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Registration No. 333-226428

PROSPECTUS

Processa Pharmaceuticals

PROCESSA PHARMACEUTICALS, INC.
6,385,437 SHARES OF COMMON STOCK

This prospectus relates to the resale by certain of our stockholders and holders of warrants to purchase our stock named in the section of this prospectus titled "Selling Stockholders" (collectively, the "Selling Stockholders") of up to 6,385,437 shares (collectively, the "Shares") of our common stock, par value $0.0001. The Shares being offered under this prospectus are comprised of:

(a) 2,017,203 shares of common stock that were purchased by certain Selling Stockholders in private placements with us pursuant to exemptions from the registration requirements of the Securities Act;

(b) 1,073,466 shares of common stock that were issued to certain Selling Stockholders after conversion of our 8.0% Senior Convertible Notes;

(c) 2,148,927 shares of common stock issuable upon exercise of warrants allowing the holder to purchase shares of common stock at an exercise price of $2.724 per share through June 29, 2021; and

(d) 1,145,841 shares of common stock issuable upon exercise of warrants allowing the holder to purchase shares of common stock at an exercise price of $2.452 per share through June 29, 2021.

Although we will pay substantially all the expenses incident to the registration of the Shares, we will not receive any proceeds from the sales by the Selling Stockholders. The Selling Stockholders and any underwriter, broker-dealer or agent that participates in the sale of the Shares or interests therein may be deemed "underwriters" within the meaning of Section 2(a)(11) of the Securities Act. Any discounts, commissions, concessions, profit or other compensation any of them earns on any sale or resale of the shares, directly or indirectly, may be underwriting discounts and commissions under the Securities Act. The Selling Stockholders who are "underwriters" within the meaning of Section 2(a)(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act.

Our common stock is presently quoted for trading under the symbol "PCSA" on the OTC Pink Tier of the OTC Markets Group, Inc. (the "OTCPink"). On November 6, 2018, the closing price of our common stock, as reported on the OTCPink was $3.25 per share. We intend to apply to have our shares of common stock included on the OTCQB, although there can be no assurance that our application will be approved. You are urged to obtain current market quotations of our common stock before purchasing any of the Shares being offered for sale pursuant to this prospectus.

The Selling Stockholders will initially offer their Shares at $3.65 per share until such time as the Shares are approved for and quoted on the OTCQB. This price represents the average of the last 45 days closing price as shown on the OTCPink ending October 25, 2018. Thereafter, the Selling Stockholders, to the extent a public market exists at such time, may offer and sell Shares through public transactions at prices related to the prevailing market prices, or through private transactions at privately negotiated prices.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act ("JOBS Act") and, as such, are subject to reduced public company reporting requirements.

The purchase of the Shares offered through this prospectus involves a high degree of risk. Please refer to "Risk Factors" beginning on page 6.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is November 9, 2018

TABLE OF CONTENTS

You should rely only on the information contained in this prospectus or any related prospectus supplement. We have not authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. The information contained in this prospectus or incorporated by reference herein is accurate only on the date of this prospectus. Our business, financial condition, results of operations and prospects may have changed since such date. Other than as required under the federal securities laws, we undertake no obligation to publicly update or revise such information, whether as a result of new information, future events or any other reason.

This prospectus is not an offer to sell, nor is it an offer to buy, these securities in any jurisdiction where the offer or sale is not permitted.

GLOSSARY OF CERTAIN SCIENTIFIC TERMS

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

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

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

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

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

"CRO" means a Contract Research Organization.

"EMA" means the European Medicines Agency.

"FDA" means the Food and Drug Administration.

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

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

"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.

PROSPECTUS SUMMARY

This summary highlights certain information that we present more fully in the rest of this prospectus. This summary does not contain all of the information you should consider before investing in the Shares offered pursuant to this prospectus. You should read the entire prospectus carefully, including the "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes, before making an investment decision.

Except where the context otherwise requires and for purposes of this prospectus only, "we," "us," "our," "Company," and "Processa" refer to Processa Pharmaceuticals, Inc., a Delaware corporation, and its consolidated subsidiaries and include the acquired assets from Promet Therapeutics, LLC, a Delaware limited liability company. For other defined terms, please see the Glossary on page ii.

In 2017, the Company completed a reverse split resulting in a one-for-seven exchange of its shares of common stock in connection with the transaction with Promet (as defined below). All share information outside of our consolidated financial statements and related notes reflect such reverse split as if it occurred when Processa was incorporated.

Organizational History

On October 2, 2017, Heatwurx, Inc. ("Heatwurx") entered into an Asset Purchase Agreement with Promet Therapeutics, LLC, a Delaware limited liability company ("Promet") pursuant to which, on October 4, 2017, Heatwurx acquired the assets of Promet, in exchange for issuing to Promet approximately 31,745,242 shares of its common stock. Following the closing, Heatwurx changed its name to Processa Pharmaceuticals, Inc. and abandoned Heatwurx's prior business plan. We are now pursuing Promet's historical and proposed business.

Processa (formerly Heatwurx) was incorporated under the laws of the State of Delaware on March 29, 2011.

Description of Business

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

Our lead product, PCS-499, is an oral tablet that is an analog (i.e.,a compound having a structure similar to that of the approved drug, but differing from it in respect to a certain component of the molecule which may cause it to have similar or different effects on the body) of an active metabolite of an already approved drug called pentoxifylline (PTX). PTX (Trental®) was approved by the FDA on August 30, 1984 for the treatment of patients with intermittent claudication on the basis of chronic occlusive arterial disease of the limbs. Trental is a registered trademark of Aventis Pharma Deutschland. In the body PCS-499 is broken down to multiple metabolites with PCS-499 and many of these metabolites being pharmacologically active. In animal and healthy human volunteer studies, higher exposure of certain active metabolites are seen after PCS-499 administration compared to PTX. Despite the greater exposure to these pharmacologically active molecules, PCS-499 appears to be well tolerated, even at higher doses than the standard dosing of PTX. We have identified unmet medical need conditions in the PTX literature where the use of PCS-499 may provide clinical benefit over other on-label or off-label products used for the various conditions. These conditions include NL and RIF in head and neck cancer patients. NL is a chronic, disfiguring condition for which most patients do not have any treatment options. It develops more commonly in women than in men on the lower extremities, and ulceration can occur in approximately 30% of NL patients, which may lead to more severe complications, such as deep tissue infections and osteonecrosis that can threaten life of the limb.

PCS-499 had previously been investigated for a different indication, diabetic nephropathy in Phase 2 studies before we exercised an option to license PCS-499 from CoNCERT Pharmaceuticals, Inc. in March 2018. Based on the diverse pharmacological activity of PCS-499, we have defined a strategy to develop this product in indications where physicians and patients seek significant medical help. Due to the previous preclinical, Phase 1 and Phase 2 clinical work completed in support of PCS-499, we are able to move the product into Phase 2 studies for the new indications. In October 2017, we met with the FDA at a pre-IND (Investigational New Drug) meeting for the NL indication and defined the steps to move PCS-499 into Phase 2 studies and the path to eventual approval. Additionally, on June 22, 2018, the FDA granted orphan drug designation to PCS-499 for the treatment of NL. An IND application for NL was submitted to the FDA on August 29, 2018 with the plan to initiate a Phase 2 study in NL patients in late 2018.

The development of our lead product is in the early stage and we anticipate that we will be required to expend significant time and resources to further develop our technology and determine whether a commercially viable product can be developed. Research and development of new products involves a high degree of risk and there is no assurance that our development activities will result in a commercially viable product. Our ability to generate meaningful revenue from PCS-499 or any products in the United States depends on obtaining FDA authorization. Even if our products are authorized and approved by the FDA, we must still meet the challenges of successful marketing, distribution and consumer acceptance.

Risk Factors

Our business operations are subject to numerous risks, including the risk of delays in, or discontinuation of, our research and development due to lack of financing, poor results, inability to commercialize our technologies or to obtain necessary regulatory approvals to market the products, unforeseen safety issues relating to the products and dependence on third party collaborators to conduct research and development of the products.

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. We have not initiated any clinical trials 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.

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 a number of factors, including market conditions, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates, restrict our operations or obtain funds by entering into agreements on unattractive terms, which would likely have a material adverse effect on our business, stock price and our relationships with third parties with whom we have business relationships, at least until additional funding is obtained. As a result, substantial doubt existed about our ability to continue as a going concern as of the date of the filing of our annual report on Form 10-K for the year ended December 31, 2017 and our quarterly report on Form 10-Q for the six months ended June 30, 2018. The accompanying consolidated financial statements do not include any adjustment for the possible future effects on the recoverability and classification of recorded assets, or the amount and classification of liabilities that might be different should we be unable to continue as a going concern based on the outcome of the uncertainties described above.

Because we are an early stage company with a limited history of operations, we are also subject to many risks associated with early-stage companies. For a more detailed discussion of some of the risks you should consider, you are urged to carefully review and consider the section titled "Risk Factors" beginning on page 6 of this

prospectus.

Implications of Being an Emerging Growth Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of relief from certain reporting requirements and other burdens that are otherwise applicable generally to public companies. These provisions include:

- an exception from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act");
- reduced disclosure about our executive compensation arrangements in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding non-binding advisory votes on executive compensation or golden parachute arrangements.

We may take advantage of these provisions for up to five years or such earlier time that we no longer qualify as an emerging growth company. We would cease to qualify as an emerging growth company if we have more than $1.07 billion in annual revenue, we are deemed to be a "large accelerated filer" under the rules of the SEC, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th or we issue more than $1.0 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these reduced reporting burdens. For example, we may take advantage of the exemption from auditor attestation on the effectiveness of our internal control over financial reporting. To the extent that we take advantage of these reduced reporting burdens, the information that we provide stockholders may be different than you might obtain from other public companies in which you hold equity interests.

In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Corporate Information

Our principal executive offices are located at 7380 Coca Cola Drive, Suite 106, Hanover, Maryland 21076. Our telephone number is (443) 776-3133. Our website is www.processapharmaceuticals.com. The information found on, or otherwise accessible through, our website is not incorporated into, and does not form a part of, this prospectus or any other report or document we file with or furnish to the U.S. Securities and Exchange Commission (the "SEC").

THE OFFERING

Securities Being Offered by the Selling Stockholders :	6,385,437 shares of common stock, consisting of: (a) 2,017,203 shares of common stock that were purchased by the Selling Stockholders in private placements with us; (b) 1,073,466 shares of common stock that were issued to certain Selling Stockholders after conversion of our 8.0% Senior Convertible Notes; (c) 2,148,927 shares of common stock issuable upon exercise of warrants allowing the holders to purchase shares of common stock at an exercise price of $2.724 per share through June 29, 2021; of which warrants for 924,676 shares of common stock contain cashless exercise provisions; and (d) 1,145,841 shares of common stock issuable upon exercise of warrants allowing the holders to purchase shares of common stock at an exercise price of $2.452 per share through June 29, 2021; of which warrants for 72,375 shares of common stock contain cashless exercise provisions. The warrants are referred to collectively as the "Warrants." The Warrants may not be exercised until November 15, 2018.
Offering Price:	The Selling Stockholders will initially offer their Shares at $3.65 per share until such time as the Shares are approved for and quoted on the OTCQB, although there can be no assurance that our application will be approved. This price represents the average of the last 45 days closing price as shown on the OTCPink ending October 25, 2018. Thereafter, the Selling Stockholders, to the extent a public market exists at such time, may offer and sell Shares through public transactions at prices related to the prevailing market prices, or through private transactions at privately negotiated prices.
Selling Stockholders:	The Selling Stockholders are existing stockholders who either purchased shares of our common stock and warrants to purchase shares of our common stock or notes convertible into shares of our common stock and warrants to purchase shares of our common stock, or will become stockholders upon conversion of our convertible notes. Please refer to the section titled "Selling Stockholders" of this prospectus.
Shares Outstanding:	We have 38,674,265 shares outstanding as of October 25, 2018.*
OTCPink Symbol:	"PCSA"
Transfer Agent:	Corporate Stock Transfer, Inc.
Risk Factors:	Our business operations are subject to numerous risks. Because we are an early stage company with a limited history of operations, we are also subject to many risks associated with early-stage companies. For a more detailed discussion of some of the risks you should consider, you are urged to carefully review and consider the section titled "Risk Factors" beginning on page 6 of this prospectus.
Use of Proceeds:	Although we will pay substantially all the expenses for the registration of the Shares, we will not receive any proceeds from the sales by the Selling Stockholders. We will, however, receive proceeds from the exercise of any Warrants; if such proceeds are received by us, they will be used to fund our working capital and for general corporate purposes. See "**Use of Proceeds**."
Duration of Offering:	We have agreed with the Selling Stockholders to keep the registration statement, of which this prospectus is a part, effective until the due date for our next annual report on Form 10-K, which we anticipate to be April 1, 2019.

*The number of shares of common stock outstanding, excludes as of such date:

- 2,327,118 shares of our common stock issuable upon the exercise of outstanding warrants, having an exercise price of $2.724 per share through June 29, 2021;
- 1,278,620 shares of common stock issuable upon exercise of warrants allowing the holders to purchase shares of common stock at an exercise price of $2.452 per share through June 29, 2021;
- 117,459 shares of common stock issuable upon conversion of our outstanding 8.0% Senior Convertible Notes; and
- 124,507 shares of common stock issuable upon exercise of warrants at an exercise price of $2.452 per share through June 29, 2021 that will be issued upon conversion of our 8.0% Senior Convertible Notes.

SUMMARY HISTORICAL CONSOLIDATED FINANCIAL DATA

The following table sets forth our summary historical consolidated financial data for the periods presented below. The summary consolidated financial data as of December 31, 2017 and 2016 and for each of the years in the two-year period ended December 31, 2017 have been derived from our audited consolidated financial statements included herein. The summary unaudited condensed consolidated financial data as of June 30, 2018 and the six-month period ended June 30, 2018 has been derived from our unaudited condensed consolidated financial statements included herein.

Our historical results are not necessarily indicative of the results of operations for future periods. You should read the following summary consolidated financial data in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Risk Factors" and our consolidated financial statements and the related notes included elsewhere in this prospectus.

Balance Sheet Data	As of June 30, 2018 (Unaudited)	As of December 31, 2017	As of December 31, 2016
Cash, cash equivalents and certificates of deposit	$ 3,346,654	$ 2,847,429	$ 1,071,894
Total Current Assets	$ 3,594,169	$ 2,951,584	$ 2,336,992
Total Assets	$ 14,437,672	$ 2,982,940	$ 2,364,921
Total Liabilities	$ 3,130,785	$ 2,609,776	$ 97,692
Total Stockholders' Equity	$ 11,306,887	$ 373,164	$ 2,267,229

Statements of Operations Data	Six Months Ended June 30, 2018 (Unaudited)	Year Ended December 31, 2017	Year Ended December 31, 2016
Research and development costs	$ 1,865,921	$ 926,117	$ 1,536,996
General and administrative expenses	$ 853,918	$ 876,316	$ 384,524
Operating Loss	$ (2,719,839)	$ (1,802,433)	$ (1,921,520)
Net Loss	$ (2,302,870)	$ (1,856,315)	$ (1,917,066)
Net Loss Applicable to Common Shares – Basic and Diluted	$ (0.06)	$ (0.06)	$ (0.07)
Weighted average Common Shares Used to Compute Net Loss Applicable to Common Shares – Basic and Diluted	35,951,894	32,595,680	29,321,049

RISK FACTORS

An investment in our securities involves a high degree of risk. You should carefully consider the risks described below before purchasing any of the Shares. 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 acquire the shares to which this prospectus relates only if you can afford to lose your entire investment. You should also refer to the other information contained in this prospectus, 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 $3.253 million incurred since its inception on August 31, 2015 through the date of acquisition on October 4, 2017. Subsequent to the date of acquisition, the accumulated deficit increased to approximately $6.2 million at June 30, 2018. The Company will incur additional losses as we continue our research and development activities, seek regulatory approvals for our product candidates and engage in clinical trials. These losses will cause, among other things, our stockholders' equity and working capital to decrease. Any future earnings and cash flow from operations of our business are dependent on our ability to further develop our products and on revenues and profitability from sales of products or successful joint venture relationships.

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

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

We will require additional financing.

We will require substantial additional capital in the future to further our development and license of 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.

Substantial doubt existed at the time of filing of our annual report on Form 10-K for the year ended December 31, 2017 and our quarterly report on Form 10-Q for the six months ended June 30, 2018 about the Company's ability to continue as a going concern. Our ability to obtain additional financing will be subject to a number of factors, including market conditions, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates, restrict our operations or obtain funds by entering into agreements on unattractive terms, which would likely have a material adverse effect on our business, stock price and our relationships with third parties with whom we have business relationships, at least until additional funding is obtained. If we do not have sufficient funds to continue operations, we could be required to seek bankruptcy protection or other alternatives that would likely result in our stockholders losing some or all of their investment in us.

We do not have any credit facilities as a source of future funds, and there can be no assurance that we will be able to raise sufficient additional capital on acceptable terms, or at all. We may seek additional capital through a combination of private and public equity offerings, debt financings and strategic collaborations. If we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly issued securities may have rights, preferences or privileges senior to those of existing stockholders. Debt financing, if obtained, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, could increase our expenses and require that our assets secure such debt. Moreover, any debt we incur must be repaid regardless of our operating results. If we choose to pursue additional indications and/or geographies for our product candidates, in-license additional development assets, or otherwise expand more rapidly than we presently anticipate, we may also need to raise additional capital sooner than expected.

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 a number of factors, including market conditions, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates, restrict our operations or obtain funds by entering into agreements on unattractive terms, which would likely have a material adverse effect on our business, stock price and our relationships with third parties with whom we have business relationships, at least until additional funding is obtained. As a result, substantial doubt existed about our ability to continue as a going concern as of the date of the filing of our annual report on Form 10-K for the year ended December 31, 2017 and our quarterly report on Form 10-Q for the six months ended June 30, 2018. The accompanying consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of recorded assets, or the amounts and classification of liabilities that might be different should the Company be unable to continue as a going concern based on the outcome of these uncertainties described above.

