Deferred rent	2,742	
Stock option expense	20,380	
Depreciation	4,549	
Intangible asset	-	
Start-up expenditures	468,872	95,632
Total non-current deferred tax assets	1,230,103	166,787
Valuation allowance for deferred tax assets	(496,542)	(166,787)
Total deferred tax assets	$ 733,561	$ -
Deferred Tax Liabilities:		
Non-current:		
Intangible asset, net of tax effect of intangible asset amortization	(2,867,907)	-
Total non-current deferred tax liabilities	(2,867,907)	-
Total deferred tax asset (liability)	$ (2,134,346)	$ -

The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, the projected future taxable income and tax planning strategies in making this assessment. Based on management's analysis, a reserve has been established against the deferred tax assets related to deferred start-up expenditures and net operating loss. The change in the valuation allowance in 2018 and 2017 was $329,755 and $166,787, respectively.

Our total deferred tax asset as of December 31, 2018 and 2017 include $1,703,904 ($468,872 tax effected) and $347,530 ($95,504 tax effected) of general and administrative expenses treated as deferred start-up expenditures for tax purposes, respectively, and $2,665,796 ($733,560 tax effected) and $258,583 ($71,283 tax effected) of tax losses resulting in tax loss carryforwards as of the same periods. We have had no revenues and recognized cumulative loses since inception. Due to the uncertainty regarding future profitability and recognition of taxable income to utilize the amortization of deferred start-up expenditures and the tax loss carryforwards, except for its offset against the deferred tax liability created by our acquisition of the Contributed Assets, a valuation allowance against any potential deferred tax assets has been recognized for the years ended December 31, 2018 and 2017.

We recognize potential liabilities for uncertain tax positions using a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. We have not recorded any uncertain tax positions.

We are subject to taxation in the United States and state jurisdictions where applicable. Our tax years for 2014 through 2017 are subject to examination by the Internal Revenue Service and state tax authorities. There are currently no income tax examinations underway in any jurisdiction in which we file.

Note 9 - Stock-based Compensation

The amended and restated Heatwurx, Inc. 2011 Equity Incentive Plan (the "Plan") was adopted on April 15, 2011 by the Board of Directors and approved by the shareholders on October 15, 2012. Under this Plan, our employees, non-employee directors, advisors, and consultants are eligible to receive grants under the Plan. The Plan authorizes the issuance of up to 257,143 shares of common stock. If unexercised options expire or are terminated, the underlying shares will again become available for future grants under the Plan.

The Plan provides for the grant of options to purchase shares of our common stock. 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. We can grant incentive stock options only to our employees, however, we can grant non-statutory stock options to our employees, nonemployee directors, advisors, and consultants.

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 our common stock. 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 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.

During the year ended December 31, 2018, there was one grant for the purchase of 50,000 shares of our common stock outstanding under this Plan. We also granted non-qualified stock options outside of the Plan for a total of 334,400 shares of common stock. An option for the purchase of 316,400 shares of common stock vests over a four-year term and an option for the purchase of 18,000 shares of common stock vests over one-year term. Stock option granted in 2018 all have a maximum contractual term of ten years. Vesting is subject to the holder's continuous service with us.

The fair value of each stock option grants was estimated using the Black-Scholes option-pricing model at the date of grant. We recently completed a reverse merger, as described in Note 1, and as such, lack company-specific historical and implied volatility information. Therefore, we determined our expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expect to continue to do so until such time as it has adequate historical data regarding the volatility of our own traded stock price. Due to the lack of historical exercise history, the expected term of our stock options was determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that we have never paid cash dividends and do not expect to pay any cash dividends in the foreseeable future.

The fair value of our option awards granted during the year ended December 31, 2018 was estimated using the following assumptions:

Risk-free rate of interest	3.09%
Expected term (years)	5.0 to 6.25
Expected stock price volatility	85.31%
Dividend yield	0%

The following table summarizes our stock option activity for the year ended December 31, 2018:

	Total options Outstanding	Weighted average exercise price	Weighted average remaining contractual life (in years)
Outstanding as of January 1, 2018	-	$ -	-
Options granted	384,400	2.92	9.9
Exercised	-	-	-
Forfeited	-	-	-
Outstanding as of December 31, 2018	384,400	$ 2.92	9.9

No options were vested or exercisable as of December 31, 2018. The weighted average grant date fair value per share of options granted during the year ended December 31, 2018 was between $2.00 and $2.57. No forfeiture rate was applied to these stock options.

We recorded $74,063 of stock-based compensation expense for the year ended December 31, 2018 for awards issued as general and administrative expense.

