As filed with the Securities and Exchange Commission on December 13, 2019

**Registration No. 333-**

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

# FORM S-1
**REGISTRATION STATEMENT**
**UNDER**
**THE SECURITIES ACT OF 1933**

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

| **Delaware** | **2834** | **45-1539785** |
|---|---|---|
| (State or other jurisdiction of incorporation or organization) | (Primary Standard Industrial Classification Code Number) | (I.R.S. Employer Identification Number) |

**7380 Coca Cola Drive, Suite 106**
**Hanover, Maryland 21076**
**(443) 776-3133**
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**David Young, Pharm.D, Ph.D.**
**Chairman and Chief Executive Officer**
**Processa Pharmaceuticals, Inc.**
**7380 Coca Cola Drive, Suite 106**
**Hanover, Maryland 21076**
**(443) 776-3133**
(Name, address, including zip code, and telephone number, including area code, of agent for service)

**Copies to:**

**Michael B. Kirwan**
**John J. Wolfel, Jr.**
**Foley & Lardner LLP**
**One Independent Drive, Suite 1300**
**Jacksonville, Florida 32202**
**(904) 359-2000**

Approximate date of commencement of proposed sale to the public:
**As soon as practicable after the effective date of this registration statement.**

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. [ ]

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering. [ ]

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act. [X]

**CALCULATION OF REGISTRATION FEE**

| **Title of Each Class of Securities to be Registered** | **Proposed Maximum Aggregate Offering Price[(2)]** | **Amount of Registration Fee** |
|---|---|---|

| | | |
|---|---|---|
| Common Stock, $0.0001 par value per share[1] | $ 15,000,000 | $ 1,947 |
| Underwriters' Warrants[3] | — | — |
| Shares of Common Stock underlying Underwriters' Warrants | $ 750,000 | $ 97.35 |
| **Total:** | **$ 15,750,000** | **$ 2,044.35** |

(1) Includes shares that the underwriters have the option to purchase to cover over-allotments, if any.

(2) Estimated solely for purposes of calculating the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended. Pursuant to Rule 416 of the Securities Act of 1933, as amended, such number of shares of common stock registered hereby also shall include an indeterminate number of shares of common stock that may be issued in connection with stock splits, stock dividends, recapitalizations or similar events.

(3) Registers warrants to be granted to the underwriters, or their designees, for an amount equal to 4.0% of the number of the shares of common stock sold to the public, and assuming a per share exercise price equal to 125% of the price per share in this offering. See "Underwriting" on page 89 for information on underwriting arrangements. No registration fee required pursuant to Rule 457(g) under the Securities Act of 1933, as amended.

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS, SUBJECT TO COMPLETION, DATED DECEMBER 13, 2019

# Processa Pharmaceuticals

**Shares of Common Stock**

This is a firm commitment public offering of ● shares of our common stock. Prior to this offering, there has been a limited public market for our common stock. We currently expect the public offering price to be between $● and $● per share.

Our common stock is currently quoted on the OTCQB Marketplace under the symbol "PCSA." On December●, 2019, the last reported sale price for our common stock as reported on the OTCQB Marketplace was $● per share, after giving effect to the one for seven reverse stock split completed on December ●, 2019. We intend to apply to list our common stock on the Nasdaq Capital Market under the symbol "PCSA." No assurance can be given that our application will be approved. If our application is not approved or we otherwise determine that we will not be able to secure the listing of our common stock on the Nasdaq, we will not complete this offering.

We are an "emerging growth company" as that term is defined in the Jumpstart Our Business Startups Act of 2012, and as such, have elected to take advantage of certain reduced public company reporting requirements.

**Investing in our common stock is highly speculative and involves a high degree of risk. See "Risk Factors" beginning on page 8.**

| | Per Share | Total |
|---|---|---|
| Public offering price | $ | $ |
| Underwriting discounts and commissions[(1)] | $ | $ |
| Proceeds, before expenses, to us | $ | $ |

(1) Does not include warrants that are issuable by us to the underwriters for 4% of the shares of common stock sold in the offering at a price per share equal to 125% of the public offering price or certain out-of-pocket expenses of the underwriters that are reimbursable by us. See "Underwriting" beginning on page 89 of this prospectus for a description of the compensation payable to the underwriters.

We have granted the underwriters an option to purchase up to ● additional shares of our common stock. The underwriters can exercise this option at any time within ● days after the date of this prospectus.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

Delivery of the shares of common stock is expected to be made on or about ●, 2019.