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

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

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

We have no corporate history of conducting clinical trials. Our planned clinical trials or those of our collaborators may reveal significant adverse events, toxicities or other side effects not seen in our preclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates

Our operations to date have been limited to financing and staffing the Company, conducting research and developing our core technologies, and identifying and optimizing our lead product clinical candidates. Although we have recruited a team that has experience with clinical trials in the United States and outside the United States, as a company, we have no corporate experience conducting clinical trials in any jurisdiction and have not had previous experience commercializing product candidates or submitting an investigational new drug application or any Application to the FDA or similar submissions to initiate clinical trials or obtain marketing authorization to foreign regulatory authorities. We cannot be certain that planned clinical trials will begin or be completed on time, if at all, that our planned development programs would be acceptable to the FDA or other regulatory authorities, or that, if regulatory approval is obtained, our product candidates can be successfully commercialized. Clinical trials and commercializing our product candidates will require significant additional financial and management resources, and reliance on third-party clinical investigators, contract research organizations ("CROs"), consultants and collaborators. Relying on third-party clinical investigators, CROs or collaborators may result in delays that are outside of our control.

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

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

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

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

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

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

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

- demonstration of clinical safety and efficacy;
- relative convenience, dosing burden and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe our product candidates, and the target patient population to try new therapies;
- efficacy of our product candidates compared to competing products;
- the introduction of any new products that may in the future become available targeting indications for which our product candidates may be approved;
- new procedures or therapies that may reduce the incidences of any of the indications in which our product candidates may show utility;
- pricing and cost-effectiveness;
- the inclusion or omission of our product candidates in applicable therapeutic and vaccine guidelines;
- the effectiveness of our own or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in approved labeling from regulatory authorities;

- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors or to receive the necessary pricing approvals from government bodies regulating the pricing and usage of therapeutics; and

- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement or government pricing approvals.

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

In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our product candidates successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render our product candidates not commercially viable. For example, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for any of our product candidates, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve any of our product candidates with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that indication.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Relating to Our Intellectual Property Rights

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

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

Our current patent portfolio consists of patents licensed from CoNCERT Pharmaceuticals for PCS-499 and related compounds that are directed to claims for composition of matter, methods of use, and certain processes. This includes approximately 26 issued patents (including 8 in the United States, 2 in Europe, and 2 in Japan) and approximately 7 pending patent applications (including 3 in the United States and 2 in Europe). The issued U.S., European, and Japanese patents are expected to expire in 2029 and 2030, excluding any extension or adjustment of patent term that may be available.

In addition, we do not own any intellectual property rights, including any patents that underlie our drug candidates. These drugs are in-licensed from other biotech or pharmaceutical companies and our rights to develop and commercialize the product candidates we license are subject to the validity of the owner's intellectual property rights. All of our product candidates are either in the early stages of clinical development or late stages of preclinical development and we have not initiated any clinical trials 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. Certain of our licenses contained in our agreements with CoNCERT Pharmaceuticals contain provisions that allow the licensor to terminate the license if (i) we breach any payment obligation or other material provision under the agreement and fail to cure the breach within a fixed time following written notice of termination, (ii) we or any of our affiliates, licensees or sublicensees directly or indirectly challenge the validity, enforceability, or extension of any of the licensed patents, or (iii) we declare bankruptcy or dissolve. Our rights under the licenses are subject to our continued compliance with the terms of the license, including the payment of royalties due under the license. Termination of these licenses could prevent us from marketing some or all of our products. Because of the complexity of our products and the patents we have licensed, determining the scope of the license and related royalty obligations can be difficult and can lead to disputes between us and the licensor. An unfavorable resolution of such a dispute could lead to an increase in the royalties payable pursuant to the license. If a licensor believed we were not paying the royalties due under the license or were otherwise not in compliance with the terms of the license, the licensor might attempt to revoke the license. If such an attempt were successful, we might be barred from producing and selling some or all of our products.

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

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

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

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

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

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

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

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

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

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

General Company-Related Risks

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

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

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

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

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

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

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

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

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

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

If we suffer negative publicity concerning the safety of our products in development, our sales may be harmed and we may be forced to withdraw such products.

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

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

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

To induce valuable personnel to remain at our Company, in addition to salary and cash incentives, we expect that we will provide stock options, restricted stock units or other equity securities that vest over time upon approval of a plan by the Board of Directors. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we expect to have employment agreements with our key employees, these employment agreements may still allow these employees to leave our employment at any time, for or without cause. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical and scientific personnel.

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

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

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

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

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

Currently, we have material weaknesses relating to a lack of accounting staff to implement effective financial reporting, internal controls and disclosure controls. As a result of such internal control weakness, we experienced a cybersecurity breach in January 2018 that resulted in a fraud loss of $144,000 where the probability of recovery of the loss is remote. While we are taking steps to prevent these control weaknesses from reoccurring, we cannot provide assurance that we will be successful. We are in the early stages of operations and fund raising so we currently lack the financial resources necessary to implement an effective internal control system to prevent and/or detect and correct material misstatements due to fraud or error. Our inability to implement an effective internal control system in the future to prevent and/or detect and correct material misstatements could have a material and adverse effect on our financial condition.

Risks Related to Ownership of Our Common Stock and This Offering

You will experience immediate dilution.

Because the price per share of our common stock being offered is substantially higher than the tangible book value per share of our common stock, you will suffer substantial dilution with respect to the common stock you purchase in this offering. If you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution. See "Dilution" on page 24.

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

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

Our common stock price is expected to be volatile.

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

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

- Common stock sales in the public market by one or more of our larger stockholders, officers or directors;
- our filing for protection under federal bankruptcy laws; or
- a negative outcome in any litigation or potential legal proceeding.

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

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

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

We intend to apply to have our shares of common stock included on the OTCQB, although there can be no assurance that our application will be approved. You are urged to obtain current market quotations of our common stock before purchasing any of the Shares being offered for sale pursuant to this prospectus.

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

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

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

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

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

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

Based on the number of outstanding shares of our common stock held by our stockholders as of October 25, 2018, our directors, executive officers and their respective affiliates beneficially owned or controlled over 49% of our outstanding shares of common stock. In addition, our 5% stockholders along with our officers and directors and their affiliates collectively own more than 80% of our outstanding shares of our common stock. As a result, these stockholders and our officers and directors, collectively, have the ability to exert a significant degree of influence with respect to the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. The interests of these persons may not always coincide with our interests or the interests of our other stockholders. This concentration of ownership could harm the market price of our common stock by (i) delaying, deferring or preventing a change in corporate control, (ii) impeding a merger, consolidation, takeover or other business combination involving us, or (iii) discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

Our common stock is highly illiquid and the public market for the common stock may be minimal; therefore you may find it difficult to sell shares of our common stock you may acquire in this offering.

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

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

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

Substantial amounts of our common stock may be sold under Rule 144 into the public market which may adversely affect prevailing market prices for the common stock and could impair our ability to raise capital in the future through the sale of equity securities. Rule 144 permits a person who presently is not and who has not been an affiliate of ours for at least three months immediately preceding the sale and who has beneficially owned the shares of common stock for at least six months to sell such shares without restriction other than the requirement that there be current public information as set forth in Rule 144. If a non-affiliate has held the shares for more than one year, such person may make unlimited sales pursuant to Rule 144 without restriction. Shares held by directors, executive officers, and other affiliates will also be subject to volume limitations under Rule 144 under the Securities Act. Rule 144 will be available to stockholders beginning on October 18, 2018.

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

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

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

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

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

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

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus 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 prospectus. These statements may be found under the section of this prospectus captioned "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as in prospectus generally. In particular, these include statements relating to future actions, prospective products, applications, customers, technologies, future performance or results of anticipated products, expenses, and financial results. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from our historical experience and our present expectations or projections. Factors that could cause actual results to differ from those discussed in the forward-looking statements include, but are not limited to:

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

The forward-looking statements are based upon management's beliefs and assumptions and are made as of the date of this prospectus. We undertake no obligation to publicly update or revise any forward-looking statements included herein 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 disclosed herein. In light of these risks and uncertainties, we cannot assure you that the forward-looking statements contained herein will in fact occur. You should not place undue reliance on these forward-looking statements. Before making a decision to purchase shares of our stock, you should carefully consider all of the factors identified in this prospectus that could cause actual results to differ.

This prospectus also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources

USE OF PROCEEDS

This prospectus relates to the resale of certain shares of our common stock that may be offered and sold from time to time by the Selling Stockholders. This prospectus also relates to shares of our common stock that will be issued to the Selling Stockholders upon exercise of outstanding Warrants. We will not receive any proceeds from the sale of shares of our common stock in this offering. We will receive proceeds from the exercise of any Warrants, but cannot predict when or if the warrants will be exercised, and it is possible that the warrants may expire and never be exercised. To the extent we do receive any such proceeds they will be used to fund our working capital and for general corporate purposes.

DETERMINATION OF OFFERING PRICE

The offering price of the common stock has been arbitrarily determined and bears no relationship to any objective criterion of value. The price does not bear any relationship to our assets, book value, historical earnings or net worth. In determining the offering price, our Board of Directors considered such factors as the prospects, if any, for similar companies, anticipated results of operations and present financial resources. No third party valuation was obtained concerning the offering price for the shares or the fairness of the offering price used for the shares. We cannot assure you that a public market for our securities will develop or continue or that the securities will ever trade at a price higher than the offering price.

MARKET PRICE OF OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS

Our authorized capital stock consists of 350,000,000 shares of common stock, $0.0001 value per share, and 10,000,000 shares of preferred stock, $0.0001 par value per share. As of October 25, 2018, we have 38,674,265 shares of common stock outstanding and no shares of preferred stock outstanding.

Our common stock is quoted on the OTCPink under the symbol “PCSA”. We have one class of common stock. As of October 25, 2018, there were approximately 198 registered holders of record of our common stock.

We intend to apply to have our shares of common stock included on the OTCQB, although there can be no assurance that our application will be approved. You are urged to obtain current market quotations of our common stock before purchasing any of the Shares being offered for sale pursuant to this prospectus.

There can be no assurances that our shares will be accepted for trading on the OTCQB or any other recognized market. Also, there can be no assurances that a public trading market will develop following acceptance by the OTCQB or at any other time in the future or that if such a market does develop, that it can be sustained.

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

Quarter Ended	High	Low
December 31, 2018 (through October 26, 2018)	$ 4.40	$ 3.70
September 30, 2018	$ 4.78	$ 1.85
June 30, 2018	$ 4.70	$ 3.00
March 31, 2018	$ 5.125	$ 2.50
December 31, 2017	$ 5.11	$ 0.48
September 30, 2017	$ 4.69	$ 0.98
June 30, 2017	$ 0.98	$ 0.98
March 31, 2017	$ 1.75	$ 0.98
December 31, 2016	$ 2.31	$ 1.12
September 30, 2016	$ 2.31	$ 1.12
June 30, 2016	$ 2.31	$ 1.12
March 31, 2016	$ 2.80	$ 1.05

DIVIDEND POLICY

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

DILUTION

At June 30, 2018, our net tangible book value was $2,968,347, or $0.08 per share of the outstanding common stock as adjusted. Net tangible book value per share is determined by dividing our net tangible book value by the total number of shares of common stock outstanding. We will not receive any proceeds from the sales by Selling Stockholders. While we will receive proceeds from the exercise of Warrants, there can be no assurance that any Warrants will be exercised. Assuming that no Warrants are exercised, our net tangible book value will not change after sales by the Selling Stockholders. Assuming sales by the Selling Stockholders occur at the price of $3.65 per share, our net tangible book value of $0.08 per share as of June 30, 2018 remains, and new investors will experience an immediate dilution of $3.57 per share relative to their purchase price.

The foregoing assumes that outstanding warrants have not been exercised. None of the warrants may be exercised prior to November 15, 2018.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes included elsewhere in this prospectus. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our results and the timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under "Risk Factors" and elsewhere in this Prospectus.

Background

On October 2, 2017 Heatwurx and Processa Therapeutics, LLC, a Delaware limited liability company and a wholly-owned subsidiary of Heatwurx entered into the Acquisition Agreement with Promet pursuant to which, on October 4, 2017, Heatwurx acquired the assets of Promet in exchange for issuing to Promet 31,745,242 shares of the common stock of Heatwurx in a reverse acquisition transaction. Following the closing, Heatwurx changed its name to Processa Pharmaceuticals, Inc.

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

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 two indications and searching for additional products for our portfolio. Our lead product, PCS-499, is an oral tablet that is an analog of an active metabolite of an already approved FDA drug. The advantage of PCS-499 is that it may potentially work in many conditions because it has multiple pharmacological targets that it affects that are important in the treatment of these conditions. Based on its pharmacological activity, we have identified other unmet medical need conditions where the use of PCS-499 may result in clinical efficacy. These conditions include NL and RIF in head and neck cancer patients. We have met with the FDA on the NL condition and have developed a strategy for moving the program for NL forward starting with a Phase 2 clinical trial in NL patients in late 2018.

On June 22, 2018, the FDA granted orphan-drug designation to our leading clinical compound PCS-499 for treatment of NL.

Going Concern and Management's Plan

Our consolidated financial statements are prepared using U.S. GAAP and are based on the assumption that the Company will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. We face certain risks and uncertainties that are present in many emerging growth companies regarding product development and commercialization, limited working capital, recurring losses and negative cash flow from operations, future profitability, ability to obtain future capital, protection of patents, technologies and property rights, competition, rapid technological change, navigating the domestic and major foreign markets' regulatory and clinical environment, recruiting and retaining key personnel, dependence on third party manufacturing organizations, third party collaboration and licensing agreements, lack of sales and marketing activities and no customers or pharmaceutical products to sell or distribute. These risks and other factors raised substantial doubt about our ability to continue as a going concern as of the date of the filing of our annual report on Form 10-K for the year ended December 31, 2017 and our quarterly report on Form 10-Q for the six months ended June 30, 2018.

We have relied exclusively on private placements with a small group of accredited investors to finance our business and operations. We do not have any credit facilities as a source of future funds. We have not had any revenue since our inception on August 31, 2015 and we do not currently have any revenue under contract or any immediate sales prospects. As of June 30, 2018, we had an accumulated deficit of approximately $6.2 million incurred since inception. For the six months ended June 30, 2018, we incurred a net loss from continuing operations of approximately $2.3 million and used approximately $2.2 million in net cash from operating activities. We expect our operating costs to be substantial as we incur costs related to the clinical trials for our product candidates and that we will operate at a loss for the foreseeable future.

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

We are looking at ways to add an additional revenue stream to offset some of our expenses. We are planning on raising additional funds in the first half of 2019. In addition, we are seeking alternative options to add additional cash. However, no assurance can be given that we will be successful in securing adequate funds that may be required. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates, restrict our operations or obtain funds by entering into agreements on unattractive terms, which would likely have a material adverse effect on our business, stock price, and our relationships with third parties with whom we have business relationships, at least until additional funding is obtained.

As a result, substantial doubt existed about our ability to continue as a going concern as of the date of the filing of our annual report on Form 10-K for the year ended December 31, 2017 and our quarterly report on Form 10-Q for the six months ended June 30, 2018. The accompanying consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of recorded assets, or the amounts and classification of liabilities that might be different should the Company be unable to continue as a going concern based on the outcome of these uncertainties described above.

Recent Developments

Investigative New Drug Application and Orphan Drug Designation. On June 22, 2018, the FDA granted orphan-drug designation to our leading clinical compound PCS-499 for treatment of NL.

On September 28, 2018, the FDA cleared our IND for PCS-499 in NL such that we can move forward with the Phase 2 study and enroll patients in the fourth quarter of 2018.

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

PIPE Transaction. On May 15, 2018, and June 29, 2018, we entered into Subscription and Purchase Agreements (the "Purchase Agreements") with certain accredited investors (who are now part of the Selling Stockholders) and conducted closings pursuant to which we sold 1,402,442 shares of common stock at a purchase price of $2.27 per share. In addition, each investor received a warrant to purchase one share of common stock for each share of common stock purchased by such investor at an exercise price equal to $2.724, subject to adjustment thereunder.

We received total gross proceeds of approximately $3.2 million prior to deducting placement agent fees and estimated expenses payable by us. We currently intend to use the proceeds of the Private Placement to fund research and development of our lead product candidate, PCS-499, including clinical trial activities, and for general corporate purposes.

Boustead Securities, Ltd. ("Boustead") acted as placement agent and received $167,526 and a Placement Agent Warrant to purchase up to 84,146 shares of common stock at an exercise price equal to $2.724.

Clinical Trial Funding. On May 25, 2018, we entered into an agreement with an accredited investor to whom we sold 792,952 shares of common stock at a purchase price of $2.27 per share for $1.8 million of gross proceeds. We will use these committed funds for our Phase 2a clinical trial of PCS-499 in patients with NL which is planned to begin in the fourth quarter of 2018. The investor will make payments not to us, but rather directly to the CRO conducting our Phase 2 Necrobiosis Lipoidica Trial based on their invoicing. The investor also received warrants to purchase one share of common stock for each share of common stock purchased at an exercise price equal to $2.724. The investor has pledged 50% of the 792,952 shares and 50% of the 792,952 warrants to us to secure the investor's funding obligation. We will release 198,238 of the pledged shares and 198,238 of the pledged warrants when the investor has funded $720,000. When the investor has funded $1,260,000, we will release the remaining shares and warrants.

Boustead acted as placement agent and received $108,000 and a warrant to purchase up to 47,578 shares of common stock at an exercise price equal to $2.724.

Note Conversion. On May 25, 2018, we converted approximately $2.35 million of our mandatory convertible 8.0% Senior Notes and accrued interest of $109,000 into 1,206,245 shares of common stock, at a price of $2.043 per share. The noteholders also received warrants to purchase one share of common stock for each share of common stock purchased at an exercise price equal to $2.452.

Boustead acted as placement agent and received $144,955 and a warrant to purchase up to 72,375 shares of common stock at an exercise price equal to $2.452.

The shares of common stock for both PIPE Transactions and the clinical trial funding were sold in a private placement pursuant to exemptions from the registration requirements of the Securities Act afforded by Rule 506 of Regulation D promulgated thereunder.

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

Results of Operations

Comparison of the three and six months ended June 30, 2018 and 2017

Our consolidated results of operations for the three and six months ended June 30, 2018 and 2017 were as follows:

	Three Months Ended June 30,			Six Months Ended June 30,		
	2018	2017	Change	2018	2017	Change
Operating Expenses						
Research and development costs	$ 1,077,643	$ 160,867	$ 916,776	$ 1,865,921	$ 311,164	$ 1,554,757
General and administrative expenses	350,581	119,467	231,114	853,918	192,759	661,159
Total operating expenses	1,428,224	280,334	1,147,890	2,719,839	503,923	2,215,916
Other Income (Expense)						
Interest Expense	(58,314)	-	(58,314)	(146,054)	-	(146,054)
Interest Income	2,681	1,889	792	3,706	3,387	319
Total other income (expense)	(55,633)	1,889	(57,522)	(142,348)	3,387	(145,735)
Net Operating Loss Before Income Tax Benefit	(1,483,857)	(278,445)	1,205,412	2,862,187	500,536	2,361,651
Income Tax Benefit	277,783	-	(277,783)	(559,317)	-	(559,317)
Net Loss	$ (1,206,074)	$ (278,445)	$ (927,629)	$ (2,302,870)	$ (500,536)	$ (1,802,334)

Revenues. We had no revenues during the three and six months ended June 30, 2018 and 2017. We have had no revenue since our inception on August 31, 2015. We do not currently have any revenue under contract, nor does it have any immediate sales prospects.

