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, 2019

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	[ ]

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 28, 2019, the last business day of the most recently completed second quarter, based upon the closing price of Common Stock on such date as reported on OTCQB, was approximately $44.8 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 February 28, 2020, was 5,486,476.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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GLOSSARY OF CERTAIN SCIENTIFIC TERMS

The medical and scientific terms used in this Annual Report on Form 10-K have the following meanings:

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

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

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

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

"CRO" means a Contract Research Organization.

"EMA" means the European Medicines Agency.

"FDA" means the Food and Drug Administration.

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

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

"IPR&D" means In-Process Research and Development.

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

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

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

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

"RIF" means Radiation-Induced Fibrosis, a side effect of external beam radiation therapy for the treatment of cancer.

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

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

Part of our business strategy is:

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

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

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

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

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

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

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

Processa Portfolio: PCS499

Processa's lead product, PCS499, is an oral tablet that 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) 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. In the body, PCS499 is broken down into multiple metabolites. PCS499 and many of these metabolites are pharmacologically active. In animal and healthy human volunteer studies, higher exposure of certain active metabolites are seen after PCS499 administration compared to PTX. Despite the greater exposure to these pharmacologically active molecules, PCS499 is tolerated at higher doses than the maximum recommended FDA dose of PTX based on animal toxicology studies as well healthy human volunteer trials.

Based on the pharmacological activity of PCS499 and the off-label use of PTX, we have identified multiple unmet medical need conditions where the use of PCS499 may result in clinical efficacy. The lead indication currently under development for PCS499 is Necrobiosis Lipoidica (NL). NL is a chronic, disfiguring condition affecting the skin and the tissue under the skin typically on the lower extremities with no currently approved FDA treatments. NL presents more commonly in women than in men and ulceration can occur in approximately 30% of NL patients. More severe complications can occur, such as deep tissue infections and osteonecrosis threatening life of the limb. Approximately 74,000 - 185,000 people in the United States and more than 200,000 – 500,000 people outside the United States are affected by NL.

The degeneration of tissue occurring at the NL lesion site is caused by a number of pathophysiological changes which has made it extremely difficult to develop effective treatments for this condition. PCS499 may provide a solution since PCS499 and its metabolites affect a number of the biological pathways which contribute to the pathophysiology associated with NL.

On June 22, 2018, the FDA granted orphan-drug designation to PCS499 for the treatment of NL. On September 28, 2018, the FDA cleared our IND for PCS499 in NL such that we could move forward with the Phase 2a safety-dose tolerability trial. We dosed our first NL patient in this Phase 2a clinical trial on January 29, 2019 and completed enrollment on August 23, 2019. The main objective of the trial is to evaluate the safety and tolerability of PCS499 in patients with NL and to use the collected safety and efficacy data to design future clinical trials. Based on toxicology studies and healthy human volunteer studies, Processa and the FDA agreed that a PCS499 dose of 1.8 grams/day would be the highest dose administered to NL patients in this Phase 2 trial. As anticipated, the PCS499 dose of 1.8 grams/day, 50% greater than the maximum tolerated dose of PTX, appears to be well tolerated with no serious adverse events reported. To date, nine of the patients dosed at 1.8 grams/day have reported only mild adverse events related to the treatment, which occurred mostly in the first month of treatment and were quickly resolved. As expected, gastrointestinal or CNS adverse events were reported most often.

In our evaluation of the efficacy, after nine months of treatment we have seen significant changes in the two patients with more severe NL, one patient having a single ulcer and the second having multiple ulcers. In both patients, all of these ulcers have completely closed. Historically, less than 20% of all the patients with NL naturally progress to complete healing. Although the natural healing of the more severe NL patients with ulcers has not been evaluated independently, medical experts who treat NL patients believe that the natural progression of an open ulcerated wound to complete closure would be less than 5-10% if followed for approximately 12 months after presentation. In those patients without ulcers in our clinical trial, we have only seen a slight change in the NL lesion. One patient after three months of treatment and after altering her hypertension medication had a transient prolonged QTc interval four days after adding a beta blocker to her hypertension regimen. Her PCS499 regimen was decreased to 1.2 grams/day even though her QTc prolongation was only transient.

We have a meeting scheduled with the FDA in March 2020 to further discuss the development of PCS499, including a future clinical trial.

Processa is also evaluating other unmet medical need conditions for PCS499 such as primary glomerulonephritis and other conditions which would benefit from the diverse pharmacological properties associated with PCS499 and its active metabolites. Although our evaluation to date has identified numerous conditions which are likely to benefit from the use of PCS499, we are presently evaluating which indications meet our portfolio requirement of high potential return on investment and lower risk of development failure.

Processa Portfolio: PCS100

Processa recently entered into a license agreement for an anti-fibrotic, anti-inflammatory drug which affects collagen expression and the TGF-β pathway. PCS100 was previously developed for Duchenne Muscular Dystrophy (DMD) in pediatric patients but an incomplete toxicology package and a mismanaged DMD pediatric trial resulted in a serious adverse event, placing the drug temporarily on clinical hold. Since efficacy was observed in some DMD pediatric patients and FDA has removed the clinical hold, Processa plans to better define the therapeutic window and develop PCS100 in an adult unmet medical need condition (e.g., idiopathic pulmonary fibrosis, primary glomerulonephritis) and then move back to the pediatric focused indications at a later time.

Processa Portfolio: Additional Drugs

The Processa team is also looking to acquire additional drug candidates that fit our drug portfolio criteria.

Manufacturing and Clinical Supplies

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

We anticipate that these CMOs will have the capacity to support both clinical supply and commercial-scale production, but we do not have any formal agreements at this time with any of these CMOs to cover commercial production. We believe that we have or will have sufficient quantities of drug substance and drug product to supply our current Phase 2a trial of PCS499 for patients with NL.

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

Competition

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

The key competitive factors affecting the success of PCS499, if approved, are likely to include its efficacy, safety, convenience and price. There are currently no FDA-approved drugs for the treatment of patients with NL.

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

Intellectual Property

Our success will depend in large part on our ability 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 ("CoNCERT") for PCS499 and related compounds. The portfolio includes approximately 29 allowed or issued patents (of which nine are in the United States), which are directed to claims for composition of matter, methods of use, and certain chemical processes. Of these, three allowed or issued patents in the U.S. and Europe, as well as two in each of Australia, Canada, China, Japan and Mexico and one in each of Taiwan, Hong Kong, Russia, South Korea, the Philippines, South Africa, and Brazil cover the composition of matter of PCS499. The allowed or issued U.S. and European patents are expected to expire between 2029 and 2031, 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 a license agreement with CoNCERT (the "CoNCERT Agreement"). On March 19, 2018, we, Promet, and CoNCERT entered into an Amended Option Licensing Agreement ("March Amendment") that, among other things, assigned the CoNCERT Agreement from Promet to us and we exercised the exclusive commercial license option for the PCS499 compound from CoNCERT.

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

- 4% of the net sales of the portion less than or equal to $100 million;
- 5% of the net sales of the portion greater than $100 million and less than or equal to $500 million;
- 6% of the net sales of the portion greater than $500 million and less than or equal to $1.0 billion; and
- 10% of the net sales of the portion greater than $1 billion if such sales are made by us or our affiliates.

With respect to net sales made by us or any of our affiliates, we will pay 10% of net sales and with respect to sales by our sublicensees, we will pay the greater of (i) 6% or (ii) 50% of all payment received by us with respect to such sublicencee. We will also pay 15% of any sublicense revenue earned by us for a period equivalent to the royalty term (as defined in the CoNCERT Agreement) until the earliest of (a) our raising $8 million of gross proceeds and (b) CoNCERT being able to sell its shares of our common stock without restrictions pursuant to the terms of the amended Agreement. All other terms of the CoNCERT Agreement remained unchanged.

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

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

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

License Agreement with Akashi Therapeutics, Inc.

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

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

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

Government Regulation

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

U.S. Government Regulation

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

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

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

Pre-clinical studies

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

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

Clinical trials

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

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

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

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

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

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

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

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

Marketing Approval

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

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

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

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

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

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

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

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

Orphan drug designation

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

Expedited review and approval

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

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

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

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

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

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

Post-approval requirements

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

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

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

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

- restrictions on the marketing or manufacturing of the product;
- complete withdrawal of the product from the market or product recalls;
- safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warning or other safety information about the product;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals; product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

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

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

Other Regulatory Matters

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

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

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

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

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

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

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

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

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

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

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

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

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

U.S. Patent-Term Restoration and Marketing Exclusivity

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

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

European Union Drug Development

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

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

European Union Drug Review and Approval

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

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

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

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

Coverage and Reimbursement

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

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

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

Healthcare Reform

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

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

Some of the provisions of the ACA have yet to be implemented, and there have been judicial, Congressional and executive branch challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have passed. On December 22, 2017, President Trump signed into law new federal tax legislation commonly referred to as the Tax Cuts and Jobs Act (the Tax Act) which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare Part D drug plans. In July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA-qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA.

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

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

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

Employees

As of February 28, 2020, we had 13 employees, (full and part time). 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.

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) 4,535,121 shares of its common stock. Immediately following the transaction, Promet owned approximately 84% of our common stock and, as part of the Section 351 transaction, held approximately 6% of our common stock for the benefit of CoNCERT, until the CoNCERT transaction had been concluded whereupon CoNCERT took title to their shares. Following the closing, we changed our name from "Heatwurx Inc." to "Processa Pharmaceuticals Inc." and abandoned Heatwurx's prior business plan. We are now pursuing Promet's historical and proposed business.

We accounted for the net asset acquisition transaction as a reverse acquisition in accordance with U.S. GAAP, Financial Accounting Standards Board ("FASB"), Accounting Standards Codification ("ASC") 805-40-45, *Business Combinations – Reverse Acquisitions,* where Promet was considered the accounting acquirer, 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 transaction. 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.

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.

Reverse Stock Split

On December 23, 2019, we effected a one-for-seven reverse split of our shares of common stock. The number of authorized shares of common stock remained unchanged at 100,000,000 shares and the number of authorized shares of preferred stock remained unchanged at 1,000,000 shares. All share and per share amounts, conversion and exercise prices presented herein have been adjusted retroactively to reflect this change.

Corporate Information

We were 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.

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 $11.0 million at December 31, 2019. 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 recently entered into two line of credit agreements providing a revolving commitment of an aggregate of up to $1.4 million but have not drawn any amounts as of the date hereof. In December 2019 we closed our bridge financing and issued $805,000 of 8% Senior Convertible Notes (“2019 Senior Notes”) to accredited investors. We have not had any revenue since our inception, and we do not currently have any revenue under contract or any immediate sales prospects. As part of our effort to conserve cash, beginning on August 1, 2019 we have also delayed some of our cash outflows, primarily through the deferred payment of salaries ($122,175, which has been accrued and included in accrued expenses at December 31, 2019) until such time as we have raised sufficient funding.

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

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.

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.

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

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

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

Through our IND, we are conducting a Phase 2 safety tolerability evaluation of PCS499 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 (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 PCS499. If this occurs, there may not be any way to differentiate PCS499 from PTX thus making development and commercialization of PCS499 in NL not worth pursuing.

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.

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 PCS499 originally manufactured for CoNCERT Pharmaceuticals. Since PCS499 is a deuterated molecule requiring special facilities and chemicals for manufacturing, the manufacturing costs for PCS499 could result in the cost of goods being too high for the commercial price to be obtainable or too high to even manufacture the amount of drug needed to run the clinical studies prior to approval.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as (i) the drug's orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant's product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. If a drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity. While the FDA granted orphan-drug designation to PCS499 for the treatment of NL on June 22, 2018, there can be no assurance that we will receive orphan drug designation for any additional product candidates in the indications for which we think they might qualify, if we elect to seek such applications.

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

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

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

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

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

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 PCS499 and related compounds. The portfolio includes approximately 29 allowed or issued patents (of which nine are in the United States), which are directed to claims for composition of matter, methods of use, and certain chemical processes. Of these, three allowed or issued patents in the U.S. and Europe, as well as two in each of Australia, Canada, China, Japan and Mexico and one in each of Taiwan, Hong Kong, Russia, South Korea, the Philippines, South Africa, and Brazil cover the composition of matter of PCS499. The allowed or issued U.S. and European patents are expected to expire between 2029 and 2031, 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.

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

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

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

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

We identified a material weakness in our internal control over financial reporting. Our assessment has indicated we have material weaknesses related to certain entity level controls; inadequate segregations of duties throughout the entire year; and our formal documentation of certain policies and procedures, their related controls, and the operation thereof. We expanded our finance team, hiring a Director of Finance and Accounting in July 2018 and a CFO in September 2018. We are continuing to remediate our material weakness and to improve our internal controls and are in the process of implementing more fully documented formal policies and procedures.

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

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

We plan to implement a number of measures to address the material weaknesses we have identified, including hiring additional accounting personnel or consultants with appropriate expertise as necessary. We intend to complete the implementation of our remediation plan in 2020. However, we cannot assure you that we will be successful in remediating the material weaknesses we identified or that our internal control over financial reporting, as modified, will enable us to identify or avoid material weaknesses in the future.

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

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

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 are currently planning a capital raise to obtain additional funds to support additional clinical trials of PCS499, the development of PCS100, general research and development activities and general corporate activities, as well as to meet the minimum requirements necessary to list our common stock on the Nasdaq Capital Market. 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;
- changes in estimates or recommendations by securities analysts, if any, who cover our common stock;
- the timing and results of our current and any future preclinical or clinical trials of our product candidates;
- the entry into or termination of key agreements, including, among others, key collaboration and license agreements;
- the results and timing of regulatory reviews relating to the approval of our product candidates;
- the initiation of, material developments in, or conclusion of, litigation to enforce or defend any of our intellectual property rights;
- failure of any of our product candidates, if approved, to achieve commercial success;
- general and industry-specific economic conditions that may affect our research and development expenditures;
- the results of clinical trials conducted by others on products that would compete with our product candidates;
- issues in manufacturing our product candidates or any approved products;
- the introduction of technological innovations or new commercial products by our competitors;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- future sales of our common stock by us, our insiders or our other stockholders;
- a negative outcome in any litigation or potential legal proceeding;
- additions and departures of key personnel;
- negative publicity or announcements regarding regulatory developments relating to our products;
- actual or anticipated fluctuations in our financial condition and operating results, including our cash and cash equivalents balance, operating expenses, cash burn rate or revenue levels;
- our filing for protection under federal bankruptcy laws; or
- the other factors described in this “Risk Factors” section.

The stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. 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.

There is not now, and there may never be, an active, liquid and orderly trading market for our common stock, which may make it difficult for you to sell your shares of our common stock.

There is not now, nor has there been since our inception, any significant volume of trading activity in our common stock or an active market for shares of our common stock, and the warrants are a class of securities for which there is no existing market. An active trading market for our securities may never develop or be sustained. As a result, investors must bear the economic risk of holding our common stock for an indefinite period of time. Although our common stock is quoted on the OTCQB Marketplace, or OTCQB, over-the-counter quotation system, trading of our common stock on such system has only recently commenced and continues to be extremely limited and sporadic and at very low volumes. Although we expect to apply for listing on Nasdaq, an active trading market for our securities may never develop or be sustained. If an active market for our securities does not develop, it may be difficult for you to sell your securities without depressing the market price for such securities or at all. Further, an unestablished trading market for our securities may also impair our ability to raise capital by selling additional equity in the future, and may impair our ability to enter into strategic partnerships or acquire companies or products by using shares of our common stock as consideration.

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

Our executive officers and directors, combined with our stockholders who owned more than 5% of our outstanding common stock, in the aggregate, beneficially own shares representing approximately 57.8% of our outstanding capital stock. As a result, if these stockholders were to choose to act together, they would be able to influence our management and affairs and potentially control the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our assets. This concentration of ownership control may adversely affect the market price of our common stock by:

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

See the Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" section of this Annual Report on Form 10-K for more information regarding the ownership of our outstanding common stock by our executive officers, directors, principal stockholders and their affiliates.

Sales of substantial amounts of our common stock 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. 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 declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. There is no guarantee that our valuation will appreciate in value or even maintain the valuation at which our stockholders have purchased their shares.

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

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

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

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

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

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

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 until September 2022.

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 2019 and 2018. The quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

On December 23, 2019, we effected a one-for-seven reverse split of our shares of common stock. The number of authorized shares of common stock remained unchanged at 100,000,000 shares and the number of authorized shares of preferred stock remained unchanged at 1,000,000 shares. All share and per share amounts, conversion and exercise prices presented herein have been adjusted retroactively to reflect this change.

Quarter Ended	High	Low
December 31, 2019	$ 18.00	$ 9.80
September 30, 2019	19.25	17.01
June 30, 2019	19.60	15.75
March 31, 2019	25.55	13.72
December 31, 2018	30.45	11.90
September 30, 2018	33.46	17.50
June 30, 2018	32.90	22.75
March 31, 2018	35.00	18.20

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 February 28, 2020, there were 5,486,476 shares of common stock outstanding and 136 shareholders of record.

Transfer Agent and Registrar

Our transfer agent is Corporate Stock Transfer (acquired in November 2019 by Equiniti Group, LLC), 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 2019 Omnibus Incentive Plan as of December 31, 2019.

	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	129,190	$ 17.19	370,810
Equity compensation plans not approved by security holders	47,772	19.88	-
Total	176,962		370,810[(1)]

(1) Consists of shares available for issuance under the 2019 Omnibus Incentive Plan.

Recent Sales of Unregistered Securities

During the fourth quarter of 2019 existing shareholders purchased $805,000 of 8% Senior Convertible Notes ("2019 Senior Notes") from us. The 2019 Senior Notes bear interest at 8% per year and if converted, the interest is payable in kind (in common stock). The 2019 Senior Notes mature on December 15, 2020.

The 2019 Senior Notes are convertible by the holder upon (i) completion of listing our common stock on either the Nasdaq Capital Market or the New York Stock Exchange or if we raise at least $14 million, prior to December 15, 2020, the maturity date of the 2019 Senior Notes, in one or more qualified financings. If the 2019 Senior Notes are not paid or converted prior to their maturity date, the principal and any accrued interest will be automatically or mandatorily converted into our common stock. The 2019 Senior Notes, plus any accrued interest is convertible into shares of our common stock at a conversion price equal to the lower of (i) $14.28 per share or (ii) a price per share equal to a 10% discount to the pre-money valuation of a Qualified Financing or an Equity State Transaction, both as defined in the 2019 Senior Note agreement, occurring after the closing of the 2019 Senior Note financing. Upon either mandatory conversion or conversion at the holder's option, the holder will also receive stock purchase warrants on a 1:1 basis to the number of shares of common stock received that have an exercise price equal to the greater of (i) the closing price of our common stock on the date of conversion or (ii) $19.04 per share.

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

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

The 2019 Senior Notes were sold pursuant to the exemption from registration requirements of the Securities Act of 1933, as amended (the "Securities Act") in reliance on Section 4(a)(2) of the Securities Act.

Repurchases of Equity Securities

We did not repurchase any shares of our common stock during the fourth quarter of 2019.

Item 6. Selected Financial Data

Not applicable.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes and other financial information included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis contains forward-looking statements that involve risks and uncertainties. You should review the section titled "Risk Factors" in this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described below.

We completed a one for seven reverse stock split of our common stock on December 23, 2019. Unless otherwise indicated, all share amounts (and corresponding exercise and conversion prices of derivative securities) in this Annual Report on Form 10-K have been retroactively adjusted to give effect to this reverse stock split (subject to rounding up fractional shares).

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), will begin developing a newly acquired drug once adequate funding is obtained, and are 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 4,535,121 shares of our common stock. Immediately following the transaction, the former equity holders of Promet owned approximately 84% and held approximately 6% of the shares for the benefit of CoNCERT in relation to the CoNCERT contribution of the license to Processa as part of the Section 351 transaction, and our stockholders immediately prior to the transaction owned approximately 10% of our common stock. In December 2019, Promet distributed 4,135,396 shares of the common stock it held to its partners. In 2019, our common stock was traded 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. We were considered a non-operating public shell corporation.

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 PCS499, 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, 2019, we had an accumulated deficit of $11.0 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will continue to increase in connection with our ongoing activities, as we:

- continue to invest in the development of PCS499 for the treatment of NL;
- manufacture our drug candidate;
- begin developing PCS100;
- 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 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 regarding product development and commercialization, limited working capital, recurring losses and negative cash flow from operations, future profitability, ability to obtain future capital, protection of patents, technologies and property rights, competition, rapid technological change, navigating the domestic and major foreign markets' regulatory and clinical environment, recruiting and retaining key personnel, dependence on third party manufacturing organizations, third party collaboration and licensing agreements, lack of sales and marketing activities and having no customers or pharmaceutical products to sell or distribute. These risks and other factors raise substantial doubt about our ability to continue as a going concern.

We have relied exclusively on private placements with a small group of accredited investors to finance our business and operations. As described in more detail below, we recently entered into two line of credit agreements providing a revolving commitment of an aggregate of up to $1.4 million but have not drawn any amounts as of the date of this report. We have not had any revenue since our inception, and we do not currently have any revenue under contract or any immediate sales prospects. For the year ended December 31, 2019, we incurred a net loss from continuing operations of approximately $3.4 million and used approximately $2.8 million in net cash from operating activities. We expect our operating costs to be substantial as we incur costs related to the clinical trials for our product candidates and that we will operate at a loss for the foreseeable future. At December 31, 2019, we had cash and cash equivalents totaling $691,536.

On September 20, 2019, we entered into two separate Line of Credit Agreements ("LOC Agreements") with DKBK Enterprises, LLC ("DKBK") and current shareholder CorLyst, LLC ("CorLyst"), both related parties ("Lenders"), which provide a revolving commitment of up to $700,000 each ($1.4 million total). Under the LOC Agreements, all funds borrowed will bear an 8% annual interest rate. The lenders have the right to convert all or any portion of the debt and interest into Processa common shares. Our Chief Executive Officer (CEO) is also the CEO and Managing Member of both Lenders. CorLyst beneficially owns 996,376 shares of Processa common stock, representing approximately 17.8% of the Company's outstanding shares of voting capital stock. We have not drawn any amounts under these LOC agreements as of February 28, 2020.

In connection with the LOC Agreements, we amended the existing pledge agreement with PoC Capital on September 30, 2019 to reduce the committed funds from $1.8 million to $900,000, which has now been paid in full as of December 31, 2019. As part of the original pledge agreement, we issued 113,280 shares of common stock and 113,280 warrants to purchase shares of common stock to PoC Capital but held 56,639 shares and warrants to purchase 56,639 shares as collateral until certain payment milestones were met. PoC Capital forfeited the pledged collateral in the amended agreement. The forfeited shares and warrants have been returned to us.

In December 2019 we closed our bridge financing and issued $805,000 of the 2019 Senior Notes to accredited investors. In order to preserve cash, we have also delayed some of our cash outflows, primarily through the deferred payment of salaries ($122,175, which has been accrued and included in accrued expenses at December 31, 2019) until such time as we have raised sufficient funding.

We believe that our existing cash and LOC Agreements will enable us to fund our operating expenses and capital expenditure requirements into Q3 2020. With our existing resources, we expect to be able to complete our Phase 2a trial. We have based these estimates on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect. We also expect to raise capital in an underwritten public offering during the first half of 2020.

As a result, substantial doubt existed about our ability to continue as a going concern as of the date of the filing of this Annual Report on Form 10-K for the year ended December 31, 2019. 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.

Status of our Phase 2a Clinical Trial in Necrobiosis Lipoidica

Our lead product, PCS499, is an oral tablet that is a deuterated analog of one of the major metabolites of pentoxifylline (Trental®). The advantage of PCS499 is that it potentially may work in many conditions because it has multiple pharmacological targets it affects that are important in the treatment of these conditions. Based on its pharmacological activity, we have identified multiple unmet medical need conditions where the use of PCS499 may result in clinical efficacy. The lead indication currently under development for PCS499 is Necrobiosis Lipoidica (NL). NL is a chronic, disfiguring condition affecting the skin and the tissue under the skin typically on the lower extremities with no currently approved FDA treatments. NL presents more commonly in women than in men and ulceration can occur in approximately 30% of NL patients. More severe complications can occur, such as deep tissue infections and osteonecrosis threatening life of the limb. Approximately 74,000 - 185,000 people in the United States and more than 200,000 – 500,000 people outside the United States are affected by NL.

The degeneration of tissue occurring at the NL lesion site is caused by a number of pathophysiological changes, which has made it extremely difficult to develop effective treatments for this condition. PCS499 may provide a solution since PCS499 and its metabolites affect a number of biological pathways, several of which contribute to the pathophysiology associated with NL.

On June 22, 2018, the FDA granted orphan-drug designation to PCS499 for the treatment of NL. On September 28, 2018, the FDA cleared our IND for PCS499 in NL such that we could move forward with the Phase 2 safety-dose tolerability trial. We dosed our first NL patient in this Phase 2a clinical trial on January 29, 2019 and completed enrollment on August 23, 2019. The main objective of the trial is to evaluate the safety and tolerability of PCS499 in patients with NL and to use the collected safety and efficacy data to design future clinical trials. Based on toxicology studies and healthy human volunteer studies, Processa and the FDA agreed that a PCS499 dose of 1.8 grams/day would be the highest dose administered to NL patients in this Phase 2 trial. As anticipated, the PCS499 dose of 1.8 grams/day, 50% greater than the maximum tolerated dose of PTX, appears to be well tolerated with no serious adverse events reported. To date, nine of the patients dosed at 1.8 grams/day have reported only mild adverse events related to the treatment, which occurred mostly in the first month of treatment and were quickly resolved. As expected, gastrointestinal or CNS adverse events were reported most often.

In our evaluation of the efficacy, after nine months of treatment we have seen significant changes in the two patients with more severe NL, one patient having a single ulcer and the second having multiple ulcers. In both patients, all of these ulcers have completely closed. Historically, less than 20% of all the patients with NL naturally progress to complete healing. Although the natural healing of the more severe NL patients with ulcers has not been evaluated independently, medical experts who treat NL patients believe that the natural progression of an open ulcerated wound to complete closure would be less than 5-10% if followed for approximately 12 months after presentation. In those patients without ulcers in our clinical trial, we have only seen a slight change in the NL lesion. One patient after three months of treatment and after altering her hypertension medication had a transient prolonged QTc interval four days after adding a beta blocker to her hypertension regimen. Her PCS499 regimen was decreased to 1.2 grams/day even though her QTc prolongation was only transient.

We have a meeting scheduled with the FDA in March 2020 to further discuss the development of PCS499, including a future clinical trial.

License Agreement for PCS100

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

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

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

Results of Operations

Comparison of the year ended December 31, 2019 and 2018

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

	Year Ended December 31,		
	2019	2018	Change
Operating Expenses			
Research and development costs	$ 2,320,573	$ 3,085,317	$ (764,744)
General and administrative expenses	1,614,909	1,439,623	175,286
Total operating expenses	3,935,482	4,524,940	
Other Income (Expense)			
Interest expense	(36,658)	(161,205)	124,547
Interest income	11,548	18,297	(6,749)
Total other income (expense)	(25,110)	(142,908)	
Net Operating Loss Before Income Tax Benefit	(3,960,592)	(4,667,848)	
Income Tax Benefit	602,716	902,801	(300,085)
Net Loss	$ (3,357,876)	$ (3,765,047)	

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

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

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

During the year ended December 31, 2019, our research and development costs decreased by $764,744 to $2,320,573 from $3,085,317 for year ended December 31, 2018.