No tax benefits were attributed to the stock-based compensation expense because a valuation allowance was maintained for all net deferred tax assets.

As of December 31, 2018, there was $754,877 of total unrecognized compensation expense, related to the unvested stock options which are expected to be recognized over a weighted average period of 3.6 years.

Note 10 – Net Loss per Share of Common Stock

Basic net loss per share is computed by dividing net loss by the weighted average common shares outstanding. Diluted net loss per share is computed by dividing net loss by the weighted average common shares outstanding without the impact of potential dilutive common shares outstanding because they would have an anti-dilutive impact on diluted net loss per share. The treasury-stock method is used to determine the dilutive effect of our stock options and warrants grants, and the if-converted method is used to determine the dilutive effect of the Senior Notes.

The computation of net loss per share for the year ended December 31, 2018 and 2017 was as follows:

	2018	2017
Basic and diluted net loss per share:		
Net loss	$ (3,765,047)	$ (1,856,315)
Weighted-average number of common shares-basic and diluted	37,324,267	32,595,680
Basic and diluted net loss per share	$ (0.10)	$ (0.06)

The outstanding options and warrants to purchase common stock and the shares issuable under the Senior Notes were excluded from the computation of diluted net income per share as their effect would have been anti-dilutive for the periods are presented below:

	2018	2017
Stock options and purchase warrants	3,917,763	-
Senior convertible notes	112,580	1,262,849

Note 11 – Related Party Transactions

A shareholder, CorLyst, LLC, reimburses us for shared costs related to payroll, health care insurance and rent based on actual costs incurred and recognized as a reduction of the general and administrative operating expenses being reimbursed in our condensed consolidated statement of operations. The reimbursed amounts totaled $134,881 and $49,089 for the years ended December 31, 2018 and 2017, respectively. Amounts due from CorLyst at December 31, 2018 and 2017 were $21,583 and $62,709, respectively. CorLyst also purchased 132,159 shares of our common stock for $300,001 in our private placement transaction on April 15, 2018.

One of our Directors is also the manager of the JMW Fund, LLC, San Gabriel Fund, LLC, and Richland Fund, LLC, collectively known as the “Funds.” The Funds received 515,583 shares of our common stock and warrants to purchase 515,583 shares of our common stock upon the conversion of $1 million of Senior Convertible Notes held by the Funds purchased on October 4, 2017. At December 31, 2018, the Funds owned a total of 2,566,639 shares of common stock and warrants to purchase 515,583 shares of common stock.

Entities affiliated with our Chairman of the Board of Directors and Chief Executive Officer (CEO) received 103,117 shares of our common stock and warrants to purchase 103,117 shares of our common stock upon the conversion of $200,000 in Senior Notes purchased on October 4, 2017. Our CEO and entities affiliated with our CEO also purchased a total of 132,160 shares of common stock and warrants to purchase 132,160 shares of common stock in private placement transactions in April and May 2018.

Note 12 – Commitments and Contingencies

Operating Lease Obligations

We currently lease office space and equipment from third parties under non-cancelable operating leases.

Our 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 our current office lease for the years ended December 31, 2018 and 2017 was $79,704 and $83,025, respectively. We also incurred common area maintenance and real estate tax reimbursements of $23,648 and $22,929 for the years ended December 31, 2018 and 2017, respectively. At December 31, 2018 and 2017, we included the current portion of our deferred rent liability of $9,963 and $3,321 in accrued expenses.

Our 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, 2018 and 2017 was $8,533 and $6,626, respectively.

Future minimum rental payments under the leases as of December 31, 2018, are as follows:

	Office	Equipment	Total
2019	$ 91,328	$ 7,036	$ 98,364
2020	87,176	4,691	91,867
2021	90,497		90,497
2022	69,741		69,741
Total future minimum lease payments	$ 338,742	$ 11,727	$ 350,469

Purchase Obligations

We enter into contracts in the normal course of business with contract research organizations and subcontractors to further develop our products. The contracts are cancellable, with varying provisions regarding termination. If a contract with a specific vendor were to be terminated, we would only be obligated for products or services that it received as of the effective date of the termination and any applicable cancellation fees. We had purchase obligations of approximately $35,000 and $896,000 at December 31, 2018 and 2017, respectively.

Note 13 – Concentration of Credit Risk

We maintain cash accounts in two commercial banks. Balances on deposit are insured by the Federal Deposit Insurance Corporation (FDIC) up to specified limits. Total cash held by one bank was $1,328,049 at December 31, 2018 which exceed FDIC limits.