Operating Expenses.

Research and Development Expenses. Our research and development expenses consist primarily of (i) licensing of compounds for product testing and development, (ii) program and testing related expenses, (iii) amortization of the exclusive license intangible asset used in research and development activities, and (iv) internal research and development staff related payroll, taxes and employee benefits, external consulting and professional fees related to the product testing and development activities of the Company. Non-refundable advance payments for goods and services to be used in future research and development activities are recorded as prepaid expenses and expensed when the research and development activities are performed. Research and development expenses were approximately $1.1 million and $161,000 for the three months ended June 30, 2018 and 2017, respectively, representing an increase of approximately $917,000. Research and development expenses were approximately $1.9 million and $311,000 for the six months ended June 30, 2018 and 2017, respectively, representing an increase of approximately $1.6 million.

The increase in research and development expenses relate primarily to the substantial completion of a licensing, program and testing costs incurred in 2016 and no replacement compound available for testing until the CoNCERT license and option agreement for the replacement compound PCS-499 was executed in October 2017. As a result, research and development expenses for licensing, program and testing costs were approximately $692,000 and $1.3 million higher in the three and six months ended June 30, 2018 compared to the same period in 2017. These costs were primarily related to the establishment of a new site to manufacture the tablets of PCS-499 since the original CoNCERT tablet manufacturing site could no longer be used. As a result of exercising the option, the Company recognized approximately $197,000 and $223,000 of amortization expense on the intangible asset in the three and six months ended June 30, 2018 with no similar cost in the same period in 2017. In addition, research and development staff related payroll, taxes and employee benefits increased approximately $42,000 and $90,000 in the three and six months ended June 30, 2018 compared to the same period in 2017 related to an increase in full-time equivalent staff and related costs.

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

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

We expect research and development expenses to increase as we advance our lead candidates and pipeline product candidates. The funding necessary to bring a drug candidate to market is subject to numerous uncertainties. Once a drug candidate is identified, the further development of that drug candidate can be halted or abandoned at any time due to a number of factors. These factors include, but are not limited to, funding constraints, safety or a change in market demand. For each of our drug candidate programs, we periodically assess the scientific progress and merits of the programs to determine if continued research and development is economically viable. Certain of our programs may be terminated due to the lack of scientific progress and lack of prospects for ultimate commercialization.

General and Administrative Expenses. General and administrative expenses for the three months ended June 30, 2018 increased approximately $231,000 to approximately $351,000 compared to approximately $120,000 for the three months ended June 30, 2017. General and administrative expenses for the six months ended June 30, 2018 increased approximately $661,000 to approximately $854,000 compared to approximately $193,000 for the six months ended June 30, 2017. In the three months ended June 30, 2018 compared to the same period in 2017, the increase in general and administrative expenses relate primarily to professional fees for legal and accounting of approximately $185,000 due to the SEC filings required for a newly public company; the increase of approximately $15,000 in payroll, taxes, and employee benefits for internal general and administrative staff; increased business insurance costs of approximately $12,000, and the increase in other administrative costs such as training and repairs and maintenance of approximately $19,000, In the six months ended June 30, 2018 compared to the same period in 2017, the increase in general and administrative expenses relate primarily to professional fees for legal, accounting, advisory and consulting costs of approximately $411,000 related to Company operations and costs of being a public company; a cybersecurity fraud loss in January 2018 of approximately $144,000 for which the Company does not have insurance coverage; increased internal general and administrative staff related payroll, taxes and employee benefits of approximately $62,000 due to an increase in full-time equivalent staff and related costs to support the growth in Company operations and public company reporting requirements; increased repairs and maintenance of approximately $14,000 related to computer and website support; increased business insurance costs of approximately $10,000; and the increase in other administrative costs such as travel and training of approximately $20,000. Cost reimbursements (payroll, health care and office rent) by CorLyst, LLC ("CorLyst") were $27,000 and were comparable for the three months ended June 30, 2018 and 2017, while they decreased by approximately $3,000 to $54,000 from $57,000 for the six months ended June 30, 2018 when compared to the same period in 2017.

We expect the general and administrative expenses to continue to increase as we add staff to support our research and development activities and the administration required to operate as a public company. As a result of the cybersecurity breach, we implemented certain review and approval procedures internally and with our banks; our technology consultants have implemented system changes; and, we reported the fraud to our banks and the Federal Bureau of Investigation Cyber Crimes Unit. While we are taking steps to prevent such an event from reoccurring, we cannot provide assurance that similar issues will not reoccur.

Other Income (Expense).

Interest Expense. Interest expense was approximately $58,000 and $0 for the three months ended June 30, 2018 and 2017, respectively. Interest expense was approximately $146,000 and $0 for the six months ended June 30, 2018 and 2017, respectively. For the three months ended June 30, 2018, interest expense represents accrued interest of approximately $33,000 and the amortization of debt issuance costs of approximately $25,000. For the six months ended June 30, 2018, interest expense represents accrued interest of approximately $85,000 and the amortization of debt issuance costs of approximately $61,000. These expenses were incurred on the $2.58 million issuance of 8% Senior Notes issued on October 4, 2017 ($1.25 million) and November 21, 2017 ($1.33 million). See Recent Developments above regarding the conversion of the Senior Convertible Notes.

Interest Income. Interest income was approximately $2,700 and $1,900 for the three months ended June 30, 2018 and 2017, respectively. Interest income was approximately $3,700 and $3,400 for the six months ended June 30, 2018 and 2017, respectively. Interest income represents interest earned on money market funds and certificates of deposit.

Income Tax Benefit. An income tax benefit of $278,000 and $0 was recognized for the three months ended June 30, 2018 and 2017, respectively. An income tax benefit of approximately $559,000 and $0 was recognized for the six months ended June 2018 and 2017, respectively. A deferred tax liability was recorded when CoNCERT sold its license and "Know-How" to Processa for stock in an Internal Revenue Code Section 351 transaction on March 19, 2018. A Section 351 transaction treats the acquisition of the Know-How for stock as a tax-free exchange. As a result, under ASC 740-10-25-51 Income Taxes, we recorded a deferred tax liability of approximately $3,037,000 for the acquired temporary difference between the financial reporting basis of approximately $11,039,000 and the tax basis of approximately $2,000. The deferred tax liability may be offset by the deferred tax assets resulting from 2017 and 2018 taxable net operating losses. Under ACS 740-270 Income Taxes – Interim Reporting, the Company is required to project its 2018 federal and state effective income tax rate and apply it to the June 30, 2018 operating loss before income taxes. Based on the projection, the Company expects to recognize a tax benefit from the 2017 taxable net operating loss carryover and the projected 2018 taxable loss that offset the deferred tax liability from the acquired Know How. This offset results in the recognition of a deferred tax benefit shown in the consolidated statements of operations for 2018.

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.

Comparison of years ended December 31, 2017 and 2016

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

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

Revenues. To date we have not generated any revenue and do not expect to generate any revenue from any drug candidates that we develop unless and until we obtain regulatory approval and commercialize these drugs or enter into collaborative agreements.

Operating Expenses.

Research and Development Expenses. Research and development expenses consist primarily of (i) licensing of compounds for product testing and development, (ii) program and testing related expenses, and (iii) internal research and development staff related payroll, taxes and employee benefits, external consulting and professional fees related to our product testing and development activities.

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

We expect research and development expenses to increase as we advance our lead candidates and pipeline product candidates. The funding necessary to bring a drug candidate to market is subject to numerous uncertainties. Once a drug candidate is identified, the further development of that drug candidate can be halted or abandoned at any time due to a number of factors. These factors include, but are not limited to, funding constraints, safety or a change in market demand. For each of our drug candidate programs, we periodically assess the scientific progress and merits of the programs to determine if continued research and development is economically viable. Certain of our programs may be terminated due to the lack of scientific progress and lack of prospects for ultimate commercialization.

General and Administrative Expenses. General and administrative expenses for the year ended December 31, 2017 increased by approximately $492,000, or 127.9% to $876,000 in 2017 compared to $384,000 in 2016. The increase in general and administrative expenses relate primarily to professional fees for legal, accounting, advisory and consulting costs of approximately $234,000 related to our operations and costs of being a public company; increased internal general and administrative staff related payroll, taxes and employee benefits of approximately $214,000 due to growth in our operations and a full year of expense for 2016 hires; increase in office rent of approximately $55,000 as a result of being the primary obligor on the headquarters lease for a full year in 2017 compared to one-quarter in 2016 and sharing office rent costs with CorLyst, a related party of Promet and a shareholder of ours, during the balance of 2016; and, one-time costs incurred in 2017 related to the reverse acquisition of Heatwurx by Promet, which closed on October 4, 2017, of approximately $59,000 and the impairment of software costs of approximately $15,000 related to obsolete software costs as a result of the reverse acquisition transaction.

CorLyst reimburses us for shared costs related to payroll, health care insurance and rent based on actual costs incurred. We recognize the reimbursement as a reduction of our general and administrative operating expenses. Reimbursements amounts totaled $111,799 and $32,327 for the years ended December 31, 2017 and 2016, respectively. We had a receivable from CorLyst at December 31, 2017 and 2016 of $62,709 and 0, respectively.

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

We expect the general and administrative expenses to increase as we add staff to support the growing research and development activities of the Company and administration requirements.

Other Income (Expense).

Interest Expense. Interest expense was approximately $59,000 and $0 for the years ended December 31, 2017 and 2016, respectively. Interest expense represents accrued interest of approximately $35,700 and the amortization of debt issuance costs of approximately $23,300 on the $2.58 million issuance of 8.0% Senior Convertible Notes issued on October 4, 2017 ($1,250,000) and November 21, 2017 ($1,330,000). The interest accrues monthly at 8.0% annually on the principal balance outstanding and is payable in kind through the issuance of common stock of the Company at maturity, which is not later than one-year from the date of issuance of the Senior Convertible Notes. On May 25, 2018, $2.35 million of these Notes, along with the related accrued interest were converted into 1,206,245 shares of common stock and warrants to purchase an equivalents number of shares of our common stock at $2.452 per share. There was no debt outstanding in 2016.

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

Financial Condition

Total assets increased by approximately $11.4 million to $14.4 million at June 30, 2018 compared to $3.0 million at December 31, 2017. This increase is primarily attributable to the acquisition of the exclusive license intangible asset from CoNCERT Pharmaceuticals, Inc. for the PCS-499 compound in exchange for CoNCERT receiving $8.0 million of our common stock that was held by Promet and the recognition of approximately a $3.0 million deferred tax liability related to the acquired temporary difference for the intangible asset between book and tax basis and transaction costs. Management believes the intangible asset is used in research and development activities and has alternative future uses (in research and development projects or otherwise). As a result, the acquisition cost of approximately $11.0 million was capitalized and is amortized over the intangible asset's useful life in accordance with Topic 350, Intangibles – Goodwill and Other. We also sold 1,402,442 common stock units for approximately $3.2 million in May and June of 2018.

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.

Liabilities increased approximately $0.5 million to $3.1 million at June 30, 2018 compared to $2.6 million at December 31, 2017 related primarily to (i) the conversion of $2.2 million in Senior Convertible Notes, net of debt issuance costs; (ii) the recognition of approximately $3.04 million for the deferred tax liability related to the acquired temporary difference for the intangible asset, partially offset by the recognition of approximately $559,000 of income tax benefit related to the release of the benefit from net operating losses and the amortization of the intangible asset; (iii) the decrease in accrued interest of $25,000; and (iv) an increase in accounts payable of approximately $200,000 and accrued expenses of approximately $90,000 related primarily to purchase obligations due to contract research organizations and professional fees related to being a public company.

The changes in stockholders' equity consist of the following:

- the fair value of the Promet common stock of $8 million or 2,090,301 shares exchanged with CoNCERT to acquire the exclusive license intangible asset recorded as an increase in additional paid-in capital;
- conversion of $2.35 million in senior convertible notes into 1,206,245 shares of common stock;
- private placement transactions with net proceeds totaling $2.96 million or 1,402,442 shares of common stock;
- future researching commitment of $1.8 million in exchange for 792,952 shares of common stock; and a
- $2.3 million net loss for the six months ended June 30, 2018.

Liquidity and Capital Resources

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. At June 30, 2018, we had approximately $3.3 million in cash and cash equivalents and certificates of deposit compared to approximately $2.9 million in cash and cash equivalents as of December 31, 2017 to fund ongoing operations. We do not have any credit facilities as a source of future funds, and there can be no assurance that we will be able to raise sufficient additional capital on acceptable terms, or at all. As a result, substantial doubt existed about our ability to continue as a going concern as of the date of the filing of our annual report on Form 10-K for the year ended December 31, 2017 and our quarterly report on Form 10-Q for the six months ended June 30, 2018. The accompanying consolidated financial statements do not include any adjustment 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.

As described under Recent Developments, in May and June of 2018 we received proceeds of $2.96 million dollars from the sale of 1,402,442 shares of our common stock and warrants to purchase a similar number of shares of common stock exercisable at $2.724 per share. On May 25, 2018, we also entered into an agreement with an investor for a commitment to fund up to $1.8 million to fund clinical trial expenses in exchange for 792,952 shares of our common stock and warrants to purchase a similar number of shares of common stock exercisable at $2.724 per share. We will use these clinical trial committed funds for our Phase 2a clinical trial of PCS-499 in patients with NL. Payment under this commitment will not be made to us, but rather, directly to the CRO based on their invoicing. Finally, on May 25, 2018 we converted approximately $2.35 million of our 8% convertible debt into 1,206,245 shares of our common stock.

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, it is difficult to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future capital requirements will depend on many factors, including:

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

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

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

Cash Flows

Six months ended June 30, 2018 and 2017

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

	For the Six Months Ended March 31,	
	2018	2017
Net cash provided by (used in):		
Operating activities	$ (2,233,186)	$ (355,928)
Investing activities	(497,782)	(882)
Financing activities	2,733,992	-
Net decrease in cash and cash equivalents	$ 3,024	$ (356,810)

Net cash used in operating activities

Net cash used in operating activities was approximately $2.2 million and $356,000 for the six months ended June 30, 2018 and 2017, respectively. The increase in cash used in operating activities in 2018 compared to 2017 is primarily related to the increased spending on research and development activities for PCS-499 licensing, program and testing costs, including internal staff costs and increased general and administrative costs related to internal staff growth, professional fees for legal, accounting, advisory and consulting costs for operations and the costs of being a public company. In addition, we incurred a cybersecurity fraud loss of approximately $144,000 in January 2018, which is recognized in general and administrative expenses.

We anticipate our research and development efforts and on-going general and administrative costs will generate negative cash flows from operating activities for the foreseeable future.

Net cash used in investing activities

Net cash used in investing activities was approximately $498,000 and $1,000 for the six months ended June 30, 2018 and 2017. The costs incurred related to the purchase of certificates of deposit and transaction costs incurred to acquire the exclusive license from CoNCERT, and the purchase of property and equipment in 2017.

Net cash provided by (used in) financing activities

Net cash provided from financing activities was approximately $2.7 million and $0 for the six months ended June 30, 2018 and 2017, respectively. Between May 15 and June 29, 2018, we closed on the sale of approximately 1.4 million unregistered units consisting of one share of common stock and a warrant to purchase one share of common stock (see Note 4 to the unaudited interim consolidated financial statements included herein).

See the Consolidated Statement of Cash Flows for a description of the non-cash investing and financing activities related to the acquisition of intangible assets from CoNCERT, conversion of senior convertible notes, our clinical study funding commitment and notes receivable related to the sale of common stock and related stock purchase agreement in 2018.

Years ended December 31, 2017 and 2016

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

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

Net cash used in operating activities

Net cash used in operating activities was $1.7 million during the year ended December 31, 2017 primarily attributable to our net loss for the year of $1.9 million. This amount was offset by non-cash charges for depreciation, amortization of debt issue costs and an impairment charge for our software totaling $40,000. The net change in our operating assets and liabilities of $160,000 was primarily attributable to vendor deposits made in 2016 that were applied to obligations due for research and development activities in 2017, offset by changes in our prepaid expenses, accounts payable and accrued expenses totaling $67,000.

Net cash used in operating activities was $2.2 million during the year ended December 31, 2016 primarily attributable to our net loss for the year of $1.9 million. This amount was offset by a nominal amount of non-cash charge for depreciation. The net change in our operating assets and liabilities of $239,000 was primarily attributable to the payment of vendor deposits of $228,000, offset by changes in our prepaid expenses, accounts payable and accrued expenses totaling $12,000.

We anticipate our research and development efforts and on-going general and administrative costs will generate negative cash flows from operating activities for the foreseeable future.

Net cash provided by (used in) in investing activities

Net cash provided by investing activities was $1.0 million for the year ended December 31, 2017. This was due to proceeds from the maturity of the certificates of deposit purchased in 2016, partially offset by software acquisition costs. Net cash used in investing activities was $1.04 million for the year ended December 31, 2016. This was due primarily to the purchase of certificates of deposit and the purchase of property and equipment and software acquisition costs.

Net cash provided by financing activities

Net cash provided by financing activities was $2.43 million for the year ended December 31, 2017 from the proceeds of the issuance of $2.58 million of 8.0% Senior Convertible Notes, partially offset by approximately $155,000 of debt issuance costs. Net cash provided by financing activities was $4.27 million for the year ended December 31, 2016 from the proceeds of the initial issuance of the private placement of equity for Promet.

Off Balance Sheet Arrangements

At June 30, 2018, December 31, 2017 and December 30, 2016, we did not have any off-balance sheet arrangements.

Contractual Obligations and Commitments

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

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

(1) On October 4, 2017 certain entities affiliated with current shareholders purchased $1.25 million of our Senior Notes in a bridge financing undertaken by us to support our operations. On November 21, 2017, additional third party accredited investors contributed $1.33 million in financing proceeds. As of December 31, 2017, $2.58 million of Senior Notes were issued and outstanding. On May 25, 2018, $2.35 million of these Senior Notes, along with the related accrued interest were converted into 1,206,245 shares of common stock and warrants to purchase an equivalent number of shares of our common stock at $2.452 per share.