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

We incurred $554,935 in costs related to our Phase 2a trial during the year ended December 31, 2019 and expect to spend approximately an additional $487,000 through 2020 to complete our current trial. We believe, based on our estimates, the cost of our current Phase 2a trial to be approximately $1.5 million. PoC Capital paid for $900,000 of the clinical trial costs, and we will cover the remaining $600,000 with funds received from the sale of our 2019 Senior Notes and our LOC Agreements, as necessary. During the year ended December 31, 2018, we made payments to our CRO related to our Phase 2a trial of approximately $239,000. We have accounted for these payments as either a prepaid expense or a research and development expense depending on whether the related service has been provided. During the year ended December 31, 2019, PoC Capital made payments directly to our CRO totaling $689,168 for amounts invoiced. PoC Capital also repaid us $210,832 for clinical trial expenses we previously paid to our CRO, $180,119 of which is included in Prepaid and Other on our consolidated balance sheet at December 31, 2019. We amended the existing pledge agreement with PoC Capital on September 30, 2019 to reduce the committed funds from $1.8 million to $900,000, which has now been paid in full as of December 31, 2019. As part of the original pledge agreement, we issued 113,280 shares of common stock and warrants to purchase 113,280 shares of common stock to PoC Capital but held 56,640 shares and warrants to purchase 56,640 shares as collateral until certain payment milestones were met. PoC Capital forfeited the pledged collateral in the amended agreement. The forfeited shares and warrants have been returned to us.

The funding necessary to bring a drug candidate to market is, however, subject to numerous uncertainties. Once a drug candidate is identified, the further development of that drug candidate can be halted or abandoned at any time due to a number of factors. These factors include, but are not limited to, funding constraints, safety or a change in market demand. For each of our drug candidate programs, we periodically assess the scientific progress and merits of the programs to determine if continued research and development is economically viable. Certain of our programs may be terminated due to the lack of scientific progress and lack of prospects for ultimate commercialization. We anticipate our research and development costs to increase in the future as we continue our Phase 2a clinical trial activities for NL and initiate our research activities related to PSC100 in 2020.

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 services are recorded as prepaid expenses until the services are rendered.

General and Administrative Expenses.

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

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

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 $36,658 and $161,205 for the years ended December 31, 2019 and 2018, respectively, related to our 2019 and 2017 Senior Notes. In May 2018, $2.35 million of the 2017 Senior 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 $1,783 and $67,069 for the years ended December 31, 2019 and 2018, respectively.

Interest Income.

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

Income Tax Benefit.

An income tax benefit of $602,716 and $902,801 was recognized for the years ended December 31, 2019 and 2018, respectively, as a result of our recording and amortizing the deferred tax liability created in connection with our acquisition of CoNCERT's license and "Know-How" in exchange for Processa stock that had been issued in the Internal Revenue Code Section 351 transaction on March 19, 2018. The Section 351 transaction treated the acquisition of the Know-How for stock as a tax-free exchange. As a result, under ASC 740-10-25-51 *Income Taxes*, Processa recorded a deferred tax liability of $3,037,147 for the acquired temporary difference between the financial reporting basis of $11,038,929 and the tax basis of $1,782. Each year, the deferred tax liability is decreased for the non-deductibility of the amortization of the intangible asset for the current period. Additionally, the liability is being offset for the deferred tax assets resulting from our net taxable operating losses. Our taxable net operating loss for 2019 was $1,043,567 less than that of 2018 as we focus on the Phase 2a clinical trial study and decrease administrative costs such as professional fees.

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, 2019, we had $691,536 in cash. Net cash used in our operating activities during the year ended December 31, 2019 totaled $2,750,145 compared to $3,707,914 for the years ended December 31, 2018.

Our total assets decreased by approximately $1.6 million to $10.9 million at December 31, 2019 compared to $12.5 million at December 31, 2018. This decrease is a result of the operating costs we have incurred during the year ended December 31, 2019, net of operating costs funded through the stock subscription receivable, offset by the recording of right-of-use assets in conjunction with the adoption of ASC 842.

At December 31, 2019, our total liabilities, not including the impact of deferred income taxes, increased by $693,250 to $1,338,954 when compared to $645,704 at December 31, 2018. The increase was primarily due to the $572,000 increase in senior convertible debt due to the sale of 2019 Senior Notes, net of debt issuance costs; the recognition of approximately $225,000 in operating lease liabilities in accordance with the adoption of ASC 842; and an increase of approximately $112,000 in accrued expenses and interest. The increase was offset by a decrease in accounts payable of approximately $216,000.

We had $805,000 of 2019 Senior Notes and $230,000 of 2017 Senior Notes outstanding at December 31, 2019 and 2018, respectively. In December 2019 we closed our bridge financing and issued $805,000 of the 2019 Senior Notes to accredited investors. The 2017 Senior Notes outstanding at December 31, 2018 were held by Canadian investors that, although qualifying for automatic and mandatory conversion, could not be converted until the Alberta Securities Commission released us from a cease trade order, which predated our merger with Heatwurx, and permitted us to issue common stock units (consisting of shares of our common stock and stock purchase warrants) to these Canadian investors. In June 2019, the Alberta Securities Commission released the cease trade order and assessed us a $10,000 fine. On July 2, 2019, we converted the principal and related accrued interest of approximately $259,000 into 18,107 shares of common stock and 18,107 stock purchase warrants.

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

The following transactions had a direct impact on our stockholders' equity in 2019:

- clinical trial expenses paid directly by clinical trial investor;
- the conversion of approximately $259,000 in 2017 Senior Notes, including accrued interest, into 18,107 shares of common stock;
- pledged shares of common stock forfeited and reduction in subscription receivable upon revised agreement with clinical trial investor; and
- the results of our operations, including stock-based compensation of $510,478.

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. In December 2019, we closed our bridge financing and issued $805,000 of the 2019 Senior Notes to accredited investors. In order to preserve cash, we have also delayed some of our cash outflows, primarily through the deferred payment of salaries ($122,175, which has been accrued and included in accrued expenses during the year ended December 31, 2019) until such time as we have raised sufficient funding.

At December 31, 2019, we had $691,536 in cash and cash equivalents compared to $1.7 million at December 31, 2018. During the year ended December 31, 2019, PoC Capital made payments directly to our CRO totaling $689,168 for amounts invoiced. PoC Capital also repaid us $210,832 for clinical trial expenses we previously paid to our CRO, $180,119 of which is included in "Prepaid expenses and other" on our consolidated balance sheet at December 31, 2019.

On September 20, 2019, we entered into two separate LOC Agreements" with DKBK and current shareholder CorLyst, both related parties, which provide a revolving commitment of up to $700,000 each ($1.4 million total). Under the LOC Agreements, all funds borrowed will bear an 8% annual interest rate. The lenders have the right to convert all or any portion of the debt and interest into Processa common shares. Our Chief Executive Officer (CEO) is also the CEO and Managing Member of both Lenders. CorLyst beneficially owns 996,376 shares of Processa common stock, representing approximately 17.8% of the Company's outstanding shares of voting capital stock. We have not drawn any amounts under these LOC agreements as of February 28, 2020.

In connection with the LOC Agreements, we amended the existing pledge agreement with PoC Capital on September 30, 2019 to reduce the amount committed from $1.8 million to $900,000, which has now been paid in full as of December 31, 2019. As part of the original pledge agreement, we issued 113,280 shares of common stock and warrants to purchase 113,280 shares of common stock to PoC Capital but held 56,640 shares and warrants to purchase 56,640 shares as collateral until certain payment milestones were met. PoC Capital forfeited the pledged collateral in the amended agreement. The forfeited shares and warrants have been returned to us. We anticipate the total cost to fund our current Phase 2a clinical trial of PCS499 for patients with NL to be approximately $1.5 million. We will fund the remaining $600,000 with funds received from the sale of our 2019 Senior Notes and our LOC Agreements, as necessary.

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

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

We believe that the net proceeds from our 2019 Senior Notes and our LOC Agreements, together with our existing cash, will enable us to fund our operating expenses and capital expenditure requirements into Q3 2020. With our existing cash and funds available under the LOC Agreements, we expect to be able to complete our Phase 2a trial. We have based these estimates on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect. We also expect to raise capital in an underwritten public offering during the first half of 2020.

Cash Flows

The following table sets forth our sources and uses of cash and cash equivalents for the years ended December 31, 2019 and 2018:

	For the Year Ended December 31,	
	2019	2018
Net cash provided by (used in):		
Operating activities	$ (2,750,145)	$ (3,707,914)
Investing activities	-	(22,282)
Financing activities	1,700,720	2,623,728
Net increase in cash and cash equivalents	$ (1,049,425)	$ (1,106,468)

Net cash used in operating activities

We used net cash in our operating activities of $2,750,145 and $3,707,914 during the years ended December 31, 2019 and 2018, respectively. The decrease in cash used in operating activities in 2019 compared to the comparable period in 2018 was related to a decreased amount of direct cash costs incurred. Our net loss for the year ended December 31, 2019 was $407,171 less than the comparable period in 2018. This was due primarily to our focus on PCS499 leading to an overall reduction in our research and development expenses. We also incurred amortization expense of $795,328 (versus $621,647 for the comparable period in 2018) and $510,478 of stock-based compensation (versus $74,063 for the comparable period in 2018) during the year ended December 31, 2019. During the year ended December 31, 2018, we incurred a one-time cybersecurity fraud loss of $144,200, 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 had no cash sources or uses for investing activities during the year ended December 31, 2019. We used net cash in our investing activities of $22,282 during the year ended December 31, 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 PCS499 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 (298,615 shares).

Net cash provided by financing activities

During the year ended December 31, 2019, we received net proceeds of $1,700,720 from the issuance of $805,000 of 2019 Senior Notes, offset by $4,280 of debt issuance costs. Our clinical trial investor also paid $900,000 in satisfaction of the subscription receivable. During the year ended December 31, 2018, we sold 200,369 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 2017 Senior Notes and accrued interest of $114,333 into 172,327 shares of common stock, at a price of $14.301 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 $17.164. In connection with our capital raising and debt conversion transactions in 2018, we incurred $559,789 of placement agent and other professional fees.

Funding Requirements

We believe that our existing cash and LOC Agreements will enable us to fund our operating expenses and capital expenditure requirements into Q3 2020. We expect to be able to complete our Phase 2a trial for PCS499, but we do not have sufficient funds to begin developing PCS100. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based these estimates on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect.

Our future capital requirements will depend on many factors, including:

- the cost of future trials for PCS499 and the cost of manufacturing;
- the initiation, progress, timing, costs and results of drug discovery, pre-clinical studies and clinical trials of PCS100 and any other future product candidates;
- the number and characteristics of product candidates that we pursue;
- the outcome, timing and costs of seeking regulatory approvals;
- the costs associated with hiring additional personnel and consultants as our pre-clinical and clinical activities increase;
- the emergence of competing therapies and other adverse market developments;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the extent to which we in-license or acquire other products and technologies; and
- the costs of operating as a public company.

Until such time, if ever, as we can generate substantial product revenues to support our capital requirements, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, collaborations and licensing arrangements or other capital sources. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders.

Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may need to relinquish valuable rights to our product candidates, future revenue streams, research programs or may have to grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings as and when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates.

Identifying potential product candidates and conducting pre-clinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of product candidates that we do not expect to be commercially available for the next couple of years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2019:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating lease obligations	$ 252,839	$ 92,603	$ 160,236	$ -	$ -
Total	$ 252,839	$ 92,603	$ 160,236	$ -	$ -

We enter into contracts in the normal course of business with CROs, clinical supply manufacturers and vendors for pre-clinical studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts and not included in the table above.

We have also entered into license and collaboration agreements with third parties, which are in the normal course of business. We have not included future payments under these agreements in the table of contractual obligations above since obligations under these agreements are contingent upon future events such as our achievement of specified development, regulatory, and commercial milestones, or royalties on net product sales

See Note 14 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 $487,000 of future services under the agreement, but our actual contractual obligations will vary depending on the progress and results of the clinical trial.

Off Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

Critical Accounting Policies and Use of Estimates

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

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

Valuation of Intangible Assets

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

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

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

Clinical Trial Accruals / Research and Development

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

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

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

Stock-Based Compensation

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

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

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

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

Income Taxes

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

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

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

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

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

During the years ended December 31, 2019 and 2018, we incurred net operating losses of $3,960,592 and $4,667,848, respectively. We did not record any income tax benefit for the $1,205,811 ($331,809 tax effected) and $1,356,840 ($373,368 tax effected) of general and administrative expenses treated as deferred start-up expenditures for tax purposes for the years ended December 31, 2019 and 2018, respectively. We did not record any income tax benefit for the $283,189 of federal orphan drug tax credits for the year ended December 31, 2019. Additionally, we did not record any income tax benefit in 2017 for the $258,583 ($71,283 tax effected) of tax losses incurred in 2017 which resulted in tax loss carryforwards. The benefit was recognized in 2018 in the calculation of the valuation allowance. The 2017 net operating loss carry forwards are available for application against future taxable income for 20 years expiring in 2037. Tax losses incurred after December 31, 2017 have an indefinite carry forward period. However, the tax loss incurred after December 31, 2017 and carried forward can only offset 80 percent of future taxable income in any one year, with any excess losses being carried forward indefinitely. We have recorded the benefit of our 2019 and 2018 net operating losses in our consolidated financial statements as a reduction in the deferred tax liability created by the future financial statement amortization of the intangible asset from the acquired Know-How. The benefit associated with the net operating loss carry forward will more-likely-than-not go unrealized unless future operations are successful except for their offset against the deferred tax liability created by the acquired CoNCERT license and "Know-How."