Prospectus dated ●, 2019

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You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations, market position and market opportunity, is based on our management's estimates and research, as well as industry and general publications and research, surveys and studies conducted by third parties. We believe that the information from these third-party publications, research, surveys and studies included in this prospectus is reliable. Management's estimates are derived from publicly available information, their knowledge of our industry and their assumptions based on such information and knowledge, which we believe to be reasonable. These data involve a number of assumptions and limitations which are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors." These and other factors could cause our future performance to differ materially from our assumptions and estimates.

This prospectus includes trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included in this prospectus are the property of their respective owners.

As used in this prospectus, unless the context indicates or otherwise requires, "the Company," "our Company," "we," "us," and "our" refer to Processa Pharmaceuticals, Inc., a Delaware corporation, and its consolidated subsidiary. For other defined terms, please see the Glossary on the following page.

## GLOSSARY OF CERTAIN SCIENTIFIC TERMS

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

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

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

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

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

"CRO" means a Contract Research Organization.

"EMA" means the European Medicines Agency.

"FDA" means the Food and Drug Administration.

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

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

"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 selected information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making an investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our financial statements and the related notes thereto and the information set forth under the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this prospectus.*

*On December ●, 2019, we completed a one for seven reverse stock split of our common stock. Unless otherwise indicated, all share amounts (and corresponding exercise and conversion prices of derivative securities) in this prospectus have been retroactively adjusted to give effect to this reverse stock split (subject to rounding up fractional shares), except for the financial statements and notes thereto.*

**Description of Business**

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

Our lead product, 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. Our lead indication currently under development for PCS-499 is Necrobiosis Lipoidica (NL). NL is a chronic, disfiguring condition affecting the skin and the tissue under the skin typically on the lower extremities with no currently approved FDA treatments. NL presents more commonly in women than in men and ulceration can occur in approximately 30% of NL patients. More severe complications can occur, such as deep tissue infections and osteonecrosis threatening life of the limb. Approximately 74,000 - 185,000 people in the United States and more than 200,000 – 500,000 people outside the United States are affected by NL.

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. On June 22, 2018, the FDA granted orphan-drug designation to PCS-499 for the treatment of NL. On September 28, 2018, the FDA cleared our IND for PCS-499 in NL such that we could move forward with the Phase 2a safety-dose tolerability trial. We dosed our first NL patient in this Phase 2a clinical trial on January 29, 2019. On August 23, 2019, our study was fully enrolled as the twelfth patient was dosed. The main objective of the trial is to evaluate the safety and tolerability of PCS-499 in patients with NL. We expect the safety and efficacy data collected to provide information for the design of future clinical trials. Based on toxicology studies and healthy human volunteer studies, Processa and the FDA agreed that a PCS-499 dose of 1.8 grams/day would be the highest dose administered to NL patients in this Phase 2 trial. As anticipated, the PCS-499 dose of 1.8 grams/day, 50% greater than the maximum tolerated dose of pentoxifylline, appears to be well tolerated with no serious adverse events reported. Twelve patients have been dosed with nine patients on treatment for at least four months, seven patients on treatment for at least six months, and two patients on treatment for at least nine months. Currently, nine patients remain in the study. To date, six patients dosed at 1.8 g/day have reported only mild adverse events related to the treatment, which occurred mostly in the first month of treatment and were quickly resolved. As expected, gastrointestinal or central nervous system (CNS) adverse events were reported most often.

Our findings as of December 4, 2019, based on our early efficacy data, showed that the two patients in the trial with more severe ulcerated NL (both ulcerated patients had ulcers for more than two months prior to dosing) had the ulcers fully closed after two and nine months after starting the trial, respectively. In addition, while in the trial, one of the ulcerated patients developed small ulcers at other sites as a result of contact trauma to the site and these ulcers resolved within one month. Ten patients presented with mild to moderate NL and no ulceration. These patients have shown a slight improvement but not as dramatic as the more serious ulcerated patients. Based on the literature and clinical experience, approximately 30% of the patients with NL are expected to have open ulcers with the ulceration naturally healing in less than 20% of these patients.

The degeneration of tissue occurring at the NL lesion site is caused by a number of pathophysiological changes, which has made it extremely difficult to develop effective treatments for this condition. PCS-499 may provide a solution since PCS-499 and its metabolites affect a number of biological pathways, several of which contribute to the pathophysiology associated with NL. We are continually evaluating the data we receive.