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

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

(3) We enter into contracts in the normal course of business with contract research organizations and subcontractors to further develop our products. The contracts are cancellable, with varying provisions regarding termination. If a contract with a specific vendor were to be terminated, we would only be obligated for products or services that we had received as of the effective date of the termination and any applicable cancellation fees.

Critical Accounting Policies and Use of Estimates

The discussion and analysis of our financial condition and results of operations are based on our audited consolidated financial statements which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis. We base our estimates on historical experience and on other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

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

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

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

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

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

During the year ended December 31, 2017, we incurred operating losses of approximately $606,400. However, we recorded no income tax benefit for the approximately $347,500 ($95,632 net of tax) of general and administrative expenses treated as deferred start-up expenditures for tax purposes and approximately $258,600 ($71,155 net of tax) of tax losses resulting in tax loss carryforwards. The net operating loss carry forwards are available for application against future taxable income for 20 years expiring in 2037. Tax losses incurred after December 31, 2017 have an indefinite carry forward period. However, the tax loss incurred after December 31, 2017 and carried forward can only offset 80 percent of future taxable income. The benefit associated with the net operating loss carry forward will more likely than not go unrealized unless future operations are successful. Since the success of future operations is indeterminable, the potential benefits resulting from these net operating losses have not been recorded in the consolidated financial statements. As of December 31, 2016 and through October 4, 2017, the Company had no net operating losses for federal and state income tax purposes since Promet’s members were taxed separately on their proportionate share of Promet’s income, deductions, losses and credits.

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, CRO's and consultants and under clinical site agreements related to conducting our clinical trials. The financial terms of these contracts vary and may result in payment flows that do not match the period over which materials or services are provided under such contracts.

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

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

We expense research and development costs as they are incurred.

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

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

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

Stock-Based Compensation: As of June 30, 2018, no stock-based compensation was outstanding. 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 term of the options will be based on the contractual term of the options as determined by the Board of Directors pursuant to our equity incentive plan. 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 makes revisions, if necessary, at each reporting period if actual forfeitures differ from those estimates. We have not estimated future unvested forfeitures since there were no option grants outstanding at June 30, 2018 or December 31, 2017.

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

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

Our equity incentive plan approved by the Heatwurx Board of Directors and stockholders in October 2012 has 257,143 shares of common stock reserved for future issuance. The plan is currently being reviewed by our Board of Directors and may be amended or terminated. Amendments are subject to stockholder approval to the extent required by applicable laws and regulations. Unless terminated sooner, the plan will automatically terminate on April 15, 2021. There are currently no outstanding option grants under the plan.

Recently Issued Accounting Pronouncements

See Note 1 to our consolidated financial statements beginning on page F-37 of this prospectus for a description of recent accounting pronouncements applicable to our consolidated financial statements.

Jobs Act Accounting Election

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

DESCRIPTION OF BUSINESS

Overview

Processa is an emerging pharmaceutical company focused on the clinical development of drug products that are intended to improve the survival and/or quality of life for patients who have a high unmet medical need. Within this group of pharmaceutical products, we currently are developing one product for two indications (i.e., the use of a drug to treat a particular disease) and searching for additional products for our portfolio.

Part of our business strategy is:

(i) to identify drugs that have potential efficacy in patients with an unmet medical need, as demonstrated by some clinical evidence, including published case studied or clinical experience, such that the patient's survival and/or quality of life might improve,

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

(iii) to identify drugs that can be quickly developed within 2-4 years to completion of a pivotal study for the submission of a new drug application ("NDA") to the U.S. Food and Drug Administration ("FDA") or to license the drug to a potential strategic partner just prior to a more expensive and time consuming pivotal study.

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

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 clinical proof-of-concept data to demonstrate that the proposed pharmacology occurs clinically in the targeted patient population to pivotal well-designed randomized controlled trial(s).

To be able to complete the clinical studies within 2 to 4 years, these drugs must (i) already have clinical proof-of-concept data demonstrating the desired pharmacological activity in humans or, minimally, clinical evidence in the form of case studies or clinical experience demonstrating the drug or a similar drug pharmacologically can successfully treat patients with the targeted indication, (ii) target indications for which FDA believes that a single positive pivotal study demonstrating efficacy provides enough evidence that the clinical benefits of the drug and of 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.

Processa's lead product, PCS-499, 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 on the basis of chronic occlusive arterial disease of the limbs. In the body PCS-499 is broken down to multiple metabolites with PCS-499 and many of these metabolites being pharmacologically active. In animal and healthy human volunteer studies, higher exposure of certain active metabolites are seen after PCS-499 administration compared to PTX. Despite the greater exposure to these pharmacologically active molecules, PCS-499 appears to be well tolerated, even at higher doses than the standard dosing of PTX. Based on our findings in the literature that PTX has some activity in a number of conditions, PCS-499 may potentially provide clinical benefit over other on-label or off-label products used for the various conditions. These conditions include NL and RIF in head and neck cancer patients. NL is a chronic, disfiguring condition for which most patients do not have any treatment options. It develops more commonly in women than in men on the lower extremities, and ulceration can occur in approximately 30% of NL patients, which may lead to more severe complications, such as deep tissue infections and osteonecrosis that can threaten life of the limb. RIF or radiation-induced fibrosis can occur after radiation treatment in head and neck cancer. Some patients develop late radiation-induced fibrotic effects 90 days after initiation of radiation therapy and sometimes months or years later. RIF can significantly affect the quality of life of these patients causing symptoms such as dry mouth, oral mucositis, muscular atrophy, swallowing dysfunction, vascular damage, and neural damage.

PCS-499 had previously been investigated for a different indication in Phase 2 studies before we exercised an option to license PCS-499 from CoNCERT Pharmaceuticals in March 2018. Based on the diverse pharmacological activity of PCS-499, the Processa team has defined a strategy to develop this product in NL and RIF in head and neck cancer where physicians and patients seek significant medical help. Both of these conditions occur as a result of multiple pathophysiological changes. Besides the diverse pharmacological properties of PCS-499 targeting many of the physiological changes that occur for these two indications, an analog drug with similar pharmacology, presently approved for a different indication, has been successfully used in some patients for the treatment of both NL and RIF but cannot be used in many patients because it has dose limiting side effects, not allowing for higher doses to be administered to obtain adequate efficacy. The PCS-499 dose limiting side effects appear to occur at a much higher dose based on the existing clinical and pre-clinical data for PCS-499, which would allow physicians to potentially increase the dose to effectively treat significantly more patients with NL or RIF. These two indications do not have any FDA-approved treatments, and have the potential to seriously affect a patient's day-to-day quality of life.

Our team had a successful pre-IND (Investigating New Drug) meeting with the FDA on NL in October 2017, defining the next steps to move PCS-499 into Phase 2 studies and the path to eventual approval. Processa has also entered into an agreement with Integrium, LLC ("Integrium"), a CRO, to conduct the planned Phase 2 clinical study to further evaluate PCS-499 for the treatment of NL. Integrium is a full-service Clinical Proof of Concept firm based in Tustin, California, that specializes in a wide range of therapeutic areas including cardiovascular, metabolic disease and dermatology research. The budget agreed to with Integrium for the completion of the Phase 2 Clinical study is approximately $1.6 to $1.8 million, and this clinical trial funding (of up to $1.8 million) has been committed to by PoC Capital. Enrollment in the study is planned to start in late 2018.

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

In addition to the literature on the off-labeled use of PTX (Trental®) in NL, there are also some published reports on the positive clinical treatment of RIF or radiation-induced fibrosis in head and neck cancer using PTX off-label. Just as in NL, the dose limiting toxicity of PTX appears to prevent more widespread use in RIF. RIF is a condition that occurs after radiation exposure causes multiple pathophysiological changes in the head and neck area. RIF can significantly affect the quality of life of these patients causing symptoms such as dry mouth, oral mucositis, muscular atrophy, swallowing dysfunction, vascular damage, and neural damage. A drug that attacks the multiple pathophysiological changes in RIF may increase the probability of positively treating patients with this condition. The complex mechanism of action of PCS-499 (e.g., enhanced inhibition of cytokines such as TNF-α, and IFN-γ that induce inflammation and granuloma formation, effect on red blood cell deformability and promotion of platelet

deaggregation resulting in an improvement of microcirculatory flow) and the ability to administer a greater yet safer dose than PTX could provide a much needed treatment for these patients.

The development program to date has included five Phase 1 studies, which were conducted to support the clinical pharmacology program for PCS-499, and one Phase 2 study in patients with chronic kidney disease (CKD) with Type 2 diabetes. Of the five Phase 1 studies, four were conducted by CoNCERT (CP505.1001, CP.505.1002, CP505.1003 and CP505.1004) and one by Processa (PCS499.1005). Four of the Phase 1 studies were conducted in healthy volunteers and one Phase 1 study was performed in patients with chronic kidney disease (CKD). Each of the Phase 1 studies was conducted to assess the safety, tolerability and pharmacokinetics (PK) of PCS-499 oral tablets. No serious adverse events related to PCS-499 have been experienced during the conduct of these studies. The initial Phase 1 clinical trial (CP505.1002) evaluated the safety and PK in 16 healthy volunteers after administration of single doses of 400 mg of three different tablet formulations of PCS-499 (slow, medium, fast release), with comparison to Trental® (pentoxifylline) 400 mg extended-release tablets. A formulation was chosen from this study and was used in subsequent studies. The second Phase 1 trial (CP505.1001) assessed the safety and PK in 6 healthy volunteers after single ascending doses from 600 mg to 2400 mg of the modified release (MR) formulation tablets of PCS-499 as well as a single dose of PCS-499 immediate-release (IR) capsules. Doses of PCS-499 up to 1800 mg were well tolerated. The third study (CP505.1003) was designed to evaluate the safety and PK of 4 weeks of treatment with PCS-499 compared to placebo in non-dialysis patients associated with moderate CKD. Doses of PCS-499 administered in this study started with 600 mg once daily for 2 weeks, followed by 600 mg twice daily for 2 weeks. Four weeks of treatment with PCS-499 was found to be safe and well tolerated in the patients with moderate CKD in this study. The fourth study (CP505.1004) was designed to assess the effect of food on the bioavailability of single 600 mg doses of PCS-499 in 14 healthy volunteers. Based on the results of this study the product appears to be better tolerated when administered with food. A fifth study (PCS499.1005) conducted by Processa, was a Phase 1 study to evaluate the safety and PK of single and optional multiple dosing regimens of MR formulations of PCS-499 compared to Trental® (pentoxifylline) administered to healthy subjects under fed conditions. Part 1 was a single-dose administration of three MR formulations of PCS-499 and Trental® to 12 healthy volunteers. Part 2 of the study was an open-label, 3-period crossover comparison in 6 healthy volunteers administered of two different dosage regimens of PCS-499 (900 mg twice daily or 600 mg three times a day) and Trental® after multiple dosing over 4 days. Administration of PCS-499 produced higher concentrations/exposures of the parent and primary metabolite (PCS-499 and D-PTX) on a per mg basis as compared to the concentrations/exposures of the parent and primary metabolite (PTX and PTX-M1) following PTX administration with no increase in frequency or severity of adverse events. From this study a new MR formulation was chosen based on the PK results and both dosage regimens of PCS-499 were shown to be well tolerated.

In addition to the Phase 1 studies, CoNCERT had previously conducted a Phase 2 study (CP505.2001) which was a randomized, double-blind, placebo-controlled multicenter study designed to assess the safety and efficacy of treatment with PCS-499 600 mg tablets orally, twice daily, in CKD patients with Type 2 diabetes receiving concomitant angiotensin-converting enzyme inhibitor (ACEi) and/or angiotensin II receptor blocker (ARB) therapy. This study included a 48-week double-blind, randomized, placebo-controlled period to evaluate the safety and efficacy of 600 mg PCS-499 twice daily in which 177 patients were enrolled. Of the patients that completed the double-blind period of the study, 102 patients chose to enroll in a 48-week open-label period (in which all patients received PCS-499). The primary endpoint of this Phase 2 study was the change after 24 weeks in urinary albumin to creatinine ratio (UACR), a marker of kidney tissue damage. The UACR outcomes at 24 weeks of treatment resulted in no significant differences between the PCS-499 and placebo groups. However, at 48 weeks, UACR in patients receiving PCS-499 increased 24 mg/g from baseline compared to 223 mg/g increase in patients receiving placebo ($p = 0.097$). While not statistically significant, the longer-term treatment duration suggests a favorable trend in UACR for patients receiving PCS-499 as compared to placebo. At 48 weeks, a measurable impact on serum creatinine, a key secondary endpoint, was also observed. The mean serum creatinine level in patients receiving PCS-499 increased by 0.13 mg/dL compared to an increase of 0.21 mg/dL in patients receiving placebo through the 48 weeks of treatment ($p = 0.057$), reflecting 38% lower levels in the PCS-499 treatment group. Furthermore, 10.3% of patients receiving placebo experienced a 50% or greater increase in serum creatinine levels after 48 weeks compared with 1.5% of patients receiving PCS-499 ($p = 0.026$). In this Phase 2 study, the overall incidence of serious adverse events was consistent with what might be expected, given the target population studied and the underlying medical histories and characteristics of the patients. Of the patients enrolled in the double-blind phase of the study, a total of 33 patients experienced at least one serious adverse event (SAE) with no meaningful differences between treatment groups (18 (20.2%) of the PCS-499 patients and 15 (17.0%) of the placebo patients). Cardiac disorders were the most frequently reported SAEs, with 4 (4.5%) PCS-499 and 7 (8.0%) placebo patients experiencing at least one event in this system organ class. Infections and infestations (6 (6.7%) PCS-499 patients and 4 (4.5%) placebo patients) and vascular disorders (4 (4.5%) PCS-499 patients and 6 (6.8%) placebo patients) were the system organ classes with the next highest incidence of SAEs. Twelve (11.8%) of the 102 patients that entered the open-label treatment phase experienced at least one SAE during the open-label treatment phase, of which, infections and infestations (5 (4.9%) patients), cardiac disorders (3 (2.9%) patients), and renal and urinary disorders (3 (2.9%) patients), were the most frequently reported SAEs by system organ class. All SAEs that occurred during the study (in both the double-blind and open-label periods) were judged to be not related to PCS-499.The most common adverse events associated with PCS-499 were gastrointestinal effects such as nausea, diarrhea and vomiting.

On June 22, 2018, the FDA granted orphan-drug designation to our leading clinical compound PCS-499 for treatment of NL. On September 28, 2018, the FDA cleared our IND for PCS-499 in NL such that we can move forward with the Phase 2 study and enroll patients in the fourth quarter of 2018.

Regarding the development of PCS-499 for RIF in head and neck cancer, Processa had an FDA pre-IND meeting in April of 2018 to better define the potential development program for PCS-499 in the treatment of RIF in head and neck cancer. Since PCS-499 would be the first approved drug targeted to treat RIF in head and neck cancer, the FDA and Processa were able to discuss the development expectations. Processa did not receive the official minutes from the FDA meeting until late August and the evaluation of a PCS-499 development program in RIF is still ongoing. Processa anticipates that an IND for RIF in head and neck cancer can be submitted the first half of 2019.

Our ability to generate meaningful revenue from any products in the United States depends on obtaining FDA authorization. Even if our products are authorized and approved by the FDA, we must still meet the challenges of successful marketing, distribution and consumer acceptance.

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

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

Research and Development, Product Manufacturing, and Clinical Supplies

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

Customers and Distribution

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

Intellectual Property

Our success will depend in large part on our ability to:

- obtain and maintain international and domestic patent and other legal protections for the proprietary technology, inventions and improvements we consider important to our business;
- prosecute and defend our patents, once obtained;
- preserve our trade secrets; and
- operate without infringing the patents and proprietary rights of other parties.

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

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

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

License Agreement with CoNCERT Pharmaceuticals, Inc.

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

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

- 4% of the net sales for the portion less than or equal to $100.0 million;
- 5% of the net sales for the portion greater than $100.0 million and less than or equal to $500.0 million;
- 6% of the net sales for the portion greater than $500.0 million and less than or equal to $1.0 billion; and
- 10% of the net sales for the portion greater than $1.0 billion if such sales are made by us or our affiliates or, with respect to sales by our sublicensees, the greater of (i) 6% or (ii) 50% of all payments received by us with respect to such sublicensee.

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

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

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

Sales and Marketing

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

Competition

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

Government Regulation

Pharmaceutical Regulation

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

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

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

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

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

Regulation in the United States

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

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

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

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

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

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

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

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

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

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

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

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

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

Foreign Regulation

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

Additional Regulation

Third-Party Reimbursement

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

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

Fraud and Abuse Laws

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

HIPAA

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

Other Laws

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

Employees

As of October 25, 2018, we had 14 employees. None of our employees is subject to a collective bargaining agreement or represented by a labor or trade union, and we believe that our relations with our employees is good. We believe that we have been successful in attracting skilled and experienced personnel, but competition for personnel is intense and there can be no assurance that we will be able to attract and retain the individuals needed.

Status as an Emerging Growth Company

We are an "emerging growth company" as that term is defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (i.e., those that have not had a registration statement declared effective under the Securities Act, or do not have a class of securities registered under the Exchange Act) are required to comply with such new or revised financial accounting standards. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We may still take advantage of all of the other provisions of the JOBS Act, which include, but are not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, the reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and the exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

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.

DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS

The following table sets forth the names and ages of the members of our executive officers and the positions held by each as of October 25, 2018.

NAME	AGE	PRINCIPAL OCCUPATION/POSITION WITH PROCESSA
David Young, Pharm.D., Ph.D.	65	Chief Executive Officer
James Stanker	60	Chief Financial Officer
Patrick Lin	52	Chief Business & Strategy Officer
Sian Bigora, Pharm.D.	58	Chief Development Officer
Wendy Guy	53	Chief Administrative Officer

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

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

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

Dr. Young is an expert in small molecule and protein non-clinical and clinical drug development. He has served on FDA Advisory Committees, was Co-Principal Investigator on a FDA funded Clinical Pharmacology contract, was responsible for the analytical and pharmacokinetic evaluation of all oral products manufactured in the UMAB-FDA contract which lead to the SUPAC and IVIVC FDA Guidance's, for 5 years taught FDA reviewers as part of the UMAB-FDA contract, has served on NIH grant review committees, and was Co-Principal Investigator on a National Cancer Institute contract to evaluate new oncology drugs.