Recently Issued Accounting Pronouncements

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

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, 2019 and 2018, the related consolidated statements of operations, stockholders' equity, and cash flows, for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ BD & Company, Inc.
Owings Mills, MD
March 6, 2020

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

Processa Pharmaceuticals, Inc.
Consolidated Balance Sheets

	December 31, 2019	December 31, 2018
ASSETS		
Current Assets		
Cash and cash equivalents	$ 691,536	$ 1,740,961
Due from related party	-	21,583
Prepaid expenses and other	315,605	257,832
Total Current Assets	1,007,141	2,020,376
Property And Equipment		
Software	19,740	19,740
Office equipment	9,327	9,327
Total Cost	29,067	29,067
Less: accumulated depreciation	20,137	11,692
Property and equipment, net	8,930	17,375
Other Assets		
Operating lease right-of-use assets, net of accumulated amortization	219,074	-
Intangible assets, net of accumulated amortization	9,642,454	10,437,782
Security deposit	5,535	5,535
Total Other Assets	9,867,063	10,443,317
Total Assets	$ 10,883,134	$ 12,481,068
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Senior convertible notes, net of debt issuance costs	$ 802,503	$ 230,000
Current maturities of operating lease liability	77,992	-
Accrued interest	21,902	20,343
Accounts payable	75,612	292,102
Due to related parties	316	-
Accrued expenses	213,239	103,259
Total Current Liabilities	1,191,564	645,704
Non-current Liabilities		
Non-current operating lease liability	147,390	-
Net deferred tax liability	1,531,630	2,134,346
Total Liabilities	2,870,584	2,780,050
Commitments and Contingencies		
Stockholders' Equity		
Common stock, par value $0.0001, 100,000,000 and 350,000,000 shares authorized; 5,486,476 and 5,525,009 issued and outstanding at December 31, 2019 and 2018, respectively	549	552
Additional paid-in capital	18,994,008	19,124,600
Common stock deemed dividend payable: 28,971 shares at par value	3	-
Stock subscription receivable	-	(1,800,000)
Accumulated deficit	(10,982,010)	(7,624,134)
Total Stockholders' Equity	8,012,550	9,701,018
Total Liabilities and Stockholders' Equity	$ 10,883,134	$ 12,481,068

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

Processa Pharmaceuticals, Inc.
Consolidated Statements of Operations
Years Ended December 31, 2019 and 2018

	December 31	
	2019	2018
Operating Expenses		
Research and development expenses	$ 2,320,573	$ 3,085,317
General and administrative expenses	1,614,909	1,439,623
Operating Loss	(3,935,482)	(4,524,940)
Other Income (Expense)		
Interest expense	(36,658)	(161,205)
Interest income	11,548	18,297
Net Operating Loss Before Income Tax Benefit	(3,960,592)	(4,667,848)
Income Tax Benefit	602,716	902,801
Net Loss	$ (3,357,876)	$ (3,765,047)
Net Loss Per Common Share - Basic and Diluted	$ (0.70)	$ (0.71)
Weighted Average Common Shares Used to Compute Net Loss Per Common Shares - Basic and Diluted	5,525,635	5,332,141

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

Processa Pharmaceuticals, Inc.
Consolidated Statement of Changes in Stockholders' Equity
Years Ended December 31, 2019 and 2018

	Common Stock		Additional Paid-In	Subscription	Common Stock Dividend	Accumulated	
	Shares	Amount	Capital	Receivable	Payable	Deficit	Total
Balance, January 1, 2018	5,039,033	$ 504	$ 4,231,746	$ -	$ -	$ (3,859,087)	$ 373,163
Recognize the fair value of exclusive license intangible asset acquired from CoNCERT in exchange for 298,615 common shares of Processa held by Promet	-	-	8,000,000	-	-	-	8,000,000
Conversion of Senior convertible notes and accrued interest for common stock and stock purchase warrants, net of costs of $82,502	172,327	17	2,312,592	-	-	-	2,312,609
Issuance of common stock units for cash, net of costs of $308,830	200,369	20	2,874,667	-	-	-	2,874,687
Issuance of common stock units for a future research funding commitment, net of costs of $168,457	113,280	11	1,631,532	(1,800,000)	-	-	(168,457)
Stock-based compensation	-	-	74,063	-	-	-	74,063
Net loss	-	-	-	-	-	(3,765,047)	(3,765,047)
Balance, January 1, 2019	5,525,009	552	19,124,600	(1,800,000)	-	(7,624,134)	9,701,018
Conversion of Senior convertible debt for common stock and stock purchase warrants	18,107	2	258,928	-	-	-	258,930
Payments made by investor for clinical trial costs	-	-	-	900,000	-	-	900,000
Pledged shares of common stock forfeited upon revised research funding commitment	(56,640)	(5)	(899,995)	900,000	-	-	-
Stock-based compensation	-	-	510,478	-	-	-	510,478
Deemed stock dividend due to full ratched anti-dilution adjustment	-	-	(3)	-	3	-	-
Net loss	-	-	-	-	-	(3,357,876)	(3,357,876)
Balance, December 31, 2019	5,486,476	$ 549	$ 18,994,008	$ -	$ 3	$ (10,982,010)	$ 8,012,550

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

Processa Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows
Years Ended December 31, 2019 and 2018

	December 31,	
	2019	2018
Cash Flows From Operating Activities		
Net Loss	$ (3,357,876)	$ (3,765,047)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	8,445	8,445
Non-cash lease expense for right-of-use assets	74,124	-
Amortization of debt issuance costs	1,783	67,069
Amortization of intangible asset	795,328	621,647
Deferred income tax (benefit) expense	(602,716)	(902,801)
Stock-based compensation	510,478	74,063
Net changes in operating assets and liabilities:		
Prepaid expenses and other	(57,773)	(216,386)
Operating lease liability	(77,779)	-
Accrued interest	30,489	94,122
Accounts payable	(216,490)	241,416
Due from related parties	21,899	40,690
Accrued expenses	119,943	28,868
Net cash (used in) operating activities	(2,750,145)	(3,707,914)
Cash Flows From Investing Activities		
Purchase of software license	-	(20,500)
Purchase of intangible asset	-	(1,782)
Net cash (used in) investing activities	-	(22,282)
Cash Flows From Financing Activities		
Net proceeds from issuance of stock	-	2,874,687
Proceeds from issuance of senior convertible notes	805,000	-
Proceeds received in satisfaction of stock subscription receivable	900,000	-
Transaction costs incurred on senior convertible notes	(4,280)	(82,502)
Payment of placement agent and legal fees associated with clinical funding commitment	-	(168,457)
Net cash provided by financing activities	1,700,720	2,623,728
Net (Decrease)/Increase in Cash and Cash Equivalents	(1,049,425)	(1,106,468)
Cash and Cash Equivalents - Beginning of Year	1,740,961	2,847,429
Cash and Cash Equivalents - End of Year	$ 691,536	$ 1,740,961

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

Processa Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows (continued)
Years Ended December 31, 2019 and 2018

Supplemental Cash Flow Information:	2,019	2,018
Cash paid for interest	$ -	$ -
Cash paid for income taxes	-	-
Non-Cash Investing and Financing Activities:		
Right-of-use asset obtained in exchange for operating lease liability	$ (293,198)	$ -
Reduction in deferred lease liability	(9,963)	-
Operating lease liability	303,161	-
Net	$ -	$ -
Recognize the exclusive license intangible asset acquired from CoNCERT	$ -	$ (11,037,147)
Recognize deferred tax liability for basis difference of Intangible asset	-	3,037,147
Recognize additional paid-in capital for consideration paid from the transfer of 298,615 common shares of Processa released by Promet to CoNCERT for Processa	-	8,000,000
Net	$ -	$ -
Conversion of $230,000 and $2,350,000, respectively, of Senior Convertible Debt and related accrued interest of $28,930 and $114,333, respectively, into 18,107 and 172,327 shares, respectively, of common stock and warrants	$ 258,930	$ 2,464,333
Common stock and stock purchase warrants (forfeited)/issued in connection with a clinical trial funding commitment	$ (900,000)	$ 1,800,000

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

Note 1 – Organization and Description of the Business

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

Our lead product, PCS499 is an oral tablet that is a deuterated analog of the major metabolites of pentoxifylline (Trental®). The advantage of PCS499 is that it potentially may work in many conditions because it has multiple pharmacological targets it affects that are important in the treatment of these conditions. Based on its pharmacological activity, we have identified multiple unmet medical need conditions where the use of PCS499 may result in clinical efficacy. The lead indication currently under development for PCS499 is Necrobiosis Lipoidica (NL). NL is a chronic, disfiguring condition affecting the skin and the tissue under the skin typically on the lower extremities with no currently approved FDA treatments. NL presents more commonly in women than in men and ulceration can occur in approximately 30% of NL patients. More severe complications can occur, such as deep tissue infections and osteonecrosis threatening life of the limb. Approximately 74,000 - 185,000 people in the United States and more than 200,000 – 500,000 people outside the United States are affected by NL.

The degeneration of tissue occurring at the NL lesion site is caused by a number of pathophysiological changes, which has made it extremely difficult to develop effective treatments for this condition. PCS499 may provide a solution since PCS499 and its metabolites affect a number of biological pathways, several of which contribute to the pathophysiology associated with NL.

On June 22, 2018, the FDA granted orphan-drug designation to PCS499 for the treatment of NL. On September 28, 2018, the FDA cleared our IND for PCS499 in NL such that we could move forward with the Phase 2a safety-dose tolerability trial. We dosed our first NL patient in this Phase 2a clinical trial on January 29, 2019 and completed enrollment on August 23, 2019. The main objective of the trial is to evaluate the safety and tolerability of PCS499 in patients with NL and to use the collected safety and efficacy data to design future clinical trials. Based on toxicology studies and healthy human volunteer studies, Processa and the FDA agreed that a PCS499 dose of 1.8 grams/day would be the highest dose administered to NL patients in this Phase 2 trial. As anticipated, the PCS499 dose of 1.8 grams/day, 50% greater than the maximum tolerated dose of PTX, appears to be well tolerated with no serious adverse events reported. To date, nine of the patients dosed at 1.8 grams/day have reported only mild adverse events related to the treatment, which occurred mostly in the first month of treatment and were quickly resolved. As expected, gastrointestinal or CNS adverse events were reported most often.

We have a meeting scheduled with the FDA in March 2020 to further discuss the development of PCS499, including a future clinical trial.

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

Note 2 – Going Concern and Management's Plans

Our consolidated financial statements are prepared using U.S. GAAP and are based on the assumption that we will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. We face certain risks and uncertainties regarding product development and commercialization, limited working capital, recurring losses and negative cash flow from operations, future profitability, ability to obtain future capital, protection of patents, technologies and property rights, competition, rapid technological change, navigating the domestic and major foreign markets' regulatory and clinical environment, recruiting and retaining key personnel, dependence on third party manufacturing organizations, third party collaboration and licensing agreements, lack of sales and marketing activities and having no customers or pharmaceutical products to sell or distribute. These risks and other factors raised substantial doubt about our ability to continue as a going concern as of the date of the filing of this Annual Report on Form 10-K for the year ended December 31, 2019.

We have relied exclusively on private placements with a small group of accredited investors to finance our business and operations. We have not had any revenue since our inception, and we do not currently have any revenue under contract or any immediate sales prospects. As of December 31, 2019, we had an accumulated deficit of approximately $11.0 million. For the year ended December 31, 2019, we incurred a net loss from continuing operations of approximately $3.4 million and used approximately $2.8 million in net cash from operating activities. We expect our operating costs to be substantial as we incur costs related to the clinical trials for our product candidates and that we will operate at a loss for the foreseeable future.

On September 20, 2019, we entered into two separate Line of Credit Agreements ("LOC Agreements") with DKBK Enterprises, LLC ("DKBK") and current shareholder CorLyst, LLC ("CorLyst"), both related parties ("Lenders") which provide a revolving commitment of up to $700,000 each ($1.4 million in total). Under the LOC Agreements, all funds borrowed will bear an 8% annual interest rate. The Lenders have the right to convert all or any portion of the debt and interest into shares of our common stock at a conversion price equal to the lower of (i) $14.28 per share, (ii) a price per share equal to a 10% discount to the pre-money valuation of a Qualified Financing or an Equity State Transaction, or (iii) at an adjusted price; all as defined in the 2019 Senior Note agreement. The Lenders will also receive stock purchase warrants on a 1:1 basis to the number of shares of common stock received that have an exercise price equal to the greater of (i) the closing price of our common stock on the date of conversion or (ii) $19.04 per share. Our Chief Executive Officer (CEO) is also the CEO and Managing Member of both Lenders. CorLyst beneficially owns 996,376 shares of Processa common stock, representing approximately 17.8% of the Company's outstanding shares of voting capital stock. We have not drawn any amounts under these LOC agreements as of February 28, 2020.

In connection with the LOC Agreements, we amended the existing pledge agreement with PoC Capital on September 30, 2019 to reduce the committed funds from $1.8 million to $900,000, which has been paid in full as of December 31, 2019. As part of the original pledge agreement, we issued 113,280 shares of common stock and 113,280 warrants to purchase shares of common stock to PoC Capital but held 56,640 shares and 56,640 warrants as collateral until certain payment milestones were met. PoC Capital forfeited the pledged collateral in the amended agreement. The forfeited shares and warrants have been returned to us.

In December 2019, we closed our bridge financing and issued $805,000 of the 2019 Senior Notes to accredited investors (see Note 7). We have also delayed some of our cash outflows, primarily through the deferred payment of salaries ($122,175, which has been accrued and included in accrued expenses at December 31, 2019) until such time as we have raised sufficient funding.

Based on our current plan, we will need to raise additional capital to fund our future operations. While we believe our current resources are adequate to complete our current Phase 2a trial for NL, we do not currently have resources to conduct other future trials or develop PCS100 without raising additional capital. As noted above, the timing and extent of our spending will depend on the costs associated with, and the results of our Phase 2a trial for NL. Our anticipated spending and our cash flow needs could change significantly as the trial progresses. There may be costs we incur during our trial that we do not currently anticipate in order to complete the trial, requiring us to need additional capital sooner than currently expected.

The additional funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of, or suspend our current or future clinical trials, or research and development programs. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. To the extent that we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Uncertainty concerning our ability to continue as a going concern may hinder our ability to obtain future financing. Continued operations and our ability to continue as a going concern are dependent on our ability to obtain additional funding in the future and thereafter, and no assurances can be given that such funding will be available at all, in a sufficient amount, or on reasonable terms. Without additional funds from debt or equity financing, sales of assets, sales or out-licenses of intellectual property or technologies, or other transactions providing funds, we will rapidly exhaust our resources and be unable to continue operations. Absent additional funding, we believe that our cash and cash equivalents will not be sufficient to fund our operations for a period of one year or more after the date that these 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 existed about our ability to continue as a going concern as of the date of the filing of this Annual Report on Form 10-K for the year ended December 31, 2019. 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.