Note 14 – Subsequent Event

In January 2019, we executed a new lease for our current space for an additional three years, extending the lease period to September 30, 2022 at a rental amount consistent with the current lease.

Item 9. Changes in and Disagreements with Accountants

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Based on an evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) required by paragraph (b) of Rule 13a-15 or Rule 15d-15, as of December 31, 2018, our Principal Executive Officer and Principal Financial Officer have concluded that, due to the material weaknesses in our internal control over financial reporting noted below, our disclosure controls and procedures were not effective. We are committed to the remediation of the material weaknesses described below, as well as the continued improvement of our internal control over financial reporting. We are in the process of taking steps to remediate the identified material weaknesses and continue to evaluate our internal controls over financial reporting, including utilizing the services of external consultants as necessary. As we continue our evaluation and improve our internal control over financial reporting, management may identify and take additional measures to address control deficiencies. We cannot assure you that we will be successful in remediating the material weaknesses in a timely manner.

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 Rule 13a-15(f) under the Exchange Act). Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2018 based on criteria established in Internal Control-Integrated Framework 2013 issued by the Committee of Sponsoring Organizations of the Treadway Commission. As a result of this assessment, management concluded that, as of December 31, 2018, our internal control over financial reporting was not effective. Our management identified the following material weaknesses in our internal control over financial reporting, which are common in many small companies with limited staff including: (i) certain entity level controls; (ii) inadequate segregation of duties throughout the entire year; and (iii) insufficient documentation of certain policies and procedures for transaction processing, accounting and financial reporting with respect to the requirements and application of both GAAP and SEC guidelines, their related controls and the operation thereof.

This annual report does not include an attestation report of our independent registered public accounting firm, BD & Company, Inc. regarding internal controls over financial reporting. Management's report was not subject to attestation by our registered public accounting form 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. Additionally, as a smaller reporting company, we are not currently subject to Section 404(b) of the Sarbanes-Oxley Act of 2002.

Changes in Internal Control Over Financial Reporting

Material Weaknesses and Related Remediation Initiatives

In July 2018 and September 2018, we hired our Director of Finance and Accounting and our Chief Financial Officer. We have begun taking steps to enhance and improve the design of our internal control over financial reporting. During the period covered by this annual report on Form 10-K, we have not remediated the material weaknesses identified above due in part to our Director of Finance and Accounting and our Chief Financial Officer both being hired in the latter part of 2018. To remediate such weaknesses, we are continuing to adopt and implement written policies and procedures for transaction processing, accounting and financial reporting and strengthening our supervisory review processes. If considered necessary, we will hire additional qualified personnel to address inadequate segregation of duties.

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) that occurred during the three months ended December 31, 2018, 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 and Executive Officers of the Registrant

The information with respect to this Item will be contained in the Proxy Statement under the captions "Election of Directors," "Board and Board Committee Information," and "Section 16(a) Beneficial Ownership Reporting Compliance" and is incorporated herein by reference thereto. The Proxy Statement or Form 10-K/A will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report. Please see section entitled "Executive Officers of the Registrant" in Item 1 of Part I of this report for information concerning executive officers.

Item 11. Executive Compensation

The information with respect to this Item will be contained in the Proxy Statement under the captions "Executive Compensation," and "Director Compensation" and is incorporated herein by reference thereto. The Proxy Statement or Form 10-K/A will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

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

The information with respect to this Item will be contained in the Proxy Statement under the headings "Principal Stockholders and Holdings of Management" and "Equity Compensation Plan Information" and is incorporated herein by reference thereto. The Proxy Statement or Form 10-K/A will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

Item 13. Certain Relationships and Related Transactions

The information with respect to this Item will be contained in the Proxy Statement under the captions "Certain Relationships and Related Party Transactions" and is incorporated herein by reference thereto. The Proxy Statement or Form 10-K/A will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

Item 14. Principal Accounting Fees and Services

The information with respect to this Item will be contained in the Proxy Statement under the captions "Ratification of the Selection of Independent Registered Public Accounting Firm" and is incorporated herein by reference thereto. The Proxy Statement or Form 10-K/A will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