Dr. Young has met more than 100 times with the FDA on more than 50 drug products and has been a key team member on more than 30 NDA/supplemental NDA approvals. Dr. Young has more than 150 presentations-authored publications-book chapters, including formal presentations to the FDA, FDA Advisory Committees, and numerous invited presentations at both scientific and investment meetings.

Dr. Young received his B.S. in Physiology from the University of California at Berkeley, his M.S. in Medical Physics from the University of Wisconsin at Madison, and his Pharm.D. - Ph.D. with emphasis in Pharmacokinetics and Pharmaceutical Sciences from the University of Southern California.

James Stanker
Chief Financial Officer

Mr. Stanker was appointed the Chief Financial Officer of Company effective September 5, 2018. Mr. Stanker brings more than 30 years of financial and executive leadership experience to Processa 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 for managing the audit quality in the Atlantic Coast Market Territory. From 2009 to 2012, he served as the Global Head of Audit Quality for Grant Thornton International. Prior to joining Grant Thornton, Mr. Stanker served as the Chief Financial officer for a NASDAQ listed company and for a privately-held life science company. Mr. Stanker is a Certified Public Accountant. He has a Bachelor's Degree in Aeronautics from San Jose State University and a Master's in Business Administration from California State University, East Bay. He currently serves on the Board of Directors, and is Chairman of the Audit Committee of GSE Systems, Inc. Mr. Stanker is also an adjunct professor in the George B. Delaplaine School of Business at Hood College. Since his retirement from Grant Thornton, Mr. Stanker has provided financial consulting services to numerous companies.

Patrick Lin
Chief Business and Strategy Officer and Founder

Mr. Lin has over 20 years of financing and investing experience in the Biopharm Sector. He was Co-Founder and Chairman of the Board of Promet Therapeutics, LLC. He is Founder and for more than past 15 years Managing Partner of Primarius Capital, a family office that manages public and private investments focused on small capitalization companies.

For 10 years prior to forming Primarius Capital, Mr. Lin worked at several Wall Street banking and brokerage firms including Robertson Stephens & Co., E*Offering, and Goldman Sachs & Co. Mr. Lin was Co-Founding Partner of E*Offering.

Mr. Lin received an MBA from Kellogg Graduate School of Management, a Master of Engineering Management, and a Bachelor of Science in Business Administration from the University of Southern California.

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

Dr. Bigora has over 20 years of pharmaceutical research, regulatory strategy and drug development experience working closely with Dr. Young. She was Co-Founder, Director, and Chief Development Officer at Promet Therapeutics, LLC. Prior to Promet, Dr. Bigora was Vice President of Regulatory Affairs at Questcor Pharmaceuticals (acquired by Mallinckrodt Pharmaceuticals in 2014) from 2009-2015, including leading efforts on modernizing the Acthar Gel label and in obtaining FDA approval in Infantile Spasms, events of material importance to Questcor's subsequent success. During her time at Questcor she assisted in building an expert regulatory group to address both commercial and development needs for complex products such as Acthar. Dr. Bigora's role at Questcor included heading up the development of a safety pharmacovigilance group and a clinical quality group.

Prior to her position at Questcor, Dr. Bigora was Vice President of Clinical and Regulatory Affairs, U.S. Operations of AGI Therapeutics, plc. In this role she was responsible for the development and implementation of Global Phase 3 studies and interactions with regulatory authorities. Previously she operated her own consulting company, serving as the regulatory and drug development expert team member for multiple small and mid-sized pharmaceutical companies. Dr. Bigora held multiple positions in regulatory affairs, operations and project management ending as VP of Regulatory Affairs at the Strategic Drug Development Division of ICON, plc, an international CRO, and at GloboMax LLC, a CRO specializing in FDA drug development, purchased by ICON plc in 2003. Prior to GloboMax, she worked in the Pharmacokinetics and Biopharmaceutics Laboratory at the School of Pharmacy, University of Maryland on the FDA funded Clinical Pharmacology contract and UMAB-FDA contract as a clinical scientist and instructor for FDA reviewers.

Dr. Bigora received a Pharm.D. from the School of Pharmacy at the University of Maryland at Baltimore. She also completed a Fellowship in Pharmacokinetics and Pediatric Infectious Diseases at the University of Maryland at Baltimore.

Wendy Guy
Chief Administrative Officer and Founder

Ms. Guy has more than 20 years of experience in business operations. She has worked closely with Dr. Young over the last 18 years in corporate management and operations, HR, and finance. She was Co-Founder, Director, and Chief Administrative Officer of Promet Therapeutics, LLC. Prior to Promet, Ms. Guy was employed at Questcor Pharmaceuticals (acquired by Mallinckrodt Pharmaceuticals in 2014) as Senior Manager, Business Operation in charge of the Maryland Office for Questcor. During the five years she spent at Questcor, she built a dynamic administrative and contracts team, grew the Maryland Office from two employees to just under 100, and expanded the facility from 1,200 sq. ft. to 15,000 sq. ft.

Prior to her position at Questcor, Ms. Guy was Senior Manager, U.S. Operations of AGI Therapeutics, plc. In this role she was responsible for the day to day business and administrative operations of the company. Previously she held multiple senior level positions with the Strategic Drug Development Division of ICON, GloboMax, and Mercer Management Consulting.

Ms. Guy received an A.A. from Mount Wachusett Community College.

The following table sets forth the names and ages of our Board of Directors as of October 25, 2018. Additional directors are being identified with a plan to have two internal directors and 3-4 independent directors.

NAME	AGE	BOARD OF DIRECTORS
David Young, Pharm.D., Ph.D.	65	Chairman and Chief Executive Officer
Patrick Lin	52	Director: Chief Business & Strategy Officer
Justin Yorke	51	Director
Virgil Thompson	78	Director

Director Biographies

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

Justin W. Yorke

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

Mr. Yorke has a B.A. from University of California, Los Angeles.

Virgil Thompson

Mr. Thompson has served as a Director of the company since October 2017 and previously served on the Board of Directors at Promet Therapeutics, LLC and Mallinckrodt Pharmaceuticals (formerly Questcor Pharmaceuticals) where he also served on its Human Resources and Compensation Committee. From July 2009 to July 2015, he served as Chief Executive Officer and Director of Spinnaker Biosciences, Inc., and now serves as Chairman of the Board of that company. Mr. Thompson is also the Chairman of the Board of Aradigm Corporation and a Director of Genz Corporation.

Mr. Thompson served as a Director of Questcor Pharmaceuticals, Inc., from 1996 and more recently served as Chairman of its board of directors until Questcor was acquired by Mallinckrodt in August 2014. Mr. Thompson served as the President, Chief Executive Officer and as a Director of Angstrom Pharmaceuticals, Inc. from 2002 until 2007. From 2000 until 2002, Mr. Thompson was President, Chief Executive Officer and a Director of Chimeric Therapies, Inc. From 1999 until 2000, Mr. Thompson was President, Chief Operating Officer and, from 1994, a Director of Bio-Technology General Corporation (subsequently Savient Pharmaceuticals, Inc.).

Mr. Thompson obtained a Bachelor's Degree in Pharmacy from the University of Kansas and a J.D. degree from the George Washington University Law School.

Family Relationships

There is no family relationship between any of our officers.

Board Leadership Structure and Role in Risk Oversight

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

In evaluating director nominees, our Board considers the following factors, among other things:

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

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

Corporate Governance

Board Committees

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

Director Independence

The Board has determined that both Justin Yorke and Virgil Thompson are independent directors as such term is defined by NASDAQ Listing Rule 5605 for service on our Board of Directors and as members of an audit committee we expect to establish in the future. In addition, Justin Yorke qualifies as an "audit committee financial expert" as such term is defined pursuant to SEC rules.

Code of Ethics and Business Conduct

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

EXECUTIVE COMPENSATION

Summary Compensation Table

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

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

Name and Principal Position	Year	Base Salary	Option Awards	Other Compensation	Total Compensation
David Young Chief Executive Officer	2017	$ 0	$ 0	$ 0	$ 0
John McGrain	2017	$ 0	$ 0	$ 0	$ 0
Former Interim Chief Executive Officer	2016	$ 1	$ 0	$ 0	$ 1

Through June 30, 2018, we have paid $56,000 in salary to our executive officers. We entered into an Employment Agreement with Mr. Stanker as of September 1, 2018 ("Stanker Agreement") to serve as the Company's Chief Financial Officer. Pursuant to the Stanker Agreement, Mr. Stanker will receive a base salary of $87,500. The Company granted Mr. Stanker stock options to purchase 334,400 shares of the Company's common stock at an exercise price equal to the closing price of the company's common stock on September 5, 2018. The options are for a 10 year term and vest 25% on September 1, 2019 and 1/48th of such options shall vest each month thereafter provided Mr. Stanker continues employment with us. In the event Mr. Stanker is terminated without Cause (as defined in the Stanker Agreement) or for Good Reason (as defined in the Stanker 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 Stanker 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 Stanker Agreement also includes confidentiality provisions.

Employment agreements for other executives will be put in place in the very near future. At this time, we do not provide compensation to our outside directors, although we expect a plan will be put in place in the near future.

Outstanding Equity Awards at Year-End

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

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

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

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

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

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

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

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

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

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

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

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

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

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

	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	**Weighted-average exercise price of outstanding options, warrants and rights (b)**	**Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c)**
Equity compensation plans approved by security holders	0	N/A	257,143
Equity compensation plans not approved by security holders	0	N/A	0
Total	0		257,143[1]

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

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth the number of shares of our common stock beneficially owned as of October 25, 2018 by each director, executive officer and beneficial owners of more than 5% of the outstanding shares of the common stock based on 38,674,265 shares of common stock issued and outstanding as of October 25, 2018. Unless otherwise indicated, the address of each person listed below is c/o 7380 Coca Cola Drive, Suite 106, Hanover, Maryland 21076.

Name of Beneficial Owner	Shares of Common Stock Beneficially Owned	% of Shares of Common Stock Beneficially Owned
Officers and Directors		
David Young[1], [2], [9]	7,961,262	20.59%
Sian Bigora[3]	3,409,316	8.82%
Patrick Lin[7]	2,402,657	6.21%
Wendy Guy[3]	2,097,952	5.42%
Virgil Thompson[8]	606,992	1.57%
Justin Yorke[4]	2,584,739	6.68%
James Stanker	0	0
Total for all Officers and Directors	19,062,191	49.29%
5% Stockholders		
Promet Therapeutics, LLC[5]	13,842,032	35.79%
Young-Plaisance Revoc. Trust[2]	3,097,462	8.01%
CorLyst, LLC[6]	2,490,924	6.44%
CoNCERT Pharmaceuticals, Inc.	2,090,301	5.40%

(1) David Young is the beneficial owner of these shares. 2,460,982 of these shares are held through Mr. Young's equity interest in Promet and are excluded from the Promet shares reported in this table.

(2) The shares reported include 3,097,462 shares held by the Young-Plaisance Revoc. Trust and 2,358,765 shares held by CorLyst, LLC. Mr. Young is the Trustee of the Young-Plaisance Revoc. Trust and the Chief Executive Officer and Managing Member of CorLyst, LLC. Mr. Young disclaims beneficial ownership of a portion of CorLyst shares.

(3) Sian Bigora and Wendy Guy are the beneficial owners of these shares through their equity interest in Promet and in CorLyst, CorLyst being an equity holder of Promet. These shares are not included in the Promet or CorLyst number of shares listed in this table.

(4) 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 and each fund owns 892,564, 1,042,528 and 638,547 shares, respectively.

(5) The Processa shares listed on this table as owned by Promet are the Processa shares beneficially owned by Promet members other than CorLyst, LLC, David Young, Sian Bigora, Patrick Lin, Wendy Guy and Virgil Thompson.

(6) The Processa shares listed on this table as owned by CorLyst are the portion of Processa shares beneficially owned by CorLyst, LLC members other than the Young-Plaisance Revocable Trust, Sian Bigora and Wendy Guy.

(7) Patrick Lin is the beneficial owner of these shares, 2,340,099 shares are held by Promet and not included in the Promet number of shares reported in this table.

(8) Virgil Thompson is the beneficial owner of these shares through his equity interest in Promet. These shares are held by Promet and are not included in the Promet shares reported in this table.

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

TRANSACTIONS WITH RELATED PERSONS, PROMOTERS AND CERTAIN CONTROL PERSONS

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

CorLyst, LLC ("CorLyst") was a related party to Promet Therapeutics, LLC ("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, LLC. David Young spends less than 1 hour per week on CorLyst activity, while averaging more than 40 hours per week on Processa activities.

DESCRIPTION OF OUR SECURITIES

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

We have the authority to issue an aggregate of 350,000,000 shares of $0.0001 par value common stock and 10,000,000 shares of $0.0001 par value preferred stock. As of October 25, 2018, there are 38,674,265 shares of common stock outstanding and no shares of preferred stock outstanding.

Common Stock

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

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

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

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

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

Preferred Stock

Our Board is authorized, subject to certain limitations prescribed by law, without further stockholder approval, to issue from time to time up to an aggregate of 10,000,000 shares of preferred stock in one or more series and to fix or alter the designations, preferences, rights and any qualifications, limitations or restrictions of the shares of each such series thereof, including the dividend rights, dividend rates, conversion rights, voting rights and terms of redemption of shares constituting any series or designations of such series The rights of holders of our common stock may be subject to, and adversely affected by, the rights of the holders of any preferred stock that may be issued in the future. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change of control and may adversely affect the voting and other rights of holders of our common stock.

Warrants

As of the date of this prospectus we have issued warrants to purchase shares of our common stock to various persons and entities, under which we could be obligated to issue up to 3,605,738 shares of common stock, including:

(a) 2,327,118 shares of common stock issuable upon exercise of warrants allowing the holders to purchase shares of common stock at an exercise price of $2.724 per share through June 29, 2021; of which warrants for 924,676 shares of common stock contain cashless exercise provisions; and

(b) 1,278,620 shares of common stock issuable upon exercise of warrants allowing the holders to purchase shares of common stock at an exercise price of $2.452 per share through June 29, 2021; of which warrants for 72,375 shares of common stock contain cashless exercise provisions.

In addition, there are 124,507 shares of common stock issuable upon exercise of warrants at an exercise price of $2.452 per share through June 29, 2021 that will be issued upon conversion of our 8.0% Senior Convertible Notes.

None of the Warrants may be exercised prior to November 15, 2018.

Debt

The Company recognizes debt issuance costs incurred on the 8.0% Senior Convertible Notes as a reduction of the carrying amount of the Senior Convertible Notes on the face of the consolidated balance sheet. The debt issuance costs are amortized to interest expense using the interest method over the term of the Senior Convertible Notes.

Principal and interest under each Senior Note is due on the earlier of (i) the mandatory and automatic conversion of the Senior Note into the next PIPE financing we undertake, provided the PIPE financing yields gross proceeds of at least $4 million at a conversion price per share equal to the lower of (a) $72 million pre-money valuation or (b) a 10% discount to the pre-money valuation (Qualified Financing) or (ii) the one-year anniversary of that Senior Note (Maturity Date). The Senior Notes bear interest at 8.0% per year and are payable in kind (in common stock). At the Maturity Date, the outstanding principal and accrued interest on the Senior Note will be automatically converted into shares of common stock of the Company equal to the lesser of (i) $72 million pre-money valuation or (ii) any adjusted price resulting from the application of down round pricing during the anti-dilution period through December 31, 2018. In such event, the anti-dilution period, as defined, will be extended for a further 12 months. The Senior Notes are secured by a security interest in the assets of the Company and contain negative covenants as defined in the note agreement.

As of June 30, 2018, $230,000 of 8.0% Senior Convertible Notes are outstanding. Although the PIPE contingency has been satisfied for purposes of converting the Senior Notes, $230,000 of such Senior Notes remain outstanding until the Alberta Securities Commission permits the issuance to our Canadian holders.

Indemnification of Directors and Officers

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

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

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

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

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

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

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

Certain Anti-Takeover Effects

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

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

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

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

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

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

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

SHARES ELIGIBLE FOR RESALE

There is currently no liquid trading market for our common stock and one may not develop in the future. Future sales of substantial amounts of common stock, including shares of common stock issued upon exercise of outstanding options and exercise of the warrants offered in this prospectus in the public market, or the anticipation of those sales, could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through sales of our equity securities.

Rule 144

As of October 25, 2018, there were 38,674,265 shares of our common stock issued and outstanding, of which 37,501,407 shares are deemed "restricted securities," within the meaning of Rule 144. Absent registration under the Securities Act, the sale of such shares is subject to Rule 144, as promulgated under the Securities Act.

In general, under Rule 144, subject to the satisfaction of certain other conditions, a person deemed to be one of our affiliates, who has beneficially owned restricted shares of our common stock for at least one year is permitted to sell in a brokerage transaction, within any three-month period, a number of shares that does not exceed the greater of 1% of the total number of outstanding shares of the same class, or, if our common stock is quoted on a stock exchange, the average weekly trading volume during the four calendar weeks preceding the sale, if greater.

Rule 144 also permits a person who presently is not and who has not been an affiliate of ours for at least three months immediately preceding the sale and who has beneficially owned the shares of common stock for at least six months to sell such shares without restriction other than the requirement that there be current public information as set forth in Rule 144. If a non-affiliate has held the shares for more than one year, such person may make unlimited sales pursuant to Rule 144 without restriction.

As a former shell company, Rule 144 is not available to our stockholders until October 18, 2018.

The possibility that substantial amounts of our common stock may be sold As under Rule 144 into the public market 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. Please refer to "**Risk Factors**."

Registration Rights

As part of the PIPE Transaction, we agreed to register the common stock issued in such transaction plus the common stock to be issued upon the exercise of the warrants issued in the PIPE Transaction. We agreed that we would file a registration statement for such shares and will use commercially reasonable efforts to ensure that the registration statement becomes effective as soon as practical. We further agreed to keep the registration statement effective until the due date of our next annual report on Form 10-K for the fiscal year ending December 31, 2018, which is expected to be on or before April 1, 2019. Aside from the Selling Stockholders paying any and all costs, fees, discounts or commissions attributable to the sale of shares as well as fees and expenses of their counsel and other advisors, we are paying all fees and expenses related to the registration statement.

In connection with the issuance of our 8.0% Senior Convertible Notes, we agreed that holders of such notes would be included in any registration of equity securities by the Company for its own account or for the account of others.