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

Basis of Presentation

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

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

On December 23, 2019, we effected a 1-for-7 reverse stock split, reducing the number of the Company's common shares outstanding on that date from 38,404,530 shares to 5,486,476 shares. The number of authorized shares of common stock remained unchanged at 100,000,000 shares and the number of authorized shares of preferred stock remained unchanged at 1,000,000 shares. Additionally, the conversion price of our 2019 Senior Notes, the exercise price of all then outstanding options and warrants, and the number of shares reserved for future issuance pursuant to our equity compensation plans were all adjusted proportionately in connection with the reverse stock split. All share and per share amounts and conversion and exercise prices presented herein have been adjusted retroactively to reflect this change.

Use of Estimates

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

Cash and Cash Equivalents

Cash and cash equivalents include cash on hand and money market funds. We consider all highly liquid investments with a maturity at the date of purchase of three months or less to be cash equivalents.

Property and Equipment

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

Intangible Assets

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

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

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

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

Impairment of Long-Lived Assets and Intangibles Other Than Goodwill

We account for the impairment of long-lived assets in accordance with ASC 360, *Property, Plant and Equipment* and ASC 350, *Intangibles – Goodwill and Other,* which require that long-lived assets and certain identifiable intangibles be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to its expected future undiscounted net cash flows generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amounts of the assets exceed the fair value of the assets based on the present value of the expected future cash flows associated with the use of the asset. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. Based on management's evaluation, there was no impairment loss recorded during the years ended December 31, 2019 and 2018.

Fair Value Measurements and Disclosure

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

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

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

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

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

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

Stock-based Compensation

Stock-based compensation expense is based on the grant-date fair value estimated in accordance with the provisions of ASC 718, *Compensation-Stock Compensation.* We expense stock-based compensation to employees over the requisite service period based on the estimated grant-date fair value of the awards. For awards that contain performance vesting conditions, we do not recognize compensation expense until achieving the performance condition is probable. Stock-based awards with graded-vesting schedules are recognized on a straight-line basis over the requisite service period for each separately vesting portion of the award. We estimate the fair value of stock option grants using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. Stock-based compensation costs are recorded as general and administrative or research and development costs in the consolidated statements of operations based upon the underlying individual's role.

Net Loss Per Share

Basic loss per share is computed by dividing our net loss available to common shareholders by the weighted average number of shares of common stock outstanding during the period. Diluted loss per share is computed by dividing our net loss available to common shareholders by the diluted weighted average number of shares of common stock during the period. Since we experienced a net loss for all periods presented, basic and diluted net loss per share are the same. As such, diluted loss per share for the years ended December 31, 2019 and 2018 excludes the impact of potentially dilutive common shares related to outstanding stock options and warrants and the conversion of our 2017 and 2019 Senior Notes since those shares would have an anti-dilutive effect on loss per share.

As more fully described in Note 11, we have determined the sale of the 2019 Senior Notes in late 2019 triggered the full ratchet anti-dilution provision of the common stock we sold in 2018 Private Placement Transactions. For purposes of computing our basic and diluted EPS, we increased our net loss available for common shareholders by the fair value of the additional shares to be issued since they did not affect all our common shareholders equally and there are no contingencies related to the issuance of these shares. We also included the related shares which will be issued in 2020 in our weighted number of shares of common shares outstanding.

Our diluted net loss per share for the years ended December 31, 2019 and 2018 excluded 715,452, and 588,586 of potentially dilutive common 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. All our assets are located within the United States.

Fair Value of Financial Instruments

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

Debt Issuance Costs

We recognized the debt issuance costs incurred related to our 2017 and 2019 Senior Notes as a reduction of the carrying amount of the 2017 and 2019 Senior Notes on the face of the consolidated balance sheet. The debt issuance costs are amortized to interest expense using the straight-line method over the term of the 2019 Senior Notes and the interest method over the term of the 2017 Senior Notes.

Research and development

Research and development costs are expensed as incurred and consisted of direct and overhead-related expenses. Research and development costs totaled $2,320,573 and $3,085,317 for the years ended December 31, 2019 and 2018, respectively. Expenditures to acquire technologies, including licenses, which are utilized in research and development and that have no alternative future use are expensed when incurred. Technology we develop for use in our products is expensed as incurred until technological feasibility has been established after which it is capitalized and depreciated. No research and development costs were capitalized during the years ended December 31, 2019 and 2018.

Income Taxes

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

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

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

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

Recent Accounting Pronouncements

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

Recently adopted accounting pronouncements

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

On January 1, 2019, we adopted Accounting Standards Codification (ASC) 842, *Leases*. ASC 842 was issued to increase transparency and comparability among entities by recognizing right-of-use assets and lease liabilities on the balance sheet and disclosing key information about our lease agreements. We elected practical expedients upon transition that allows us to not reassess the lease classification of our leases, whether initial direct costs qualify for capitalization for our leases or whether any expired contracts are or contain leases. Additionally, we elected the optional transition method that allows for a cumulative effect adjustment in the period of adoption and we did not restate prior periods. The adoption of the new guidance on leasing resulted in the recognition of a right-of-use asset of $293,198 and lease obligations of $303,161. The difference between the right-of-use asset and the lease obligations is due to deferred rent liability related to our facility operating lease at December 31, 2018.

The adoption of the new guidance did not have a material impact on the consolidated statement of operations. For further details regarding the adoption of this standard, see Note 12, "Operating Leases."

Note 4 – Acquisition

On October 4, 2017, in exchange for 90 percent or 4,535,121 shares of our common stock, we acquired the net assets of Promet, totaling $1,017,342, in a transaction that was accounted for as a reverse acquisition in accordance with ASC 805-40-45, *Business Combinations - Reverse Acquisitions*. We completed this transaction to provide improved access to the capital markets in order to obtain the resources necessary to continue the development of PCS499 and build a clinical development drug company. Immediately following the transaction, we had 5,039,033 shares of common stock issued and outstanding, which represented our total legal capital. Promet owned approximately 84% of our common stock, and as part of the Section 351 transaction, held approximately 6% for the benefit of CoNCERT until the CoNCERT transaction had been concluded, whereupon CoNCERT took title to their shares. Together, Promet's pre-transaction owners and CoNCERT held a 90% economic and voting interest in the combined company immediately following completion of the transaction and as such, Promet was considered the acquirer for accounting purposes. Subsequent to the Merger, we changed our name from "Heatwurx, Inc." to "Processa Pharmaceuticals, Inc." and our ticker symbol was changed from "HWRX" to "PCSA."

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

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

Our 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 (see Note 11).

Note 5 - Intangible Assets

Intangible assets at December 31, 2019 consisted of the capitalized costs of $20,500 for a purchased software license and $11,038,929 associated with our exercise of the option to acquire the exclusive license from CoNCERT related to patent rights and know-how to develop and commercialize compounds and products for PCS499 and each metabolite thereof and the related income tax effects. The capitalized costs for the license rights to PCS499 include $8 million purchase price, $1,782 in transaction costs and $3,037,147 associated with the initial recognition of an offsetting deferred tax liability related to the acquired temporary difference for an asset purchased that is not a business combination and has a tax basis of $1,782 in accordance with ASC 740-10-25-51 *Income Taxes*. In accordance with ASC Topic 730, *Research and Development*, we capitalized the costs of acquiring the exclusive license rights to PCS499 as the exclusive license rights represent intangible assets to be used in research and development activities that have future alternative uses.

Acquisition of the CoNCERT License

On March 19, 2018, Promet, Processa and CoNCERT amended the CoNCERT Agreement executed in October 2017. The Amendment assigned the CONCERT Agreement to us and we exercised the exclusive option for the PCS499 compound in exchange for CoNCERT receiving, in part, $8 million of our common stock that was held by Promet (298,615 shares at $26.79 per share) and for the benefit of Processa in satisfaction of the obligation due for the exclusive license for PCS499 acquired by us. There was no change in the total shares issued and outstanding of 5,039,033. Promet contributed the payment of the obligation due for the exclusive license to us without consideration paid to them. As a result of the transaction, we recognized an exclusive license intangible asset with a fair value of $8 million and an offsetting increase in additional paid-in capital resulting from the exchange.

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

- 4% of the net sales of the portion less than or equal to $100 million;
- 5% of the net sales of the portion greater than $100 million and less than or equal to $500 million;
- 6% of the net sales of the portion greater than $500 million and less than or equal to $1.0 billion; and
- 10% of the net sales of the portion greater than $1 billion if such sales are made by us or our affiliates.

With respect to net sales made by us or any of our affiliates, we will pay 10% of net sales and with respect to sales by our sublicensees, we will pay the greater of (i) 6% or (ii) 50% of all payment received by us with respect to such sublicencee. We will also pay 15% of any sublicense revenue earned by us for a period equivalent to the royalty term (as defined in the CoNCERT Agreement) until the earliest of (a) our raising $8 million of gross proceeds and (b) CoNCERT being able to sell its shares of our common stock without restrictions pursuant to the terms of the amended Agreement. All other terms of the CONCERT Agreement remained unchanged.

We estimated the fair value of the common stock issued based on the market approach and CoNCERT's requirement to receive shares valued at $8 million. The market approach was based on the final negotiated number of shares of stock determined on a volume weighted average price of our common stock over a 45 day period preceding the mid-February 2018 finalized negotiation of the modification to the option and license agreement with CoNCERT, an unrelated third party, for the exclusive license rights to PCS499. The total cost recognized for the exclusive license acquired represents the allocated fair value related to the stock transferred to CoNCERT plus the recognition of the deferred tax liability related to the acquired temporary difference and the transaction costs incurred to complete the transaction as discussed above.

Our intangible assets consist of the following at December 31, 2019:

	License Rights to PCS499	Software License	December 31, 2019
Gross intangible assets	$ 11,038,929	$ 20,500	$ 11,059,429
Less: accumulated amortization	(1,405,301)	(11,674)	(1,416,975)
Total intangible assets, net	$ 9,633,628	$ 8,826	$ 9,642,454

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

	License Rights to PCS499	Software License	December 31, 2018
Gross intangible assets	$ 11,038,929	$ 20,500	$ 11,059,429
Less: accumulated amortization	(616,807)	(4,840)	(621,647)
Total intangible assets, net	$ 10,422,122	$ 15,660	$ 10,437,782

Amortization expense was $795,328 and $621,647 for the years ended December 31, 2019 and 2018 and is included within research and development expense in the accompanying consolidated statements of operations. As of December 31, 2019, estimated amortization expense for the next year will be approximately $795,000 and approximately $788,000 per year for annual periods thereafter.

Note 6 – License Agreement for PCS100

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

The Akashi Agreement provides us with a worldwide license to research, develop, make and commercialize products comprising or containing PCS100. As partial consideration for the license, we paid $10,000 to Akashi upon full execution of the license agreement. This upfront payment was expensed as a research and development cost. As additional consideration, we will pay Akashi development and regulatory milestone payments (up to $3.0 million per milestone) upon the achievement of certain milestones, which primarily consist of having a drug indication approved by a regulatory authority in the United States or another country. In addition, we must pay Akashi one-time sales milestone payments based on the achievement during a calendar year of one or more thresholds for annual sales for products made and pay royalties based on annual licensing sales. Due to the early stage of PCS100, it is not possible to determine if any of the development or sales milestones will be achieved and no amounts have been accrued related to these contingent payments. We are also required to split any milestone payments we receive with Akashi based on any sub-license agreement we may enter into.

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

Note 7 – Notes Payable

Line of Credit Agreements

On September 20, 2019, we entered into two separate Line of Credit Agreements (“LOC Agreements”) with DKBK Enterprises, LLC (“DKBK”) and current shareholder CorLyst, LLC (“CorLyst”), both related parties (“Lenders”), which provide a revolving commitment of up to $700,000 each ($1.4 million total). Under the LOC Agreements, all funds borrowed will bear an 8% annual interest rate. The lenders have the right to convert all or any portion of the debt and interest into shares of our common stock at a conversion price equal to the lower of (i) $14.28 per share, (ii) a price per share equal to a 10% discount to the pre-money valuation of a Qualified Financing or an Equity State Transaction, or (iii) at an adjusted price; all as defined in the 2019 Senior Note agreement. The lenders will also receive stock purchase warrants on a 1:1 basis to the number of shares of common stock received that have an exercise price equal to the greater of (i) the closing price of our common stock on the date of conversion or (ii) $19.04 per share. Our Chief Executive Officer (CEO) is also the CEO and Managing Member of both Lenders. CorLyst beneficially owns 996,376 shares of Processa common stock, representing approximately 17.8% of the Company’s outstanding shares of voting capital stock at December 31, 2019.

We have not drawn any amounts under these LOC agreements as of February 28, 2020.

Senior Convertible Notes

The balance of our Senior Convertible Notes at December 31, 2019 and 2018 was as follows:

	2019	2018
2019 Senior Notes	$ 805,000	$ -
2017 Senior Notes	-	230,000
Less: Unamortized debt issuance costs	(2,497)	-
Balance	802,503	230,000
Current portion	(802,503)	(230,000)
Long term portion	$ -	$ -

Interest expense totaled $36,658 and $161,205 for the years ended December 31, 2019 and 2018, respectively. Included in interest expense is the amortization of the related debt issuance costs of $1,783, and $67,069 for the years ended December 31, 2019 and 2018, respectively. The Senior Notes and related accrued interest are classified as current liabilities in our consolidated balance sheets.

2019 Senior Notes

During the fourth quarter of 2019 existing shareholders purchased $805,000 of 8% Senior Convertible Notes ("2019 Senior Notes") from us. The 2019 Senior Notes bear interest at 8% per year and if converted, the interest is payable in kind (in common stock). The 2019 Senior Notes mature on December 15, 2020.

The 2019 Senior Notes are convertible by the holder upon (i) completion of listing our common stock on either the Nasdaq Capital Market or the New York Stock Exchange or if we raise at least $14 million, prior to December 15, 2020, the maturity date of the 2019 Senior Notes, in one or more qualified financings. If the 2019 Senior Notes are not paid or converted prior to their maturity date, the principal and any accrued interest will be automatically or mandatorily converted into our common stock. The 2019 Senior Notes, plus any accrued interest is convertible into shares of our common stock at a conversion price equal to the lower of (i) $14.28 per share or (ii) a price per share equal to a 10% discount to the pre-money valuation of a Qualified Financing or an Equity State Transaction, both as defined in the 2019 Senior Note agreement, occurring after the closing of the 2019 Senior Note financing. Upon either mandatory conversion or conversion at the holder's option, the holder will also receive stock purchase warrants on a 1:1 basis to the number of shares of common stock received that have an exercise price equal to the greater of (i) the closing price of our common stock on the date of conversion or (ii) $19.04 per share.