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+	Amended and Restated 2011 Equity Incentive Plan (incorporated by reference to exhibit 10.10 to Form S-1 filed on November 14, 2012)
10.2	License Option Agreement with CoNCERT (incorporated by reference to exhibit 10.4 to Form 10-K/A filed on April 17, 2018)
10.3	Amendment to License Agreement and Securities Purchase Agreement with CoNCERT Pharmaceuticals (incorporated by reference to exhibit 10.5 to Form 10-K/A filed on April 17, 2018)
10.4	Convertible Note (incorporated by reference to exhibit 10.5 to Form 10-K/A filed on April 17, 2018)
10.5	Boustead Engagement Letter (incorporated by reference to exhibit 10.1 to Form 10-Q filed on April 17, 2018)
10.6	Form of Purchase Agreement (incorporated by reference to exhibit 10.2 to Form 10-Q filed on May 21, 2018)
10.7	Form of Warrant (incorporated by reference to exhibit 10.3 to Form 10-Q filed on May 21, 2018)
10.8	Agreement dated May 25, 2018 by and between Processa Pharmaceuticals, Inc. and PoC Capital, LLC (incorporated by reference from Form 8-K filed June 1, 2018)
10.9	Warrant issued to PoC Capital, LLC (incorporated by reference from Form 8-K filed June 1, 2018)
10.10	Warrant issued to PoC Capital, LLC (incorporated by reference from Form 8-K filed June 1, 2018)
10.11	Warrant issued to PoC Capital, LLC (incorporated by reference from Form 8-K filed June 1, 2018)
10.12	Warrants issued to Boustead Securities (incorporated by reference from Form 8-K filed June 1, 2018)
10.13+	Employment Agreement dated September 5, 2018, between Processa and James Stanker (incorporated by reference from Form 8-K filed September 10, 2018)
10.14	Pledge Agreement dated May 25, 2018, by and between Processa Pharmaceuticals, Inc. and PoC Capital, LLC (incorporated by reference to Form S-1 filed October 9, 2018)
21.1	List of Subsidiaries (incorporated by reference to exhibit 21.1 to Form 10-K/A filed on May 21, 2018)
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

** Furnished herewith. XBRL (eXtensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act is deemed not filed for purposes of Section 18 of the Exchange Act and otherwise is not subject to liability under these sections.

SIGNATURES

Pursuant to the requirements of the Securities 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
(Principal Executive Officer)
Dated: March 28, 2019

By: */s/ James Stanker*
James Stanker
Chief Financial Officer
(Principal Financial and Accounting Officer)
Dated: March 28, 2019

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	Chief Executive Officer and Director	March 28, 2018
/s/ James Stanker James Stanker	Chief Financial Officer	March 28, 2018
/s/ Patrick Lin Patrick Lin	Director	March 28, 2018
/s/ Justin Yorke Justin Yorke	Director	March 28, 2018
/s/ Virgil Thompson Virgil Thompson	Director	March 28, 2018

Exhibit 21.1

Subsidiaries of Processa Pharmaceuticals, Inc.

Subsidiary	State of Incorporation	Percent Ownership
Processa Therapeutics LLC	Delaware	100%

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 our report, dated March 28, 2019, relating to the consolidated financial statements of Processa Pharmaceuticals, Inc. in the Annual report on Form 10-K of Processa Pharmaceuticals, Inc. for the years ended December 31, 2018 and 2017.

/s/ BD & Company, Inc.

Owings Mills, MD
March 28, 2019

Exhibit 31.1

Certification Pursuant to pursuant to Rule 13a-14(a) or Rule 15d-14(a)
of the Securities Exchange Act of 1934, as amended

I, David Young, certify that:

1. I have reviewed this Annual report on Form 10-K of Processa Pharmaceuticals, Inc. (the "Company");

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. The Registrants other certifying officers and I are 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 the material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly through 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 evaluations, 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 that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have 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 the equivalent function):

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: March 28, 2019

/s/ David Young
David Young
Chief Executive Officer

Exhibit 31.1

Certification Pursuant to pursuant to Rule 13a-14(a) or Rule 15d-14(a)
of the Securities Exchange Act of 1934, as amended

I, James Stanker, certify that:

1. I have reviewed this Annual report on Form 10-K of Processa Pharmaceuticals, Inc. (the "Company");

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. The Registrants other certifying officers and I are 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 the material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly through 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 evaluations, 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 that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have 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 the equivalent function):

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: March 28, 2019

/s/ James Stanker
James Stanker
Chief Financial Officer

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Processa Pharmaceuticals, Inc. (the "Company") for the year ended December 31, 2018 (the "Report"), David Young, as Chief Executive Officer of the Company, and James Stanker, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ David Young

David Young
Chief Executive Officer
March 28, 2019

/s/ James Stanker

James Stanker
Chief Financial Officer
March 28, 2019

This certification accompanies each Report pursuant to § 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of § 18 of the Securities Exchange Act of 1934, as amended.

A signed original of this written statement required by § 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.