As part of the private placement for our clinical trial funding, we agreed to register the common stock issued in such transaction plus the common stock to be issued upon the exercise of the warrants issued in the clinical trial funding placement. The terms of our commitment are generally the same as those we provided as part of the PIPE Transaction.

THE SELLING STOCKHOLDERS

The following table presents information regarding the Selling Stockholders. The Selling Stockholders may sell up to 6,385,437 shares of common stock (including shares issuable upon exercise of the Warrants). The percentage of outstanding shares beneficially owned is based on 38,674,265 shares of common stock issued and outstanding as of October 25, 2018. Information with respect to beneficial ownership is based upon information provided to us by the Selling Stockholders. Except as may be otherwise described below, to the best of our knowledge, the named Selling Stockholders beneficially own and have sole voting and investment authority as to all of the shares set forth opposite their names. The Selling Stockholders who are known to us to be a registered broker-dealer or an affiliate of a registered broker-dealer are identified in the notes to the table below. Each of the Selling Stockholders has acquired its shares solely for investment and not with a view to or for resale or distribution of such securities.

Selling Stockholders	# of Shares Beneficially Owned Prior to the Offering	% of Outstanding Shares Owned Prior to the Offering [1]	# of Shares Registered and to be Sold in the Offering [2] [3]	Estimated # of Shares Beneficially Owned After the Offering [2]	% of Outstanding Shares Owned After the Offering
PoC Capital, LLC[4]	1,606,332	4.15	1,606,332	0	*
Katz Family Trust	440,530	1.14	440,530	0	*
Young-Plaisance Revocable Trust[5]	3,097,462	8.01	426,500	2,670,962	6.91
JMW Fund, LLC[6]	1,042,528	2.70	360,908	681,621	1.76
San Gabriel Fund, LLC[6]	892,564	2.31	360,908	531,656	1.37
Richland Fund, LLC[6]	638,647	1.65	309,350	329,297	*
CorLyst, LLC[13]	2,623,082	6.78	264,318	2,358,764	6.10
Weintraub Capital Management	255,344	*	255,344	0	*
Thomas Hudson	220,266	*	220,266	0	*
Valley High Limited Partnership	220,266	*	220,266	0	*
The Farwell Family 1998 Trust dtd 12/2/1998	220,000	*	220,000	0	*
Prestwick Associates LLC[7]	151,312	*	151,312	0	*
The 2003 Bruce E. Whitten Trust[8]	132,160	*	132,160	0	*
Eric and Laura Lamison Family Trust	120,658	*	120,658	0	*
William F. Kruse	102,138	*	102,138	0	*
Boustead Securities, LLC[7]	52,787	*	52,787	0	*
Patrick Lin[9]	2,402,657	6.21	62,558	2,340,099	6.05
Herman Lam	321,075	*	61,284	259,791	*
Kong 1992 Family Trust	311,351	*	51,560	259,791	*
JPG Investments, LLC	54,285	*	51,070	3,215	*
Lee and Janet Keyte	58,070	*	51,070	7,000	*
Michael Gonzalez	51,070	*	51,070	0	*
Paul and Heidi Reed	51,070	*	51,070	0	*
Underwood Family Partners	51,070	*	51,070	0	*
David Young[10]	7,961,262	20.59	44,054	7,917,208	20.47
Intracoastal Capital, LLC	44,054	*	44,054	0	*
Les Walter	44,054	*	44,054	0	*
Vijay K. and Reena E. Panikar	44,054	*	44,054	0	*
Eric Cheng[11]	44,052	*	44,052	0	*
Yan Chin[12]	165,140	*	35,244	129,896	0.95
William Barham	31,000	*	31,000	0	*
Chris Lahiji	29,076	*	29,076	0	*
Jerry Yang	26,432	*	26,432	0	*
Beverly Munselle Exemption Trust	25,536	*	25,536	0	*
Phil Yu	90,484	*	25,536	64,948	*
Weston Munselle	25,536	*	25,536	0	*
Robert Lamoreaux	24,000	*	24,000	0	*
Charles A. & Diane C. Peterson	22,028	*	22,028	0	*
Conrad and Selenda Lai Family Trust	22,028	*	22,028	0	*
Gordon Wang	22,028	*	22,028	0	*
Raymond Kuo	22,028	*	22,028	0	*
Richard Yarborough	22,028	*	22,028	0	*
Robert Chen	22,028	*	22,028	0	*
Sean McNeil	22,028	*	22,028	0	*
Sharon Popp	22,028	*	22,028	0	*
Tom Yu	22,000	*	22,000	0	*
Carlo Casulo	20,000	*	20,000	0	*
King Yung Hor	9,000	*	9,000	0	*
James A. Ntambi	8,812	*	8,812	0	*
Ritu Lal and Soujanya Bhumkar	8,812	*	8,812	0	*
Kyle Miller	5,108	*	5,108	0	*
Michael and Judith Welch	5,108	*	5,108	0	*
William R Hazen	13,216		13,216	0	*
	23,939,684	53.54	6,385,437	17,554,247	45.39

* Represents beneficial ownership of less than one percent of the issued and outstanding shares of our common stock.

(1) Calculated pursuant to Rule 13d-3(d) of the Exchange Act. Beneficial ownership is calculated based on 38,674,265 shares of common stock issued and outstanding as of October 25, 2018. Under Rule 13d-3(d) of the Exchange Act, shares not outstanding which are subject to options, warrants, rights or conversion privileges exercisable within 60 days are deemed outstanding for the purpose of calculating the number and percentage owned by such person, but are not deemed outstanding for the purpose of calculating the percentage owned by each other person listed. The Warrants are not exercisable until November 15, 2018 and are not included in the beneficial ownership calculation.

(2) The Selling Stockholders may offer and sell, from time to time, any or all of our common stock issued to them and registered for resale. Because the Selling Stockholders may offer all or only some portion of the 6,385,437 shares of common stock registered, no exact number can be given as to the amount or percentage of these shares of common stock that will be held by the Selling Stockholders upon termination of the offering. The number of shares listed in the category titled "Estimated Number of Shares Beneficially Owned After This Offering," in the table above represents an estimate of the number of shares of common stock that will be held by the Selling Stockholders after the offering. To arrive at this estimate, we have assumed that the Selling Stockholders will sell all of the shares to be registered pursuant to this offering and will not be acquiring any additional shares. Please refer to "Plan of Distribution."

(3) Shares to be issued upon exercise of Warrants are included in the number of shares registered and to be sold in this offering.

(4) PoC Capital, Inc. has pledged 396,476 shares and warrants to purchase 396,476 shares to us to secure PoC Capital's funding obligations to us.

(5) David Young, the Chairman of our Board of Directors and Chief Executive Officer, is the trustee of this trust.

(6) Justin Yorke, manager of JMW Fund, LLC, San Gabriel Fund, LLC and Richland Fund, LLC, is a member of our Board of Directors.

(7) Boustead Securities, LLC and Prestwick Associates LLC are affiliates and are registered broker-dealers.

(8) Bruce Whitten, the Trustee of the 2003 Bruce E. Whitten Trust, is employed as a retail broker with Morgan Stanley.

(9) Patrick Lin is a member of our Board of Directors and our Chief Business & Strategy Officer.

(10) David Young is the Chairman of our Board of Directors and our Chief Executive Officer. The shares reported include 3,097,462 shares held by the Young-Plaisance Revoc. Trust and 2,358,765 shares held by CorLyst, LLC. Mr. Young is the Trustee of the Young-Plaisance Revoc. Trust and the Chief Executive Officer and Managing Member of CorLyst, LLC. Mr. Young disclaims beneficial ownership of a portion of CorLyst shares.

(11) Eric Cheng is employed by Roth Capital Partners, LLC.

(12) Sylvia Chin, the spouse of Yan Chin, is employed by Morling Financial Advisors, LLC, a Registered Investment Advisory firm.

(13) David Young, the Chairman of our Board of Directors and our Chief Executive Officer, is the Chief Executive Officer and Managing Member of CorLyst, LLC.

Other than the relationships described in the table and footnotes, none of the Selling Stockholders had or have any material relationship with us or any of our affiliates within the past three years.

We may require the Selling Stockholders to suspend the sales of the securities offered by this prospectus upon the occurrence of any event that makes any statement in this prospectus or the related registration statement untrue in any material respect or that requires the changing of statements in these documents in order to make statements in those documents not misleading.

PLAN OF DISTRIBUTION

Each Selling Stockholder of the common stock and any of their pledgees, assignees and successors-in-interest (other than the Company acting as a pledgee, assignee or successor-in-interest) may, from time to time, sell any or all of their shares of common stock on the OTCPink or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. The Selling Stockholders will initially offer shares at $3.65 per share until such time as the shares are approved for and quoted on the OTCQB. Thereafter, the Selling Stockholders may sell shares at prevailing market prices or at negotiated prices. A Selling Stockholder may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- a broker-dealer agreement with the Selling Stockholders to sell a specified number of such shares at a stipulated price per share;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The Selling Stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by any of the Selling Stockholders may arrange for other broker-dealers to participate in sales. Broker-dealers may receive commissions or discounts from Selling Stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA NASD Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with NASD IM-2440.

In connection with the sale of the common stock or interests therein, Selling Stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. Selling Stockholders may also sell shares of the common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. Selling Stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

Selling Stockholders and any broker-dealers or agents that are involved in selling the Shares may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Stockholder has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the common stock. Boustead is a registered broker-dealer and may be deemed to be an “underwriter” in connection with the sales of Shares.

We are required to pay certain fees and expenses incurred by Selling Stockholders incident to the registration of the shares. We have agreed to indemnify the Selling Stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

Because Selling Stockholders may be deemed to be "underwriters" within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act including Rule 172 thereunder. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. There is no underwriter or coordinating broker-dealer acting in connection with the proposed sale of the shares by the Selling Stockholders.

The Shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the Shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the Shares may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the Shares by the Selling Stockholders or any other person. We will make copies of this prospectus available to the Selling Stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

LEGAL MATTERS

The validity of the shares of common stock offered hereby has been passed upon for us by Foley & Lardner LLP in Jacksonville, Florida.

EXPERTS

Our consolidated financial statements for the fiscal years ended December 31, 2017 and 2016, appearing herein, have been audited by BD & Company, Inc., an independent registered public accounting firm, as set forth in its report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We file periodic reports with the SEC, including quarterly reports and annual reports which include our audited financial statements. This registration statement, including exhibits hereto, and all of our periodic reports may be inspected without charge at the Public Reference Room maintained by the SEC at 100 F Street, NE, Washington, D.C. 20549. You may obtain copies of this registration statement, including the exhibits hereto, and all of our periodic reports after payment of the fees prescribed by the SEC. For additional information regarding the operation of the Public Reference Room, you may call the SEC at 1-800-SEC-0330. 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. In addition, you may request a copy of any of our periodic reports filed with the SEC at no cost, by writing us at Processa Pharmaceuticals, Inc., 7380 Coca Cola Drive, Suite 106, Hanover, Maryland 21076.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Processa Pharmaceuticals, Inc. (formerly Heatwurx, Inc.) (the "Company") as of December 31, 2017 and 2016, the related consolidated statements of operations, stockholders' equity, and cash flows, for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2017 and 2016, and the consolidated results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Notes 1 and 2 to the financial statements, the Company has suffered recurring losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Change in Reporting Entity

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

Basis for Opinion

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

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

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

/s/ BD & Company, Inc.

Owings Mills, MD
April 16, 2018

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

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

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

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

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

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

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

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

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

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

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

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

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

NOTE 1 – NATURE OF BUSINESS

Company Overview

Promet Therapeutics, LLC ("Promet"), a Delaware limited liability company, was a private company founded on August 31, 2015 (inception). On October 2, 2017, Heatwurx, Inc. ("Heatwurx"), a nonoperating public shell corporation, entered into an Asset Purchase Agreement with Promet and Heatwurx's wholly-owned subsidiary, Processa Therapeutics LLC ("Processa"), a Delaware limited liability company, and closed on this agreement effective October 4, 2017. Under this agreement, Heatwurx acquired the assets and assumed all the liabilities of Promet, in exchange for 222,217,112 shares of the common stock of Heatwurx, which, at the closing, constituted 90% of the Company's issued and outstanding common stock on a fully diluted basis accounted for as a tax-free contribution under Internal Revenue Code Section 351. Immediately following the closing, there were 246,907,902 shares of common stock issued and outstanding, of which the prior Heatwurx shareholders own 24,690,790 shares after giving effect to 13,673,402 shares issued for Heatwurx's Series D Preferred stock and existing debt that converted into common stock prior to closing of the asset purchase transaction. At the closing, Heatwurx assigned to Processa the assets and operations of Promet that constitutes the operating business of Promet. Authorized capital stock consists of 350,000,000 shares of $0.0001 par value common stock and 10,000,000 shares of $0.0001 par value preferred stock.

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

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

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

Description of Business

We are an emerging clinical stage biopharmaceutical company focused on the development of drug products that are intended to provide treatment for and improve the survival and/or quality of life of patients who have a high unmet medical need condition or who have no alternative treatment. Within this group of pharmaceutical products, we currently are developing one product for two indications (i.e., the use of a drug to treat a particular disease) and searching for additional products for our portfolio. Our operations are performed in the state of Maryland and are still in the organizational and research and development phase of operations. As a result, we have a limited operating history and only a preliminary business plan from which investors may evaluate our future prospects. We have not had any sources of revenue from inception through December 31, 2017 and have a history of operating losses from operations.

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

Recent Developments

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

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

Status as an Emerging Growth Company

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

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

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Earnings per Share

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

The acquisition of Promet by Heatwurx has been accounted for as a reverse acquisition in accordance with U.S. GAAP, Financial Accounting Standards Board ("FASB"), Accounting Standards Codification ("ASC") 805-40-45, *Business Combinations - Reverse Acquisitions*. Under this method of accounting, Heatwurx, a nonoperating public shell corporation with nominal net liabilities, acquired all the assets of Promet, a private operating entity, through issuance of 90 percent of the issued and outstanding common stock of Heatwurx immediately after the asset acquisition. As a result of the change in control, Promet comprises the ongoing operations and assets of the combined entity and Promet senior management comprises the senior management of the Company and Promet is considered the accounting acquirer. Heatwurx has been treated as the "acquired" company for financial reporting purposes. The transaction is considered to be a capital transaction in substance. Accordingly, for accounting purposes, it is assumed that Promet issued shares to Heatwurx at fair value for Heatwurx's net liabilities to be assumed by Promet at closing of the reverse acquisition. The fair value of the net liabilities assumed from Heatwurx, net of the par value of the assumed shares issued to Heatwurx is recognized as a reduction of additional paid-in capital.

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

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

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

Segments

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

Going Concern and Management's Plan

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

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

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

We are in the process of raising additional funds by potentially selling additional Senior Convertible Notes, convertible loans or other securities. However, no assurance can be given that we will be successful in raising adequate funds needed. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates, restrict our operations or obtain funds by entering into agreements on unattractive terms, which would likely have a material adverse effect on our business, stock price and our relationships with third parties with whom we have business relationships, at least until additional funding is obtained.

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

As a result, substantial doubt exists about the Company's ability to continue as a going concern within one year after the date that these consolidated financial statements are available to be issued. The accompanying consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of recorded assets, or the amounts and classification of liabilities that might be different should the Company be unable to continue as a going concern based on the outcome of these uncertainties described above.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the use of estimates and assumptions by management that affect reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. These estimates and assumptions are continuously evaluated and are based on management's experience and knowledge of the relevant facts and circumstances. While management believes the estimates to be reasonable, actual results could differ materially from those estimates and could impact future results of operations and cash flows.

Cash and Cash Equivalents

Cash and cash equivalents includes cash on hand and money market funds. The Company considers all highly liquid investments with a maturity at the date of purchase of three months or less to be cash equivalents. Money market funds were $1,300,815 and $0 at December 31, 2017 and 2016, respectively.

Certificates of Deposit

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

Fair Value Measurements and Disclosure

The Company applies ASC 820, "Fair Value Measurements and Disclosures," which expands disclosures for assets and liabilities that are measured and reported at fair value on a recurring basis. Fair value is defined as an exit price, representing the amount that would be received upon the sale of an asset or payment to transfer a liability in an orderly transaction between market participants. Fair value is a market-based measurement that is determined based on assumptions that market participants would use in pricing an asset or liability. A three-tier fair value hierarchy is used to prioritize the inputs in measuring fair value as follows:

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

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

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

The asset's or liability's fair value measurement within the fair value hierarchy is based upon the lowest level of any input that is significant to the fair value measurement.

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable and the senior convertible notes approximate fair value because of the short-term maturity of these instruments, including the mandatory conversion of the senior convertible notes into the common stock of the Company upon the earlier of (i) meeting certain funding levels on the next Private Investment in Public Equity ("PIPE") financing we undertake or (ii) the one-year anniversary of the issuance of the senior convertible note.

Due From/To Related Parties and Administrative Fees

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

Property and Depreciation

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

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

Software	3 years
Equipment	5 years

Impairment of Long-lived Assets

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

Debt Issuance Costs

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

Compensated Absences

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

Advertising Costs

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

Research and development

Research and development costs are expensed as incurred and consist of direct and overhead-related expenses. Research and development costs totaled $926,117 and $1,536,996 for the years ended December 31, 2017 and 2016, respectively. Expenditures to acquire technologies, including licenses, which are utilized in research and development and that have no alternative future use are expensed when incurred. Technology the Company develops for use in its products is expensed as incurred until technological feasibility has been established after which it is capitalized and depreciated. No costs have been capitalized during the years ended December 31, 2017 and 2016.

Stock-Based Compensation

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

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

Income Taxes

As a result of the asset purchase transaction (see Note 1 Company Overview above and Note 3), there was a change in control of the Company. Prior to the closing of the asset purchase transaction, Promet was treated as a partnership for federal income tax purposes and thus was not subject to income tax at the entity level. Therefore, no provision or liability for income taxes has been included in these financial statements through the date of the asset purchase on October, 4, 2017. In addition, Promet determined that it was not required to record a liability related to uncertain tax positions as a result of the requirements of ASC 740-10-25 Income Taxes.

The net deferred tax assets of Heatwurx were principally federal and state net operating loss carry forwards. The Heatwurx net deferred tax assets were fully reserved with a valuation allowance.

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

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

With respect to uncertain tax positions, the Company would recognize the tax benefit from an uncertain tax position only if it is more-likely-than-not that the tax position will be sustained upon examination by the taxing authorities, based on the technical merits of the position. Estimated interest and penalties related to uncertain tax positions are included as a component of interest expense and general and administrative expense, respectively. The Company had no unrecognized tax benefits or uncertain tax positions at December 31, 2017 or 2016.