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

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

We incurred $4,280 in debt issuance costs related to the 2019 Senior Notes. The debt issuance costs are amortized to interest expense using straight line amortization over the term of the 2019 Senior Notes.

2017 Senior Notes

In October and November of 2017, certain entities affiliated with current shareholders and other accredited investors purchased $2.58 million of our 8% Senior Convertible Notes ("2017 Senior Notes") in a bridge financing undertaken by us to support our operations. The 2017 Senior Notes bore interest at 8% per year.

On May 25, 2018, pursuant to the mandatory and automatic conversion provisions of the Senior Notes, we converted $2,350,000 of the $2,580,000 outstanding Senior Notes, along with accrued interest of $114,333 into 172,327 shares of our common stock (at a conversion price of $14.30 per share) and issued to the debt holders warrants to purchase a total of 172,327 shares of common stock, exercisable for three years at an exercise price of $17.16. We also incurred costs totaling $82,502 related to our contractual obligations to file a resale registration statement related to this transaction with the SEC.

2017 Senior Notes totaling $230,000 held by Canadian investors remained outstanding at December 31, 2018. Although qualifying for automatic and mandatory conversion, they could not be converted until the Alberta Securities Commission released us from a cease trade order (which predated our merger with Heatwurx) and permitted us to issue common stock units (consisting of shares of our common stock and stock purchase warrants) to these Canadian investors. In June 2019, the Alberta Securities Commission released the cease trade order and assessed us a $10,000 fine, which was expensed. On July 2, 2019, we converted the remaining principal and related accrued interest of $28,930 into 18,107 shares of common stock and issued warrants to purchase 18,107 shares of common stock. We evaluated the warrants issued in this transaction and determined they should be classified as equity.

We incurred $154,800 in debt issuance costs on the 2017 Senior Notes in connection with a payment to the placement agent, which was reported as a reduction of the carrying amount of the 2017 Senior Notes on the face of the consolidated balance sheets. The debt issuance costs were amortized to interest expense using the effective interest rate method over the term of the Senior Convertible Notes. The effective interest rate on the 2017 Senior Notes was 7.72% before debt issuance costs, since no payments of interest are due until maturity and 13.96% including the debt issuance costs based on the repayment terms of the 2017 Senior Notes.

Note 8 – Stockholders' Equity

In August 2019 we amended our articles of incorporation, reducing the authorized number of shares of our preferred stock from 10,000,000 to 1,000,000 and our common stock from 350,000,000 to 100,000,000.

We have not had any sales of our preferred stock since we were incorporated on March 29, 2011 and there were no issued or outstanding shares of preferred stock at December 31, 2019 or 2018.

2019 Private Placement Transactions

During 2019 we amended our Pledge Agreement with PoC Capital to reduce the committed funds from $1.8 million to $900,000, which has been paid in full as of December 31, 2019. As part of the original Pledge Agreement, we issued 113,280 shares of common stock and 113,280 warrants to purchase shares of common stock to PoC Capital but held 56,640 shares and 56,640 warrants as collateral until certain payment milestones were met. PoC Capital forfeited the pledged collateral in the amended agreement (see below). The forfeited shares and warrants have been returned to us.

2018 Private Placement Transactions

Between May 15, 2018 and June 29, 2018, we sold an aggregate of 200,369 units in a private placement transaction at a purchase price equal to $15.89 per unit for gross proceeds of approximately $3.2 million. Each unit consisted of one share of our common stock and a warrant to purchase one share of our common stock for $19.07, subject to adjustment thereunder for a period of three years. We paid $167,526 to our placement agent and issued placement agent warrants to purchase up to 12,021 shares of common stock, with a three-year term, at an exercise price equal to $19.07. We also incurred costs totaling $141,304 related to this transaction and our contractual obligation to file a resale registration statement related to the PIPE transaction with the SEC. The issuance costs were charged against additional paid in capital.

On May 25, 2018, we entered into an Agreement with PoC Capital, LLC ("PoC"), where PoC agreed to finance $1,800,000 in study costs associated with certain clinical studies, including our Phase 2a study to evaluate the safety, tolerability, efficacy and pharmacodynamics of PCS 499 in patients with Necrosis Lipoidica in exchange for 113,280 shares of our common stock and a warrant for the purchase of 113,280 shares of common stock with an exercise price of $19.07, expiring on July 29, 2021. We paid $108,000 to our placement agent and issued our placement agent warrants to purchase 6,797 shares of common stock, with a three-year term, at an exercise price equal to $19.07. We also incurred costs totaling $60,457 related to this transaction and our contractual obligation to file a resale registration statement related to this transaction with the SEC. The issuance costs were charged against additional paid in capital.

As part of this transaction, we also entered into a Pledge Agreement with PoC, under which we received a security interest for 56,640 common stock units, or half the shares and warrants we issued to PoC, to hold as collateral. The Pledge Agreement with PoC Capital was amended on September 30, 2019 to reduce the committed funds from $1.8 million to $900,000, which has been paid in full as of December 31, 2019. As part of the Pledge Agreement amendment, PoC Capital forfeited the pledged collateral in the amended agreement. The forfeited shares and warrants have been returned to us.

We initially recorded the full amount of the commitment, $1.8 million, as a subscription receivable and reduced the subscription receivable in the period PoC made payments to our CRO or to us. We evaluated the warrants issued in the 2018 Private Placement Transactions and determined they should be classified as equity.

The common stock, but not the warrants, issued for the 2018 Private Placement Transactions and the conversion of the 2017 Senior Notes have, subject to certain customary exceptions, full ratchet anti-dilution protection. Until we have issued equity securities or securities convertible into equity securities for a total of an additional $20 million in cash or assets, including the proceeds from the exercise of the warrants issued above, in the event we issue additional equity securities or securities convertible into equity securities at a purchase price less than $15.89 per share of common stock, the above purchase prices shall be adjusted and new shares of common stock issued as if the purchase price was such lower amount (or, if such additional securities are issued without consideration, to a price equal to $0.01 per share).

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

Note 9 – Income Taxes

We account for income taxes in accordance with ASC Topic 740, *Income Taxes.* Deferred income taxes are recorded for the expected tax consequences of temporary differences between the tax basis of assets and liabilities for financial reporting purposes and amounts recognized for income tax purposes. We recorded a valuation allowance during the years ended December 31, 2019 and 2018 equal to the full recorded amount of our net deferred tax assets related to deferred start-up costs, federal orphan drug tax credit and other minor temporary differences since it is more-likely-than-not that such benefits will not be realized. The valuation allowance is reviewed quarterly and is maintained until sufficient positive evidence exists to support its reversal.

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

During the years ended December 31, 2019 and 2018, we incurred net operating losses of $3,960,592 and $4,667,848, respectively. We did not record any income tax benefit for the $1,205,811 ($331,809 tax effected) and $1,356,840 ($373,368 tax effected) of general and administrative expenses treated as deferred start-up expenditures for tax purposes for the years ended December 31, 2019 and 2018, respectively. We did not record any income tax benefit for the $283,189 of federal orphan drug tax credits for the year ended December 31, 2019. Additionally, we did not record any income tax benefit in 2017 for the $258,583 ($71,283 tax effected) of tax losses incurred in 2017 which resulted in tax loss carryforwards. The benefit was recognized in 2018 in the calculation of the valuation allowance. The 2017 net operating loss carry forwards are available for application against future taxable income for 20 years expiring in 2037. Tax losses incurred after December 31, 2017 have an indefinite carry forward period. However, the tax loss incurred after December 31, 2017 and carried forward can only offset 80 percent of future taxable income in any one year, with any excess losses being carried forward indefinitely. We have recorded the benefit of our 2019 and 2018 net operating losses in our consolidated financial statements as a reduction in the deferred tax liability created by the future financial statement amortization of the intangible asset from the acquired CoNCERT license and "Know-How." The benefit associated with the net operating loss carry forward will more-likely-than-not go unrealized unless future operations are successful except for their offset against the deferred tax liability created by the acquired CoNCERT license and "Know-How."

For the years ended December 31, 2019 and 2018, we recorded a federal income tax benefit of $602,716 and $902,801, respectively, as a result of offsetting our deferred tax liability by the deferred tax assets resulting from our net operating losses and the income tax effect of the intangible asset amortization for financial statement purposes.

Our provision (benefit) for income taxes for the years ended December 31, 2019 and 2018 was as follows:

	Year Ended December 31,	
	2019	2018
Current:		
Federal	$ -	$ -
State	-	-
Total deferred tax benefit	-	-
Deferred:		
Federal	(1,037,267)	(940,510)
State	(234,033)	(292,047)
Total deferred tax benefit	(1,271,300)	(1,232,557)
Valuation allowance	668,584	329,756
Net deferred tax benefit	(602,716)	(902,801)
Total tax provision (benefit)	$ (602,716)	$ (902,801)

A reconciliation of our effective income tax rate and statutory income tax rate for the years ended December 31, 2019 and 2018 is as follows:

	Year Ended December 31,	
	2019	2018
Federal statutory income tax rate	21.00%	21.00%
State tax rate, net	3.60%	4.58%
Permanent differences	(1.96)%	(0.90)%
Federal orphan drug tax credit	7.15%	-%
Deferred tax asset valuation allowance	(14.57)%	(5.33)%
Effective income tax rate	15.22%	19.35%

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

We applied the guidance in SAB 118 when accounting for the enactment-date effects of the TCJA in 2018 and throughout 2019. At December 31, 2019 and 2018, we had available federal net operating loss carryforwards of approximately $4.1 million and $2.7 million, respectively. The federal net operating loss generated in 2019 and 2018 of $1.4 million and $2.4 million, respectively, will carry forward indefinitely and be available to offset up to 80% of future taxable income each year. Net operating losses generated prior to 2018 will expire 2037. We are evaluating our qualified research expenditures for the federal orphan drug credit and the federal and state credit for increasing research activities to offset potential future tax liabilities. The federal research and development tax credits have a 20-year carryforward period. We have not recognized any deferred tax assets related to research and development tax credits as of December 31, 2019 or 2018. We also have available state net operating loss carryforwards of approximately $4.1 million and $2.7 million as of December 31, 2019 and 2018, respectively, which expire 2037. All federal and state net operating loss and credit carryforwards listed above are reflected after the reduction for amounts effectively eliminated under Section 382.

We do not recognize other deferred income tax assets at this time because the realization of the assets is not more-likely-than-not that they will be realized. As of December 31, 2019 and 2018, we had deferred start-up expenditures and other deductible expenses for both federal and state income tax purposes of $6,977,317 and $4,369,700, respectively. The benefit associated with the amortization of the deferred start-up expenditures and other deductible expenses will more-likely-than-not go unrealized unless future operations are successful. Since the success of future operations is indeterminable, the potential benefits resulting from these deferred tax assets have not been recorded in our consolidated financial statements.

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

	December 31,	
	2019	2018
Deferred tax assets:		
Non-current:		
Net operating loss carry forward – Federal	$ 854,196	$ 559,817
Net operating loss carry forward – State	265,106	173,743
Deferred rent	-	2,742
Stock option expense	72,504	20,380
Depreciation	8,753	4,549
Federal orphan drug credits	283,189	-
Start-up expenditures and amortization	800,681	468,872
Total non-current deferred tax assets	2,284,429	1,230,103
Valuation allowance for deferred tax assets	(1,165,126)	(496,542)
Total deferred tax assets	1,119,303	733,561
Deferred Tax Liabilities:		
Non-current:		
Intangible asset	(2,650,933)	(2,867,907)
Total non-current deferred tax liabilities	(2,650,933)	(2,867,907)
Total deferred tax asset (liability)	$ (1,531,630)	$ (2,134,346)

The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, the projected future taxable income and tax planning strategies in making this assessment. Based on management's analysis, a reserve has been established against the deferred tax assets related to deferred start-up expenditures and other deductible expenses. The change in the valuation allowance in 2019 and 2018 was $668,584 and $329,755, respectively.

Our total deferred tax asset as of December 31, 2019 and 2018 include $2,909,715 ($800,681 tax effected) and $1,703,904 ($468,872 tax effected) of general and administrative expenses treated as deferred start-up expenditures for tax purposes, respectively, $4,067,602 ($1,119,302 tax effected) and $2,665,796 ($733,560 tax effected) of tax losses resulting in tax loss carryforwards as of the same periods and $283,189 of federal orphan drug tax credits as of December 31, 2019. We have had no revenues and recognized cumulative loses since inception. Due to the uncertainty regarding future profitability and recognition of taxable income to utilize the amortization of deferred start-up expenditures, federal orphan drug tax credits and the tax loss carryforwards, except for its offset against the deferred tax liability created by our acquisition of the CoNCERT license, a valuation allowance against any potential deferred tax assets has been recognized for the years ended December 31, 2019 and 2018.

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

We are subject to taxation in the United States and state jurisdictions where applicable. There are currently no income tax examinations underway for these jurisdictions. However, tax years from and including 2016 remain open for examination by federal and state income tax authorities.

Note 10 - Stock-based Compensation

On June 19, 2019, our stockholders approved and we adopted the Processa Pharmaceuticals Inc. 2019 Omnibus Equity Incentive Plan (the "2019 Plan") and we terminated our prior equity incentive compensation plan, the Heatwurx, Inc. 2011 Amended and Restated Equity Plan (the "2011 Plan"). The 2019 Plan allows us, under the direction of our Board of Directors or a committee thereof, to make grants of stock options, restricted and unrestricted stock and other stock-based awards to employees, including our executive officers, consultants and directors. An aggregate of 500,000 shares of our common stock, adjusted for the one for seven reverse stock split completed on December 23, 2019, were initially available for issuance under the 2019 Plan. Shares available under the 2019 Plan may be authorized but unissued shares, shares purchased on the open market or treasury shares.