Net Income (Loss) per Share

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

Equity

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

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

Subsequent events

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

Recent Accounting Pronouncements

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

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

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

NOTE 3 – REVERSE ACQUISITION

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

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

Promet incurred acquisition-related transaction costs of $58,763, which are included in general and administrative expense, a component of operating expenses in the consolidated statements of operations. The operating results for Heatwurx are included in the accompanying consolidated financial statements from October 4, 2017 forward.

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

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

NOTE 4 – RELATED PARTY TRANSACTIONS

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

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

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

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

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

NOTE 5– NOTES PAYABLE

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

NOTE 6 – SENIOR CONVERTIBLE NOTES

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

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

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

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

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

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

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

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

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

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

NOTE 7 – INCOME TAXES

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

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

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

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

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

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

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

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

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

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

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

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

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

The net operating losses are available for application against future taxable income for 20 years, expiring in 2037. The benefit associated with the amortization of the deferred start-up expenditures and the net operating loss carry forward will more-likely-than-not go unrealized unless future operations are successful. Since the success of future operations is indeterminable, the potential benefits resulting from these deferred tax assets have not been recorded in the financial statements.

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

The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, the projected future taxable income and tax planning strategies in making this assessment. Based on management's analysis, a full reserve has been established against this asset. The change in the valuation allowance in 2017 and 2016 was $166,787 and $0, respectively.

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

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

NOTE 8 –STOCKHOLDERS' EQUITY

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

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

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

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

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

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

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

NOTE 9 – NET LOSS PER COMMON SHARE

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

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

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

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

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

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

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

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

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

NOTE 10 – COMMITMENTS AND CONTINGENCIES

Operating Lease Obligations

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

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

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

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

Option and License Agreement with CoNCERT Pharmaceuticals

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

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

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

Promet shall use commercially reasonable efforts to develop and obtain regulatory approval for one product in the U.S. and at least one other major market and subject to obtaining regulatory approval in the applicable major market, commercialize one product in the U.S. and at least one other major market. Failure to comply with the diligence obligation under the license agreement may result in the termination of the license agreement by CoNCERT in accordance with the relevant terms of the agreement.

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

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

CoNCERT’s Board Observer right will expire when CoNCERT’s ownership interest in Promet decreases below ten percent of the outstanding voting stock of Promet.

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

Purchase Obligations

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

NOTE 11 – CONCENTRATION OF CREDIT RISK

The Company maintains its operating cash in two commercial banks. Balances on deposit are insured by the Federal Deposit Insurance Corporation (FDIC) up to specified limits. Total cash held by one bank was $2,900,393 and the second bank held a cash balance of $2,184 at December 31, 2017.

NOTE 12 – SUPPLEMENTAL CASH FLOW INFORMATION

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

NOTE 13 – QUARTERLY DATA

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

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

NOTE 14 – SUBSEQUENT EVENTS

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

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

Cybersecurity Fraud

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

The following are the consolidated financial statements of the Company as of June 30, 2018 (Unaudited) and December 31, 2017 (Audited) and for the three months and six months ended June 30, 2018 and 2017 (Unaudited).

Processa Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets

	June 30, 2018 (Unaudited)	December 31, 2017
ASSETS		
Current Assets		
Cash and cash equivalents	$ 2,850,453	$ 2,847,429
Certificates of deposit	496,201	-
Due from related party	56,512	62,709
Prepaid expenses and other	83,513	41,446
Notes receivable	107,490	-
Total Current Assets	3,594,169	2,951,584
Property And Equipment		
Software	19,740	19,740
Equipment	9,327	9,327
Total Cost	29,067	29,067
Less: accumulated depreciation	7,469	3,246
Property and equipment, net	21,598	25,821
Other Assets		
Security deposit	5,535	5,535
Intangible asset, net of accumulated amortization	10,816,370	-
Total Other Assets	10,821,905	5,535
Total Assets	$ 14,437,672	$ 2,982,940
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Senior convertible notes, net of debt issuance costs	$ 224,063	$ 2,448,570
Accrued interest	11,143	35,693
Accounts payable	251,399	50,686
Due to related parties	1,116	436
Accrued expenses	161,913	64,428
Total Current Liabilities	649,634	2,599,813
Non-current Liabilities		
Accrued rent liability	3,321	9,963
Deferred tax liability	2,477,830	-
Total Liabilities	3,130,785	2,609,776
COMMITMENTS AND CONTINGENCIES - SEE NOTE		
Stockholders' Equity		
Preferred stock, par value $0.0001, 10,000,000 shares authorized; zero shares issued and outstanding	-	-
Common stock, par value $0.0001, 350,000,000 shares authorized; 38,674,265 issued and outstanding at June 30, 2018 and 35,272,626 issued and outstanding at December 31, 2017	3,867	3,527
Additional paid-in capital	19,264,976	4,228,723
Subscription receivable	(1,800,000)	-
Accumulated deficit	(6,161,956)	(3,859,086)
Total Stockholders' Equity	11,306,887	373,164
Total Liabilities and Stockholders' Equity	$ 14,437,672	$ 2,982,940

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

Processa Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Operating Expenses:				
Research and development costs	$ 1,077,643	$ 160,867	$ 1,865,921	$ 311,164
General and administrative expenses	350,581	119,467	853,918	$ 192,759
Total operating expenses	1,428,224	280,334	2,719,839	503,923
Operating Loss	(1,428,224)	(280,334)	(2,719,839)	(503,923)
Other Income (Expense):				
Interest expense	(58,314)	-	(146,054)	-
Interest income	2,681	1,889	3,706	3,387
Total other income (expense)	(55,633)	1,889	(142,348)	3,387
Net Loss Before Income Tax Benefit	(1,483,857)	(278,445)	(2,862,187)	(500,536)
Income tax benefit	277,783	-	559,317	-
Net Loss	$ (1,206,074)	$ (278,445)	$ (2,302,870)	$ (500,536)
Net Loss per Common Share - Basic and Diluted	$ (0.03)	$ (0.01)	$ (0.06)	$ (0.02)
Weighted Average Common Shares Used to Compute Net Loss Applicable to Common Shares - Basic and Diluted	36,623,697	31,745,242	35,951,894	31,745,242

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

Processa Pharmaceuticals, Inc.
Consolidated Statement of Changes in Stockholders' Equity
For the Six Months Ended June 30, 2018
(Unaudited)

	Common Stock		Preferred Stock		Additional Paid-In	Subscription	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Receivable	Deficit	Total
Balance, December 31, 2017	35,272,626	$ 3,527	-	$ -	$ 4,228,723	$ -	$ (3,859,086)	$ 373,164
Recognize the fair value of exclusive license intangible asset acquired from CoNCERT in exchange for 2,090,301 common shares of Processa owned by Promet	-	-	-	-	8,000,000	-	-	8,000,000
Conversion of Senior convertible notes for common stock and stock purchase warrants, net of costs of $4,742	1,206,245	121	-	-	2,390,248	-	-	2,390,369
Issuance of common stock units for cash, net of costs of $219,954	1,402,442	140	-		2,963,423	-	-	2,963,563
Issuance of common stock units for a future research funding commitment, net of costs of $117,339	792,952	79	-	-	1,682,582	(1,800,000)	-	(117,339)
Net Loss for the Six Months Ended June 30, 2018	-	-	-	-	-	-	(2,302,870)	(2,302,870)
Balance, June 30, 2018	38,674,265	$ 3,867	-	$ -	$ 19,264,976	$ (1,800,000)	$ (6,161,956)	$ 11,306,887

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

Processa Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows
(Unaudited)

	Six Months Ended June 30,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (2,302,870)	$ (510,888)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	4,223	933
Amortization of intangible asset	222,559	-
Deferred income tax (benefit) expense	(559,317)	-
Amortization of debt issuance costs	61,132	-
Accrued interest on investments	(201)	(471)
Net changes in operating assets and liabilities:		
Prepaid expenses and other	(42,067)	(511)
Vendor deposit	-	227,657
Accrued interest	84,922	-
Accounts payable	200,713	1,225
Due from related parties	6,877	(7,817)
Accrued rent liability	-	9,963
Accrued liabilities	90,843	(76,019)
Net cash used in operating activities	(2,233,186)	(355,928)
CASH FLOWS FROM INVESTING ACTIVITIES		
Proceeds from (purchase of) certificates of deposit	(496,000)	-
Purchase of property and equipment	-	(882)
Acquisition of intangible asset	(1,782)	-
Net cash used in investing activities	(497,782)	(882)
CASH FLOWS FROM FINANCING ACTIVITIES		
Net Proceeds from issuance of common stock	2,856,073	-
Transaction costs incurred on Senior Convertible Notes	(4,742)	
Payment of placement agent and legal fees associated with clinical funding commitment	(117,339)	
Net cash provided by financing activities	2,733,992	-
NET DECREASE IN CASH AND CASH EQUIVALENTS	3,024	(356,810)
CASH AND CASH EQUIVALENTS		
BEGINNING OF PERIOD	2,847,429	1,071,894
END OF PERIOD	$ 2,850,453	$ 715,084
NON-CASH FINANCING AND INVESTING ACTIVITIES		
Recognize exclusive license intangible asset acquired from CoNCERT	$ (11,037,147)	$ -
Recognize deferred tax liability for basis difference for intangible asset	3,037,147	
Recognize additional paid-in capital for consideration paid from the transfer of 2,090,301 common shares of Processa owned by Promet to CoNCERT	8,000,000	-
Cash paid for intangible asset acquired from CoNCERT	$ -	$ -
Conversion of $2,350,000 of Senior Convertible Debt and related accrued interest into 1,206,245 shares of common stock and warrants	$ 2,395,111	$ -
Common stock and stock purchase warrants issued in connection with a clinical trial funding commitment	$ 1,800,000	$ -
Note receivable related to the sale of common stock and stock purchase warrants	$ 107,490	$ -

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

Note 1 - Organization and Summary of Significant Accounting Policies

Business Activities and Organization

Company Overview

Processa Pharmaceuticals, Inc. (the "Company" and formerly known as "Heatwurx") and its wholly-owned subsidiary, Processa Therapeutics LLC ("Processa"), a Delaware limited liability company, acquired the assets of a private company, including the rights to the CoNCERT Agreement mentioned below, Promet Therapeutics, LLC ("Promet"), a Delaware limited liability company on October 4, 2017 in exchange for 31,745,242 shares of the common stock of the Company which, at the closing, constituted approximately 90% of the Company's issued and outstanding common stock on a fully diluted basis accounted for as a tax-free contribution under Internal Revenue Code Section 351. Immediately following the closing, there were 35,272,626 shares of common stock issued and outstanding. At the closing, Processa was assigned the assets and operations of Promet that constituted the operating business of Promet, while Promet, which continues as an active company, received the Processa shares mentioned above and agreed to provide the Processa shares needed if the option in the CoNCERT Agreement (see below) was exercised. Upon closing on October 4, 2017, there was a change in control of the Company to Promet. The Company abandoned its prior business plan and adopted Promet's business plan focused on developing drugs to treat patients that have a high unmet medical need. Subsequent to closing and effective October 10, 2017, the Company changed its trading symbol to "PCSA" on the OTC Pink Marketplace. The Company effected a one-for-seven reverse split of its shares in December 2017. As a result, the 2017 condensed consolidated financial statements have been retrospectively adjusted to reflect shares outstanding after the one-for-seven reverse split.

The net asset acquisition transaction was accounted for as a reverse acquisition. Prior to the acquisition, Heatwurx (subsequently renamed Processa Pharmaceuticals, Inc.) had nominal net liabilities and operations. It was considered a non-operating public shell corporation. Therefore, Promet was considered the accounting acquirer (and legal wholly-owned subsidiary of Heatwurx, now called Processa Pharmaceuticals, Inc.) and Heatwurx was considered the accounting acquiree (and legal acquirer). As a result, the consolidated financial statements of the Company reflect the financial condition, results of operations and cash flows of Promet for all periods presented prior to October 4, 2017 and Processa for the periods subsequent to October 4, 2017. The legal capital stock (number and type of equity interests issued) is that of Processa Pharmaceuticals, Inc., the legal parent, in accordance with guidance on reverse acquisitions accounted for as a capital transaction instead of a business combination (See Note 2 – Basis of Presentation and Earnings Per Share and Note 3 – Reverse Acquisition in Item 8 of the Company's Annual Report on Form 10-K filed with the SEC on April 17, 2018).

All references to the "Company" and Processa Pharmaceuticals, Inc. refer to Heatwurx, Inc., Processa Therapeutics, LLC, and the net assets acquired from Promet Therapeutics, LLC, which were assigned at acquisition to Processa Therapeutics, LLC and Promet's operations prior to October 4, 2017.

On March 19, 2018, Promet, Processa and CoNCERT Pharmaceuticals Inc. ("CoNCERT") amended the Option and License Agreement (the "Agreement") executed in October 2017. The Amendment allowed for the Option and License Agreement to be formally assigned to Processa, and Processa exercised the exclusive option for the PCS-499 compound. The option was exercised in exchange for CoNCERT receiving (i) $8 million of common stock of Company that was owned by Promet (or 2,090,301 shares representing 6.58% of Promet's common stock holding or 5.93% of total the Company's common stock issued and outstanding), and (ii) 15% of any sublicense revenue earned by the Company for a period equivalent to the royalty term (as defined in the Agreement) until the earliest of (a) Processa raising $8 million of gross proceeds; and (b) CoNCERT can sell its shares of Processa common stock without restrictions pursuant to the terms of the amended Agreement. All other terms of the Agreement remain unchanged. As a result, the Company recognized an intangible asset and additional paid-in capital in the amount of $8 million resulting from Promet satisfying Processa's liability to CoNCERT (see Note 2 Intangible Asset for the income tax effect of this transaction). There was no change in the total shares issued and outstanding, however, Promet's controlling interest in Processa was reduced from 90% to 84%.

Description of Business

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

Processa's lead product, PCS-499 is an oral tablet that is an analog of an active metabolite of an already approved FDA drug. The advantage of PCS-499 is that it potentially may work in many conditions because it has multiple pharmacological targets it affects that are important in the treatment of these conditions. Based on its pharmacological activity, Processa has identified multiple unmet medical need conditions where the use of PCS-499 may result in clinical efficacy. The lead indication currently under development for PCS-499 is Necrobiosis Lipoidica (NL). Processa has met with the FDA on the NL condition and has developed a strategy for moving the program for NL forward starting with a Phase 2 clinical trial in NL patients in late 2018 (see Note 4 for clinical trial funding). Processa will continue to evaluate other unmet need conditions for PCS-499 as well as other potential assets and develop strategies including the regulatory pathway and commercialization plans for the product(s) for these unmet need conditions over the next year.

Processa is looking to acquire additional drug candidates to help patients who have an unmet medical need.

Our operations are performed in the state of Maryland and are still in the organizational and research and development phase of operations. As a result, we have a limited operating history and only a preliminary business plan from which investors may evaluate our future prospects. We have not had any sources of revenue from inception (August 31, 2015) through June 30, 2018 and have a history of operating losses from operations. Our ability to generate meaningful revenue from any products in the United States depends on obtaining FDA authorization. Even if our products are authorized and approved by the FDA, we must still meet the challenges of successful marketing, distribution and consumer acceptance.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") for interim financial information and with the instruction of the Securities and Exchange Commission ("SEC") on Form 10-Q and Rule 10-01 of Regulation S-X.

Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. All material intercompany accounts and transactions have been eliminated in consolidation. In the opinion of management, the accompanying unaudited consolidated financial statements include all adjustments necessary, which are of a normal and recurring nature, for the fair presentation of the Company's financial position and of the results of operations and cash flows for the periods presented. These consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the SEC on April 17, 2018. The results of operations for the interim period shown in this report are not necessarily indicative of the results that may be expected for any other interim period or for the full year.

As a result of the modification of the Agreement with CoNCERT and the acquisition of an exclusive license intangible asset used in research and development activities described above, the Company adopted a new intangible asset policy and disclosure (see Intangible Assets below and Note 2 – Intangible Asset) and recognized a deferred tax liability for the acquired temporary difference between the financial reporting basis and the tax basis of the intangible asset (see Note 5 – Income Taxes).

Going Concern and Management's Plan

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

The Company has relied exclusively on private placements with a small group of accredited investors to finance its business and operations. We do not have any prospective arrangements or credit facilities as a source of future funds. The Company has had no revenue since inception on August 31, 2015. The Company does not currently have any revenue under contract nor does it have any immediate sales prospects. As of June 30, 2018, the Company had an accumulated deficit of approximately $6.2 million incurred since inception. For the six months ended June 30, 2018, the Company incurred a net loss from continuing operations of approximately $2.3 million and used approximately $2.2 million in net cash from operating activities from continuing operations. The Company had total cash and cash equivalents and certificates of deposit of approximately $3.3 million as of June 30, 2018.

We are looking at ways to add a revenue stream to offset some of our expenses. We will begin fundraising efforts in the first half of 2019. In addition, we are seeking alternative options to add additional cash. However, no assurance can be given that we will be successful in securing adequate funds that may be required. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates, restrict our operations or obtain funds by entering into agreements on unattractive terms, which would likely have a material adverse effect on our business, stock price, and our relationships with third parties with whom we have business relationships, at least until additional funding is obtained.

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

As a result, substantial doubt exists about the Company's ability to continue as a going concern within one year after the date that these consolidated financial statements are available to be issued. The accompanying consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of recorded assets, or the amounts and classification of liabilities that might be different should the Company be unable to continue as a going concern based on the outcome of these uncertainties described above.

Use of Estimates

The preparation of the accompanying unaudited consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts (including assets, liabilities, revenues and expenses) and related disclosures, including contingent assets and liabilities. Estimates have been prepared on the basis of the most current and best available information. However, actual results could differ materially from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents include cash on hand and money market funds. The Company considers all highly liquid investments with a maturity at the date of purchase of three months or less to be cash equivalents. Included in cash and cash equivalents were certificates of deposit totaling $496,201 at June 30, 2018. The certificates of deposit will mature in late September 2018.

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 and those that have no alternative future uses (in research and development projects or otherwise) and therefore no separate economic value are research and development costs 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 and those with an indefinite useful life are not amortized. The useful life is the best estimate of the period over which the asset is expected to contribute directly or indirectly to the future cash flows of the Company. The useful life is based on the duration of the expected use of the asset by the Company 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. If an income approach is used to measure the fair value of an intangible asset, the Company considers 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 the Company, the useful life is considered indefinite.