On June 20, 2019, our Board of Directors granted stock options for the purchase of 129,919 shares of our common stock to employees. The stock options awarded contained either service or performance vesting conditions, as described below, have a contractual term of five years and an exercise price equal to the closing price of our common stock on the OTCQB on the date of grant of $16.80. We granted 54,915 stock options to employees and non-employees during the year ended December 31, 2018.

Stock options representing the purchase of 65,148 shares of common stock (of the 129,919 stock options granted on June 20, 2019) contained service vesting conditions. The service condition related solely to employees rendering service over a three-year period. These awards vest one-third on the first anniversary of the grant date, and then vest ratably over the remaining twenty-four months, $1/36^{th}$ of the original award each month.

Stock options representing the purchase of 64,771 shares of common stock (of the 129,919 stock options granted on June 20, 2019) vest upon meeting the following performance criteria: (i) 12,958 shares vest when we in-license one new or additional drug; (ii) 12,958 shares vest when our current Phase 2a clinical trial for PCS499 is complete; and (iii) 38,855 shares vest when we up-list from the OTCQB to either the Nasdaq or NYSE markets. We are recognizing compensation cost for the awards related to completion of our current clinical trial and for in-licensing a new drug. The clinical trial is progressing as planned with no significant adverse events, is fully enrolled, and fully funded. Management does not foresee any reasons why this study will not be completed as planned and believes it is probable that this performance condition will be met in mid-2020. On August 29, 2019, we reached a license agreement with Akashi Therapeutics for PCS100 and as such, the performance condition related to the award for in-licensing one new or additional drug has been met. As for the last award with performance conditions related to up-listing on Nasdaq or NYSE markets, management has determined that until we complete the performance related condition, it is not probable to conclude the performance condition will be achieved. As such, no stock-based compensation expense is being recorded for those awards.

We recorded $510,478 and $74,063 of stock-based compensation expense for the years ended December 31, 2019 and 2018, respectively. The allocation of stock-based compensation expense between research and development and general and administrative expense was as follows:

	Year Ended December 31,	
	2019	2018
Research and Development	$ 113,239	$ -
General and Administrative	397,239	74,063
	$ 510,478	$ 74,063

During the year ended December 31, 2018, there was one grant for the purchase of 7,143 shares of our common stock outstanding under the 2011 Plan. We also granted non-qualified stock options outside of the Plan for a total of 47,772 shares of common stock. An option for the purchase of 45,200 shares of common stock vests over a four-year term and an option for the purchase of 2,572 shares of common stock vests over one-year term. Stock option granted in 2018 all have a maximum contractual term of ten years. Vesting is subject to the holder's continuous service with us.

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

The fair value of our option awards granted during the year ended December 31, 2019 and 2018 was estimated using the following assumptions:

	2019	**2018**
Average risk-free rate of interest	1.85%	3.09%
Expected term (years)	3.75 to 5.00	5.00 to 6.25
Expected stock price volatility	81.77%	85.31%
Dividend yield	0%	0%

The following table summarizes our stock option activity for the year ended December 31, 2019 and 2018:

	Total options Outstanding	Weighted average exercise price	Weighted average remaining contractual life (in years)
Outstanding as of January 1, 2018	-	-	-
Options granted	54,915	20.45	9.8
Exercised	-	-	-
Forfeited	-	-	-
Outstanding as of December 31, 2018	54,915	$ 20.45	9.8
Options granted	129,919	16.80	4.5
Exercised	-	-	-
Forfeited	(7,872)	16.80	4.5
Outstanding as of December 31, 2019	176,962	17.93	5.8
Exercisable (vested) at December 31, 2019	29,655	18.53	6.9

The weighted average grant date fair value per share of options granted during the year ended December 31, 2019 and 2018 was between $9.88 and $15.10. No forfeiture rate was applied to these stock options.

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

As of December 31, 2019, there was $1,450,684 of total unrecognized compensation expense, related to the unvested stock options which are expected to be recognized over a weighted average period of 5.82 years.

Note 11 – Net Loss per Share of Common Stock

Basic net loss per share is computed by dividing net loss by the weighted average common 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 2017 and 2019 Senior Notes.

The computation of net loss per share for the year ended December 31, 2019 and 2018 was as follows:

	2019	2018
Basic and diluted net loss per share:		
Net loss	$ (3,357,876)	$ (3,765,047)
Deemed dividend related to the triggering of the full ratchet anti-dilution provision at fair value	(506,993)	-
Net loss available to common shareholders	(3,864,869)	(3,765,047)
Weighted-average number of common shares-basic and diluted	5,525,635	5,332,141
Basic and diluted net loss per share	$ (0.70)	$ (0.71)

We have determined the sale of the 2019 Senior Notes in late 2019, which are convertible into common stock at a conversion rate of $14.28 per share triggered the full ratchet anti-dilution provision of the common stock we sold in 2018 Private Placement Transactions (see Note 8). As a result, those shareholders were entitled to 28,971 shares of common stock in the fourth quarter of 2019. We will issue 28,971 shares of common stock to these shareholders in 2020. We determined the value of these shares at $506,993 based on a price per share of $17.50 which represents the closing price per share on October 18, 2019, the last day investors had to rescind their investment. For purposes of computing our basic and diluted EPS, we increased our net loss available for common shareholders by the fair value of the additional shares to be issued since they did not affect all our common shareholders equally and there are no contingencies related to the issuance of these shares. We also included these shares in our weighted number of shares of common shares outstanding. Triggering the full ratchet anti-dilution provision reduced our basic and diluted net loss per share by $0.09 per share.

The outstanding options and warrants to purchase common stock and the shares issuable under the 2017 and 2019 Senior Notes were excluded from the computation of diluted net income per share as their effect would have been anti-dilutive for the periods are presented below:

	2019	2018
Stock options and purchase warrants	654,569	571,055
Senior convertible notes	60,883	17,531

Note 12 - Operating Leases

We lease our office space under an operating lease agreement. This lease does not have significant rent escalation, concessions, leasehold improvement incentives, or other build-out clauses. Further, the lease does not contain contingent rent provisions. We also lease office equipment under an operating lease. Our office space lease includes both lease (e.g., fixed payments including rent, taxes, and insurance costs) and non-lease components (e.g., common-area or other maintenance costs), which are accounted for as a single lease component as we have elected the practical expedient to group lease and non-lease components for all leases. Our leases do not provide an implicit rate and, as such, we have used our incremental borrowing rate of 8% in determining the present value of the lease payments based on the information available at the lease commencement date.

Lease costs included in our consolidated statement of operations totaled $98,020 and $88,237 for the years ended December 31, 2019 and 2018, respectively. The weighted average remaining lease terms and discount rate for our operating leases were as follows at December 31, 2019:

Weighted average remaining lease term (years) for our facility and equipment leases	2.7
Weighted average discount rate for our facility and equipment leases	8%

Maturities of our lease liabilities for all operating leases were as follows as of December 31, 2019:

2020	$	92,603
2021		90,495
2022		69,741
Total lease payments		252,839
Less: Interest		(27,457)
Present value of lease liabilities		225,382
Less: current maturities		(77,992)
Non-current lease liability	$	147,390

Note 13 – Related Party Transactions

A shareholder, CorLyst, LLC, reimburses us for shared costs related to payroll, health care insurance and rent based on actual costs incurred, which are recognized as a reduction of our general and administrative operating expenses in our consolidated statements of operations. Reimbursable expenses from CorLyst totaled $103,047 and $107,402 for rent and other costs during the years ended December 31, 2019 and 2018, respectively. Amounts due from related parties at December 31, 2019 and 2018 were $0 and $21,583, respectively.

As described further in Note 7, we also entered into two separate Line of Credit Agreements with CorLyst, LLC and DKBK Enterprises, LLC, both related parties, on September 20, 2019.

Note 14 – Commitments and Contingencies

Purchase Obligations

We enter into contracts in the normal course of business with contract research organizations and subcontractors to further develop our products. The contracts are cancellable, with varying provisions regarding termination. If a contract with a specific vendor were to be terminated, we would only be obligated for products or services that we received as of the effective date of the termination and any applicable cancellation fees. We had a purchase obligation of approximately $0 and $35,000 at December 31, 2019 and 2018, respectively.

Due to the contingent nature of the amounts and timing of the payments, we have excluded our agreement with the CRO with whom we have contracted to conduct our Phase 2a clinical trial for NL. We were contractually obligated for up to approximately $487,000 of future services under the agreement, but our actual contractual obligations will vary depending on the progress and results of the clinical trial.

Note 15 – Concentration of Credit Risk

We maintain cash accounts in two commercial banks. Balances on deposit are insured by the Federal Deposit Insurance Corporation (FDIC) up to specified limits. Total cash held by one bank was $691,536 at December 31, 2019 which exceed FDIC limits.

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, 2019, 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, 2019 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, 2019, 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 on Form 10-K 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 firm 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 yet remediated the material weaknesses identified above. 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 year ended December 31, 2019, 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 table below sets forth, as of February 28, 2020, 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	67	Director and Chief Executive Officer
Sian Bigora, Pharm.D.	59	Chief Development Officer
Wendy Guy	55	Chief Administrative Officer
Patrick Lin	54	Director and Chief Business & Strategy Officer
James Stanker	62	Chief Financial Officer
Justin Yorke	53	Director
Virgil Thompson	80	Director
Geraldine Pannu	51	Director

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

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

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

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

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

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

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

Virgil Thompson - Mr. Thompson has served as a Director since October 2017 and previously served on the Board of Directors at Promet Therapeutics, LLC. He served as a Director of Mallinckrodt Pharmaceuticals (formerly Questcor Pharmaceuticals), and Director of GenZ Corporation, both companies he resigned from in 2017. From July 2009 to July 2015, he served as Chief Executive Officer and Director of Spinnaker Biosciences, Inc., and now serves as Chairman of the Board. Mr. Thompson also served as Chairman of the Board of Aradigm Corporation, as well 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. We believe Mr. Thompson is qualified to serve on our Board because of his extensive industry and board experience with publicly traded biotechnology companies.

Geraldine Liu Pannu - Ms. Pannu has served as a Director since February 13, 2019. Ms. Pannu has over 25 years' experience in investment and financial management, fund operations, consulting and marketing. Since January 2020, she has been the Founding and Managing Partner of GLTJ Pioneer Capital, a firm that specializes in land acquisition, entitlement and vertical development of multifamily, student and senior housing in the San Francisco Bay Area. From March 2007 to December 2016, Ms. Pannu was the COO and Managing Partner for ChinaRock Capital Management, a leading hedge and venture capital fund company. She previously worked at McKinsey & Co, Monitor Company as management consultant. She had successfully raised capital for several hedge, venture capital and real estate funds. She also helped start-up companies to expand and diversify business categories, client verticals and grow revenue. Ms. Pannu was born in Shanghai and grew up in Hong Kong. She received her Bachelor of Business Administration degree from the Chinese University of Hong Kong and an MBA from Harvard Business School. She is fluent in English, Mandarin, Cantonese and Shanghainese. We believe Ms. Pannu is qualified to serve on our Board because of her extensive investment experience.

Board Composition

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

Director Independence

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

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

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

Committees of the Board of Directors

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

Audit Committee

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

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

Compensation Committee

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

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

Nominating and Governance Committee

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

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

Leadership Structure and Risk Oversight

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

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

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

Compensation Committee Interlocks and Insider Participation

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

Code of Business Conduct and Ethics

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

Item 11. Executive Compensation

Summary Compensation Table

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

Name and Principal Position	Year	Salary ($)	Option Awards ($)[2]	All Other Compensation ($)	Total ($)
David Young	2019	-	163,202	-	163,202
Chairman and Chief Executive Officer	2018	-	-	-	-
Patrick Lin	2019	52,500	163,202	-	215,702
Chief Business and Strategy Officer	2018	44,479	-	-	44,479
Sian Bigora	2019	52,500	163,202	-	215,702
Chief Development Officer	2018	50,750	-	-	50,750
Wendy Guy	2019	87,500	163,202	-	250,702
Chief Administrative Officer	2018	87,500	-	-	87,500
James Stanker	2019	87,500	163,202	-	250,702
Chief Financial Officer [1]	2018	29,167	700,440	-	729,607

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

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

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

Pursuant to the Company's employment agreement with James Stanker, Mr. Stanker will receive a base salary of $87,500. In the event Mr. Stanker is terminated without Cause (as defined in the employment agreement) or for Good Reason (as defined in the employment agreement) prior to September 1, 2019, 25% of such options shall vest. The options shall vest in full upon a Change in Control (as defined in the employment agreement) and if terminated without Cause or for Good Reason in connection therewith, he shall also receive six months of base salary as a severance payment. Mr. Stanker is entitled to participate in all employee benefits available to employees of the Company. The employment agreement also includes confidentiality provisions.

Outstanding Equity Awards at Fiscal Year-End

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

Name	Number of Securities Underlying Unexercised Options [1] Exercisable	Number of Securities Underlying Unexercised Options [1] Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options	Option Exercise Price ($)	Option Expiration Date	Number of Shares of Stock that have not Vested	Market Value of Shares of Stock that have not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights that have not Vested	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or other Rights that have not Vested ($)
David Young [2]	-	7,859	-	16.80	6/20/2024	-	-	-	-
	1,733	-	-	16.80	6/20/2024	-	-	-	-
	-	1,733	-	16.80	6/20/2024	-	-	-	-
	-	5,198	-	16.80	6/20/2024	-	-	-	-
Patrick Lin [2]	-	7,859	-	16.80	6/20/2024	-	-	-	-
	1,733	-	-	16.80	6/20/2024	-	-	-	-
	-	1,733	-	16.80	6/20/2024	-	-	-	-
	-	5,198	-	16.80	6/20/2024	-	-	-	-
Sian Bigora [2]	-	7,859	-	16.80	6/20/2024	-	-	-	-
	1,733	-	-	16.80	6/20/2024	-	-	-	-
	-	1,733	-	16.80	6/20/2024	-	-	-	-
	-	5,198	-	16.80	6/20/2024	-	-	-	-
Wendy Guy [2]	-	7,859	-	16.80	6/20/2024	-	-	-	-
	1,733	-	-	16.80	6/20/2024	-	-	-	-
	-	1,733	-	16.80	6/20/2024	-	-	-	-
	-	5,198	-	16.80	6/20/2024	-	-	-	-
James Stanker [2]	-	7,859	-	16.80	6/20/2024	-	-	-	-
	1,733	-	-	16.80	6/20/2024	-	-	-	-
	-	1,733	-	16.80	6/20/2024	-	-	-	-
	-	5,198	-	16.80	6/20/2024	-	-	-	-
	14,125	31,075	-	19.88	8/31/2028	-	-	-	-
	2,571	-	-	19.88	8/31/2028	-	-	-	-

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

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

DIRECTOR COMPENSATION

Effective February 10 2020, each non-employee director receives an annual cash retainer of $20,000, payable quarterly. In addition, each new director will receive an initial stock option grant of approximately 5,000 shares of common stock and each non-employee director will receive an annual stock option grants to a number of shares of common stock equal to $20,000 total value. All such awards are made under our 2019 Omnibus Incentive Plan. The annual stock option awards may be pro-rated in the first year of service depending on when the non-employee director joins the Board. This compensation program was reviewed by the Board of Directors in February 2020.

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

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

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

(1) The "Option Awards" column reflects the grant date fair value for all stock option awards granted under the 2015 Plan during 2019. These amounts are determined in accordance with FASB Accounting Standards Codification 718 (ASC 718), without regard to any estimate of forfeiture for service vesting. Assumptions used in the calculation of the amounts are included in footnote 10 to the Company's consolidated audited financial statements for the year ended December 31, 2019 in Item 8 of this Annual Report on Form 10-K.

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

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

The following table sets forth certain information with respect to the beneficial ownership of our common stock at February 28, 2020 for:

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

The number of shares of our common stock beneficially owned by each entity, person, director or executive officer is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days of December 31, 2019, through the exercise of any stock option, warrants or other rights. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock held by that person.

The percentage of shares beneficially owned is computed on the basis of 5,486,476 shares of our common stock outstanding as of December 31, 2019. Shares of our common stock that a person has the right to acquire within 60 days of December 31, 2019, are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group.

	Shares beneficially owned	
	Shares	Percent
Name and address of beneficial owner [1]		
Officers and Directors		
David Young [2], [9]	1,412,363	25.1%
Sian Bigora [3]	485,461	8.8%
Patrick Lin [7]	341,450	6.1%
Wendy Guy [4]	296,214	5.4%
Virgil Thompson [8]	87,626	1.6%
Justin Yorke [5]	372,571	5.4%
James Stanker [12]	18,430	*
Total for all Officers and Directors	3,014,115	52.4%
More than 5% Stockholders:		
Young-Plaisance Revoc. Trust [9], [10]	349,069	8.8%
CorLyst, LLC [6], [9], [11]	996,376	17.8%
CoNCERT Pharmaceuticals, Inc.	298,615	5.4%

* - represents less than 1%

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

(2) Consists of (i) 346,802 shares of common stock held directly by Dr. Young; (ii) 1,733 shares of common stock issuable pursuant to options held directly by Dr. Young exercisable within 60 days of December 31, 2019; (iii) 349,069 shares held by the Young-Plaisance Revoc. Trust; (iv) 161,672 shares held by two other family entities; (v) 448,915 shares held by CorLyst, LLC ("CorLyst"); (vi) 101,025 shares held by Promet that were not distributed as of February 28, 2020; and (vii) 3,147 shares that Dr. Young will receive on the exercise of stock purchase warrants. Dr. Young is the Trustee of the Young-Plaisance Revoc. Trust and the Chief Executive Officer and Managing Member of CorLyst. Dr. Young disclaims beneficial ownership of a portion of CorLyst shares.

(3) Consists of (i) 368,477 shares of common stock held directly by Dr. Bigora; (ii) 115,251 shares held by CorLyst; and (iii) 1,733 shares of common stock issuable pursuant to options held directly by Dr. Bigora exercisable within 60 days of December 31, 2019.

(4) Consists of (i) 150,410 shares of common stock held directly by Ms. Guy; (ii) 144,071 shares held by CorLyst; and (iii) 1,733 shares of common stock issuable pursuant to options held directly by Ms. Guy exercisable within 60 days of December 31, 2019.

(5) Justin Yorke, a member of our Board of Directors, is a manager of the San Gabriel Fund, LLC, JMW Fund, LLC and the Richland Fund, LLC. 372,571 shares of common stock reported for Mr. Yorke include the shares held by these Funds. Also included are 197 shares of common stock issuable pursuant to options held directly by Mr. Yorke exercisable within 60 days of December 31, 2019.

(6) CorLyst is the beneficial holder of 996,376 shares. This beneficial ownership is allocated in the above table as follows: David Young - 396,191, Sian Bigora – 115,251; Wendy Guy – 144,071; the Young-Plaisance Revoc. Trust – 288,139; other shareholders – 32,415; and stock purchase warrants of 20,309.

(7) Consists of (i) 335,248 shares of common stock held directly by Mr. Lin; (ii) 1,733 shares of common stock issuable pursuant to options held directly by Mr. Lin exercisable within 60 days of December 31, 2019; and (iii) 4,469 shares that Mr. Lin will receive on the exercise of stock purchase warrants.

(8) Consists of (i) 87,429 shares of common stock held directly by Mr. Thompson and (ii) 197 shares of common stock issuable pursuant to options held directly by Mr. Thompson exercisable within 60 days of December 31, 2019.

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

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

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

(12) Consists of 18,430 options to purchase shares of common stock that are exercisable as of December 31, 2019 or will become exercisable within 60 days after such date held by Mr. Stanker.

Item 13. Certain Relationships and Related Transactions

We do not have a formal written policy for the review and approval of transactions with related parties. Our unwritten policy with regard to transactions with related persons is that all material transactions are to be reviewed by the entire Board for any possible conflicts of interest. The Board is responsible for review, approval, or ratification of "related-person transactions" involving the Company and related persons.

With the exception of the transactions set forth below, the Company was not a party to any transaction (in which the amount involved exceeded the lesser of $120,000 or 1% of the average of our assets for the last two fiscal years) in which a director, executive officer, holder of more than five percent of our common stock, or any member of the immediate family of any such person has or will have a direct or indirect material interest and no such transactions are currently proposed.

CorLyst, LLC and DKBK Enterprises, LLC

CorLyst was a related party to Promet as one of the largest investors in Promet. As a result of the transaction with Heatwurx, all of Promet's assets were purchased in exchange for equity in the company and CorLyst is now considered a related party to Processa by association. CorLyst and Processa share certain administrative expenses (salaries, healthcare and office space). David Young, our Chief Executive Officer and Chairman of our Board of Directors, is also the Chief Executive Officer and Managing Member of CorLyst. David Young spends less than one hour per week on CorLyst activity, while averaging more than 40 hours per week on Processa activities. CorLyst beneficially owns 996,376 shares of Processa common stock, representing approximately 17.8% of the Company's outstanding shares of voting capital stock.

On September 20, 2019, we entered into two separate Line of Credit Agreements, one with DKBK and another with CorLyst ("the Lenders"), which provide a revolving commitment of up to $700,000 each ($1.4 million total). Our CEO is also the Chief Executive Officer and Managing Member of both Lenders. Under the Line of Credit Agreements, all funds borrowed will bear an 8% annual interest rate, which is prorated monthly from the date money has been borrowed to the date money has been paid back. The Company agrees to furnish certified financial statements to the Lenders upon demand so long as indebted under the Line of Credit Agreements and the Note remains unpaid. The Lenders have the right to convert all or any portion of the debt and interest into shares in the Company's common stock at the terms defined in the July 2019 Bridge Subscription Agreement.

License Agreement with CoNCERT Pharmaceuticals, Inc.

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

The CoNCERT Agreement provides us with an exclusive (including to CoNCERT) royalty-bearing license to CoNCERT's patent rights and know-how to develop, manufacture, use, sub-license and commercialize compounds (PCS499 and each metabolite thereof) and pharmaceutical products with such compounds worldwide. We are required to pay CoNCERT royalties, on a product by product basis, on worldwide net sales as more fully described in Part I, Item 1, Business.

Item 14. Principal Accounting Fees and Services

BD & Company Inc. ("BD & Company"), an independent registered public accounting firm, has audited Processa's financial statements for the years ended December 31, 2019 and 2018. The Board of Directors of Processa has selected BD & Company as the independent registered public accounting firm to audit the consolidated financial statements of Processa for the fiscal year ending December 31, 2019. A representative of BD & Company is expected to be present at the Annual Meeting of Stockholders, with the opportunity to make a statement if the representative desires to do so and is expected to be available to respond to appropriate questions.

Ratification of the appointment of BD & Company as Processa's independent registered public accounting firm is not required to be submitted to our stockholders for a vote. We will be submitting this matter to the stockholders for ratification as a matter of good corporate governance. If the appointment of BD & Company is not ratified by the stockholders at the Annual Meeting, the Board of Directors may reconsider whether to retain BD & Company and may retain BD & Company or another firm without resubmitting the matter to Processa's stockholders. Even if the stockholders vote in favor of ratification of the appointment, the Board of Directors may, in its discretion, direct the appointment of a different independent registered public accounting firm at any time during the year if it determines that such a change would be in the best interests of Processa and the stockholders.

Audit and Non-Audit Fees Billed to the Company by Independent Registered Public Accounting Firm

The following table sets forth the aggregate fees billed to Processa for the years ended December 31, 2019 and 2018 by BD & Company:

	Fiscal 2019	Fiscal 2018
Audit Fees	$ 57,000	$ 61,544
Audit-Related Fees	-	-
Tax Fees	-	11,750
All Other Fees	7,000	24,650
Total	$ 64,000	$ 97,944

Audit Fees. These fees were for professional services rendered for 2019 and 2018 in connection with the audit of our annual financial statements and review of the financial statements included in our Quarterly Reports on Form 10-Q. The amounts also include fees for services that are normally provided by BD & Company Inc. in connection with statutory and regulatory filings and engagements for the years identified.

Audit-Related Fees. These fees were for assurance and related services that were related to the performance of the audit or review of our financial statements and were not reported under the caption "Audit Fees." This category may include fees related to the performance of audits and attestation services not required by statute or regulations, or accounting consultations about the application of generally accepted accounting principles to proposed or significant transactions.

Tax Fees. These fees were for tax compliance, tax planning, tax advice and corporate tax services. Corporate tax services encompass a variety of permissible services, including technical tax advice related to tax matters; assistance with withholding-tax matters; assistance with state and local taxes; preparation of reports to comply with local tax authority transfer pricing documentation requirements; and assistance with tax audits.

All Other Fees. These fees were primarily for services related to our Registration Statements on Form S-1 in 2019 and 2018.

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 30, 2017)
3.1.2	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation (incorporated by reference to Appendix A to Information Statement filed on July 18, 2019)
3.2	Bylaws (incorporated by reference to exhibit 3.2 to Form 10-K filed on March 27, 2014)
4.1	Specimen of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Form S-1/A filed on May 15, 2013)
4.2	Warrant issued to PoC Capital, LLC (incorporated by reference from Form 8-K filed June 1, 2018)
4.3	Warrant issued to PoC Capital, LLC (incorporated by reference from Form 8-K filed June 1, 2018)
4.4	Warrant issued to PoC Capital, LLC (incorporated by reference from Form 8-K filed June 1, 2018)
4.5	Warrants issued to Boustead Securities (incorporated by reference from Form 8-K filed June 1, 2018)
4.6	Form of Warrant (incorporated by reference to exhibit 10.3 to Form 10-Q filed on May 21, 2018)
4.8	Form of 8% Senior Convertible Notes (incorporated by reference from Form S-1 filed December 13, 2019)
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	Employment Agreement dated September 5, 2018, between Processa and James Stanker (incorporated by reference from Form 8-K filed September 10, 2018)

10.5	Processa Pharmaceuticals, Inc. 2019 Omnibus Incentive Plan (incorporated by reference to Annex A to Processa's definitive proxy statement filed April 26, 2019).
10.6	Line of Credit Agreement dated September 20, 2019 between Processa Pharmaceuticals and DKBK Enterprises, LLC (incorporated by reference to Form 8-K filed October 3, 2019)
10.7	Line of Credit Agreement dated September 20, 2019 between Processa Pharmaceuticals and CorLyst, LLC (incorporated by reference to Form 8-K filed October 3, 2019)
10.8	License Agreement with Akashi Therapeutics, Inc. dated August 29, 2019 (incorporated by reference to Form 8-K filed September 4, 2019)
21.1	List of Subsidiaries (incorporated by reference to exhibit 21.1 to Form 10-K filed on March 28, 2019)
23.1*	Consent of Independent Registered Public Accounting Firm, BD & Co. Inc.
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 and 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 6, 2020

By: */s/ James Stanker*
James Stanker
Chief Financial Officer
(Principal Financial and Accounting Officer)
Dated: March 6, 2020

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 6, 2020
/s/ James Stanker James Stanker	Chief Financial Officer	March 6, 2020
/s/ Patrick Lin Patrick Lin	Chief Business and Strategy Officer and Director	March 6, 2020
/s/ Justin Yorke Justin Yorke	Director	March 6, 2020
/s/ Virgil Thompson Virgil Thompson	Director	March 6, 2020
/s/ Geraldine Pannu Geraldine Pannu	Director	March 6, 2020

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 6, 2020, relating to the consolidated financial statements of Processa Pharmaceuticals, Inc. for the years ended December 31, 2019 and 2018 included in the Annual Report on Form 10-K of Processa Pharmaceuticals, Inc. for the year ended December 31, 2019.

/s/ BD & Company, Inc.

Owings Mills, MD
March 6, 2020

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 6, 2020

/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 6, 2020

/s/ James Stanker
James Stanker
Chief Financial Officer

Exhibit 32.1

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, 2019 (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 6, 2020

/s/ James Stanker
James Stanker
Chief Financial Officer
March 6, 2020

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.