Intangibles with a finite useful life are amortized on the straight-line method unless the pattern in which the economic benefits of the intangible asset are consumed or used up are reliably determinable. The Company evaluates 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.

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

The Company accounts for the impairment of long-lived assets in accordance with ASC 360, Property, Plant and Equipment and ASC 350, Intangibles – Goodwill and Other which requires that long-lived assets and certain identifiable intangibles be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to expected future undiscounted net cash flows expected to be 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 for the three or six-month periods ended June 30, 2018 and 2017, respectively.

Fair Value Measurements and Disclosure

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

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

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

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

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

The asset's or liability's fair value measurement within the fair value hierarchy is based upon the lowest level of any input that is significant to the fair value measurement. The Company's 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.

Net Income (Loss) per Share

The Company computes basic and diluted earnings per share amounts pursuant to ASC 260-10-45. Basic earnings per share is computed by dividing net income (loss) available to common shareholders, by the weighted average number of shares of common stock outstanding during the period, excluding the effects of any potentially dilutive securities. Diluted earnings per share is computed by dividing net income (loss) available to common shareholders by the diluted weighted average number of shares of common stock during the period. Since the Company had a net loss for each of the periods presented, basic and diluted net loss per share are the same. The computation of diluted net loss per share for the periods presented does not assume the impact of the conversion of the Senior Convertible Notes or the exercise or contingent exercise of securities since that would have an anti-dilutive effect on loss per share during the three and six months ended June 30, 2018 and 2017.

Recent Accounting Pronouncements

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

From May 2014 through June 30, 2018, the FASB issued several ASUs related to ASU 2014-09, "Revenue from Contracts with Customers (Topic 606). The new guidance is effective for interim and annual periods beginning after December 15, 2017, although entities may adopt one year earlier if they choose. The two permitted transition methods under the new standard are the full retrospective method, in which case the standard would be applied to each prior reporting period presented and the cumulative effect of applying the standard would be recognized at the earliest period shown, or the modified retrospective method, in which case the cumulative effect of applying the standard would be recognized at the date of initial application. The Company is currently in the pre-revenue stages of operations; therefore, we do not currently anticipate there would be any change to timing or method of recognizing revenue. As such, the adoption of this standard did not have a material impact on our results of operations, financial condition or cash flows.

In February 2016 through June 30, 2018, the FASB issued several ASUs related to ASU-2016-02, "Leases (Topic 842)." The guidance requires that a lessee recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right of use asset representing its right to use the underlying asset for the lease term. For operating leases: the right-of-use asset and a lease liability will be initially measured at the present value of the lease payments, in the statement of financial position; a single lease cost will be recognized, calculated so that the cost of the lease is allocated over the lease term on a generally straight-line basis; and all cash payments will be classified within operating activities in the statement of cash flows. The amendments in Topic 842 are effective for the Company beginning January 1, 2019. The Company's office lease expires September 30, 2019. Management is currently evaluating the impact of adopting the new guidance on the Company's consolidated financial statements.

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

Note 2 – Intangible Asset

Intangible assets consist of the capitalized costs of $11,038,929, including transaction costs of $1,782, associated with the exercise of the option to acquire the exclusive license from CoNCERT related to patent rights and know-how to develop and commercialize compounds and products for PCS-499 and each metabolite thereof and the related income tax effects. The capitalized costs include $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*, the Company capitalized the costs of acquiring the exclusive license rights to CTP-499 as the exclusive license rights represent intangible assets to be used in research and development activities that have future alternative uses.

The negotiation of the modification to the Agreement was finalized in mid-February 2018 and the legal documents were executed and the option was exercised on March 19, 2018 in exchange for CoNCERT receiving (i) $8 million of common stock of Processa that was owned by Promet (or 2,090,301 shares representing 6.58% of Promet's common stock holding or 5.93% of total Processa common stock issued and outstanding), and (ii) 15% of any sublicense revenue earned by Processa for a period equivalent to the royalty term (as defined in the Agreement) until the earliest to occur of (a) Processa raising $8 million of gross proceeds; and (b) CoNCERT can sell its shares of Processa common stock without restrictions pursuant to the terms of the amended Agreement. All other terms of the Agreement remained unchanged. The license agreement was assigned to and deemed to have been exercised by the Company. As a result of the transaction, the Company recognized an intangible asset for the fair value of the common stock consideration paid of $8 million with an offsetting amount in additional paid-in capital resulting from Promet satisfying Processa's liability to CoNCERT.

The Company 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 Processa common stock quoted on the OTC over a 45 day period preceding the mid-February 2018 finalized negotiation of the modification to the option and license agreement with CoNCERT, an unrelated third party, for the exclusive license rights to PCS-499 however, Processa has less than 300 shareholders, the volume of shares trading for Processa's common stock is not significant and the OTCQB is not a national exchange; therefore, the volume weighted average price quotes for the Processa stock are from markets that are not active and consequently are Level 2 inputs. The total cost recognized for the exclusive license acquired represents the allocated fair value related to the stock transferred to CoNCERT plus the recognition of the deferred tax liability related to the acquired temporary difference and the transaction costs incurred to complete the transaction as discussed above.

Intangible assets consist of the following:

	June 30, 2018
Gross intangible assets	
Exclusive license rights to CTP-499	$ 11,038,929
Less: Accumulated amortization	(222,559)
Total intangible assets, net	$ 10,816,370

Amortization expense was $197,124 and $222,559 for the three and six months ended June 30, 2018, respectively. The weighted average amortization period for the intangible asset is 14 years based on the average remaining patent lives for PCS-499 and the estimated royalty period for a fully paid-up license under the terms of the license agreement. Amortization expense is included within research and development expense in the accompanying consolidated statements of operations. As of June 30, 2018, the estimated future amortization expense each year for the next five years and annual periods thereafter until fully amortized amounts to $788,495 per year.

Note 3 – Senior Convertible Notes

The balance of our Senior Convertible Notes ("Senior Notes") and accrued interest at June 30, 2018 and December 31, 2017 was as follows:

	Senior Convertible Notes	Unamortized Debt Issuance Costs	Senior Convertible Notes, Net	Accrued Interest
Balance, December 31, 2017	$ 2,580,000	$ (131,430)	$ 2,448,570	$ 35,693
Conversion of debt	$ (2,350,000)	$ 64,361	$ (2,285,639)	$ (109,472)
Accrued interest	-	-	-	84,922
Amortize debt issuance costs	-	61,132	61,132	-
Balance, June 30, 2018	230,000	(5,937)	224,063	11,143
Current portion	(230,000)	5,937	(224,063)	(11,143)
Long-term portion	$ -	$ -	$ -	$ -

Interest expense totaled $58,314 for the three months ended June 30, 2018, consisting of interest on the Senior Notes at 8% of $24,992 and the amortization of debt issuance costs of $33,322. Interest expense totaled $146,054 for the six months ended June 30, 2018 consisting of interest on the Senior Notes at 8% of $84,922 and the amortization of debt issuance costs of $61,132. The Senior Notes and related accrued interest are classified as a current liability in our balance sheet.

Issuance of our Senior Convertible Notes

As of October 4, 2017, certain entities affiliated with current shareholders had purchased $1.25 million of our Senior Notes in a bridge financing undertaken by us to support our operations. On November 21, 2017, additional third-party accredited investors contributed $1.33 million in financing proceeds. On May 25, 2018, $2,350,000 of Senior Notes was converted, as described below, leaving $230,000 of Senior Notes outstanding at June 30, 2018.

Principal and interest under each Senior Note is due on the earlier of (i) the mandatory and automatic conversion of the Senior Note into the next Private Investment in Public Equity ("PIPE") financing we undertake, provided the PIPE financing yields minimum gross proceeds and a pre-money valuation as defined in the financing agreement or (ii) the one-year anniversary of that Senior Note (Maturity Date). The Senior Notes bear interest at 8% per year and are payable in kind (in common stock).

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

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

The Company retained a placement agent and agreed to pay the placement agent (i) six percent (6%) of gross proceeds received by the Company and (ii) warrants to purchase securities in the amount of three percent (3%) of the equity issued or issuable in connection with the Senior Notes bridge financing. These warrants will be issued upon achieving certain financing levels under the next PIPE financing we undertake. Additional financing was received in May and June 2018. As a result, warrants to purchase a total of 72,375 shares of common stock were issued to the placement agent, with a three-year term, at an exercise price equal to $2.452.

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

Conversion of Our Senior Convertible Notes

On May 25, 2018, pursuant to the mandatory and automatic conversion provisions of the Senior Notes, we converted $2,350,000 of the $2,580,000 outstanding Senior Notes, along with any accrued interest into 1,206,245 shares of common stock (at a conversion price of $2.043 per share) and a warrant to purchase one share of common stock for three years, at an exercise price of $2.452.

Senior Notes totaling $230,000 held by Canadian individuals cannot be converted until the Company completes certain regulatory matters and filings in Canada. Once these regulatory matters and filings have been met, the Senior Notes held by these individuals will automatically convert on the same terms as the other noteholders.

The Company completed an evaluation of the warrants issued in this transaction and determined the warrants should be classified as equity.

Note 4 – Stockholders' Equity

2018 Private Placement Transactions

Between May 15, 2018 and June 29, 2018, the Company sold an aggregate of 1,402,442 units in a private placement transaction at a purchase price equal to $2.27 per unit for gross proceeds of approximately $3.2 million. Each unit consisted of one share of our common stock and a warrant to purchase one share of our common stock for $2.724, subject to adjustment thereunder for a period of three years. The Company paid $167,526 to their placement agent and issued placement agent warrants to purchase up to 84,146 shares of common stock, with a three-year term, at an exercise price equal to $2.724. The issuance costs were charged against additional paid in capital. The Company also recorded a note receivable of $107,490, which represented proceeds from one non-affiliated investor in the June 29, 2018 transaction that was not received until July 6, 2018.

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

The Company also entered into a pledge agreement with PoC, under which the Company received a security interest in 396,476 shares, or half the shares we issued to them. These shares will be released in two tranches of 198,238 shares each, with each tranche released upon PoC making payments totaling $720,000. As of June 30, 2018, no proceeds have been paid by PoC and the Company holds 396,476 shares as collateral.

The common stock, but not the warrants, issued for the 2018 Private Placement Transactions and the conversion of the Senior Convertible Notes have, subject to certain customary exceptions, full ratchet anti-dilution protection. Until the Company has issued equity securities or securities convertible into equity securities for a total of an additional $20.0 million in cash or assets, including the proceeds from the exercise of the warrants issued above, in the event we issue additional equity securities or securities convertible into equity securities at a purchase price less than $2.27 per share of common stock, the above purchase price 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).

The Company completed an evaluation of the warrants issued in the 2018 Private Placement Transactions and the conversion of the Senior Convertible Notes and determined the warrants should be classified as equity.

Purchase of the CoNCERT License

On March 19, 2018, Promet, Processa and CoNCERT amended the Agreement executed in October 2017. The Agreement was assigned to Processa and Processa exercised the exclusive option for the PCS-499 compound (see Note 1 – Company Overview and Note 2 – Intangible Asset) in exchange for CoNCERT receiving, in part, $8 million of common stock of the Company that was owned directly by Promet (or 2,090,301 shares at $3.83 per share representing 6.58% of Promet's common stock holding or 5.93% of the Company's total common stock issued and outstanding) in satisfaction of the obligation due for the exclusive license for CTP-499 acquired by Processa. There was no change in the total shares issued and outstanding of 35,272,626, however, Promet's controlling interest was reduced from 90% to 84%. Promet contributed the payment of the obligation due for the exclusive license to the Company without consideration paid to them. As a result of the transaction, the Company recognized an exclusive license intangible asset with a fair value of $8 million and an offsetting increase in additional paid-in capital resulting from Promet satisfying Processa's liability to CoNCERT (see Note 2 Intangible Asset for the income tax effect of this transaction).

Note 5 – Income Taxes

The Company accounts 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. The Company records a valuation allowance to reduce the Company's deferred tax assets to the amount of future tax benefit that is more likely than not to be realized.

As of June 30, 2018, and December 31, 2017, the Company recorded a valuation allowance equal to the full recorded amount of the Company's net deferred tax assets related to intangible start-up costs 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.

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

A deferred tax liability was recorded when CoNCERT sold its license and "Know-How" to Processa for stock in an Internal Revenue Code Section 351 transaction on March 19, 2018 (see Note 1 – Company Overview and Note 2 – Intangible Asset). A Section 351 transaction treats the acquisition of the license and Know-How for stock as a tax-free exchange. As a result, under ASC 740-10-25-51 *Income Taxes*, Processa recorded a deferred tax liability of $3,037,147 for the acquired temporary difference between the financial reporting basis of approximately $11,038,929 and the tax basis of approximately $1,782. The deferred tax liability may be offset by the deferred tax assets resulting from 2017 and 2018 net operating losses. Under ACS 740-270 *Income Taxes – Interim Reporting,* the Company is required to project its 2018 federal and state effective income tax rate and apply it to the June 30, 2018 operating loss before income taxes. Based on the projection, the Company expects to recognize the tax benefit from the 2017 net operating loss carryover and the projected 2018 loss, which resulted in the recognition of a deferred tax benefit shown in the consolidated statements of operations for 2018.

As required under ASC 740-270, *Interim Financial Reporting*, the Company has estimated its annual effective tax rate for the full fiscal year and applied that rate to its year-to-date consolidated pre-tax ordinary loss before income taxes in determining its benefit for income taxes. The Company recorded a benefit for income taxes of approximately $278,000 and $0 for the three months ended June 30, 2018 and 2017, respectively, and $559,000 and $0 for the six months ended June 30, 2018 and 2017, respectively.

As discussed in Note 2 – Income Taxes in the consolidated financial statements included in Item 8 of the 2017 Form 10-K filed with the SEC on April 17, 2018, the historical information presented in the consolidated financial statements prior to October 4, 2017 is that of Promet in accordance with Accounting Standards Codification ("ASC") 805-40-45, *Business Combinations – Reverse Acquisitions.* Prior to the closing of the asset purchase transaction on October 4, 2017, Promet was treated as a partnership for federal income tax purposes and thus was not subject to income tax at the entity level. Therefore, no provision or liability for income taxes has been included in these consolidated financial statements through the date of the asset purchase on October 4, 2017.

The Company expects to be in an overall taxable loss position for 2018. However, the Company expects to recognize a deferred tax benefit in 2018 to the extent the 2017 net operating loss carryover and the 2018 net operating losses can be used to offset the deferred tax liability related to the intangible asset. No current income tax expense is expected for the foreseeable future as the Company expects to generate taxable net operating losses.

Note 6 – 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 the Company's stock warrants grants, and the if-converted method is used to determine the dilutive effect of the Company's Senior Convertible Notes.

The computation of net loss per share for the three and six months ended June 30, 2018 and 2017 is shown below.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Basic and diluted net loss per share:				
Net loss	$ (1,206,074)	$ (278,445)	$ (2,302,870)	$ (500,536)
Weighted-average number of common shares-basic and diluted	36,623,697	31,745,242	35,951,894	31,745,242
Basic and diluted net loss per share	$ (0.03)	$ (0.01)	$ (0.06)	$ (0.02)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Stock purchase warrants	3,612,786	-	3,612,786	-
Senior Convertible Notes	115,128	-	115,128	-

Note 7 – Related Party Transactions

A shareholder, Corlyst, LLC, reimburses the Company for shared costs related to payroll, health care insurance and rent based on actual costs incurred and recognized as a reduction of the general and administrative operating expenses being reimbursed in the Company's condensed consolidated statement of operations. The reimbursed amounts totaled $0 and $19,660 for the three months ended June 30, 2018 and 2017, respectively, and $27,480 and $49,089 for the six months ended June 30, 2018 and 2017, respectively. Amounts due from Corlyst at June 30, 2018 and December 31, 2017 were $53,501 and $62,709, respectively.

During 2017 and 2018, Corlyst paid certain operating expenses on behalf of the Company and the Company reimbursed Corlyst based on actual costs incurred at later dates. The accounts payable amounts due to Corlyst at June 30, 2018 and December 31, 2017 were $900 and $0, respectively. In 2018, Promet paid CA state and FUTA payroll taxes on behalf of Processa. As a result, the accounts payable amount due to Promet at June 30, 2018 and December 31, 2017 were $116 and $336, respectively. In addition, there was $100 due to an officer included in due to related parties as of June 30, 2018 and December 31, 2017.

Corlyst also purchased 132,159 shares of common stock in a private placement transaction.

A Director of the Company is the manager of the JMW Fund, LLC, San Gabriel Fund, LLC, and Richland Fund, LLC, collectively known as the "Funds". The Funds received 515,583 shares of our common stock and warrants to purchase 515,583 shares of our common stock upon the conversion of $1 million of Senior Convertible Notes held by the Funds purchased on October 4, 2017. At June 30, 2018, the Funds owned a total of 2,065,789 shares of common stock and warrants to purchase 515,583 shares of common stock.

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

Note 8 – Commitments and Contingencies

Purchase Obligations

The Company enters into contracts in the normal course of business with contract research organizations and subcontractors to further develop its products. The contracts are cancellable, with varying provisions regarding termination. If a contract with a specific vendor were to be terminated, the Company would only be obligated for products or services that it received as of the effective date of the termination and any applicable cancellation fees. The Company had purchase obligations of approximately $110,000 and $896,000 at June 30, 2018 and December 31, 2017, respectively.

Cybersecurity Fraud

In January 2018, the Company incurred a loss of $144,200 due to fraud from a cybersecurity breach. As a result, we have implemented certain review and approval procedures internally and with our banks; our technology consultants have implemented system changes; and, we reported the fraud to our banks and the Federal Bureau of Investigation Cyber Crimes Unit. The Company does not have insurance coverage against the type of fraud that occurred, therefore, recovery of the loss is remote. While we are taking steps to prevent such an event from reoccurring, we cannot provide assurance that similar issues will not reoccur. The loss is included in general and administrative expenses in the consolidated statement of operations for the six months ended June 30, 2018.

Note 9 - Subsequent Events

The Company has evaluated all subsequent events through the date of filing of this Quarterly Report on Form 10-Q with the SEC, to ensure that this filing includes appropriate disclosure of events both recognized in the financial statements as of June 30, 2018, and events which occurred subsequent to June 30, 2018, but which were not recognized in the financial statements. The Company has determined that there were no subsequent events which required recognition, adjustment to or disclosure in the financial statements.

6,385,437 SHARES OF COMMON STOCK

PROCESSA PHARMACEUTICALS, INC.

PROSPECTUS

November 9, 2018