We plan to request a meeting with the FDA before the end of 2019 to further discuss the development of PCS-499, including the next clinical trial.

On August 29, 2019 we entered into an exclusive license agreement with Akashi Therapeutics, Inc. ("Akashi") to develop and commercialize an anti-fibrotic, anti-inflammatory drug (HT-100) that also promotes healthy muscle fiber regeneration. In previous clinical trials in Duchenne Muscular Dystrophy (DMD), HT-100 showed promising improvement in the muscle strength of non-ambulant pediatric patients. Although the FDA in January 2016 placed a clinical hold on the DMD trial after a serious adverse event in a pediatric patient, the FDA in March 2017 terminated the clinical hold it had placed on the DMD trial and provided specific guidelines as to how clinical trials for HT-100 could resume in DMD. Once we have obtained adequate funding, we plan to develop HT-100 for the cure of rare adult fibrotic related diseases such as focal segmental glomerulosclerosis, idiopathic pulmonary fibrosis or Scleroderma.

**Risks Associated with our Business and Related to this Offering**

We are a clinical stage biopharmaceutical company with limited operating history. We do not have any products approved for sale and have incurred, and expect we will continue to incur for the foreseeable future, significant losses and negative cash flows from operations. Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the "Risk Factors" section of this prospectus. These risks include, but are not limited to the following:

- We have incurred significant operating losses since our inception, and we expect to incur losses for the foreseeable future and may never achieve or maintain profitability;
- We are highly dependent on the success of our lead product candidate PCS-499 and if we are unable to successfully complete our clinical development program for PCS-499, our business will be materially harmed.
- There is no guarantee that PCS-499 or any other product candidates, if approved, will generate revenues.
- Drug development is a highly uncertain undertaking and involves a substantial degree of risk, and we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidate.
- Even if this offering is successful, we will need substantial additional funding. If we are unable to raise capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and development programs or future commercialization efforts.
- The price of our stock may be volatile, and you could lose all or part of your investment.
- We have limited experience in drug development and may not be able to successfully develop any drugs, which would cause us to cease operations.
- We may be unable to obtain or protect intellectual property rights relating to our products, and we may be liable for infringing upon the intellectual property rights of others, which could have a materially adverse effect on our business.
- We rely on, and expect to continue to rely on, third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize our product candidates, and our business could be substantially harmed.
- There can be no assurance that our securities will continue to be listed on Nasdaq following this offering or that there will be liquidity in the trading market for our securities;
- We have identified material weaknesses in our internal control over financial reporting and, if our remediation of the material weaknesses is not effective or if we identify additional material weaknesses in the future, we may not be able to accurately or timely report our financial results, or prevent fraud, and investor confidence in our company and the market price of our shares may be adversely affected.

**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"). We have included our website address in this prospectus solely as an inactive textual reference. Investors should not rely on any such information in deciding whether to purchase our common stock.

| The Offering | |
|---|---|
| **Common Stock Offered by Us** | ● shares of common stock (or ● shares if the underwriters exercise their option to purchase additional shares in full). |
| **Common Stock to be Outstanding After this Offering*** | ● shares (or ● shares if the underwriters exercise their option to purchase additional shares in full) and adjusted for the one for seven reverse stock split completed on December ●, 2019. |
| **Use of Proceeds** | We intend to use the net proceeds of this offering primarily to fund clinical trials of our lead product candidate PCS-499, to fund the development of HT-100 and/or other product candidates, to fund general research and development activities, working capital and other general corporate activities. See the section titled "Use of Proceeds" for more information. |
| **Risk Factors** | You should read the "Risk Factors" section of this prospectus beginning on page 8 and other information included in this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock. |
| **Proposed Nasdaq Capital Market Symbol** | Our common stock is currently quoted on the OTCQB Marketplace under the symbol "PCSA." We intend to apply to list our common stock on the Nasdaq Capital Market under the symbol "PCSA." No assurance can be given that our application will be approved. If our application is not approved or we otherwise determine that we will not be able to secure the listing of our common stock on the Nasdaq, we will not complete this offering. |

* The number of shares of our common stock to be outstanding after this offering, adjusted for the one for seven reverse stock split completed on December ●, 2019, is based on 5,486,362 shares of common stock outstanding as of December ●, 2019 and excludes the following:

- 137,033 shares of our common stock issuable upon the exercise of outstanding stock options issued under the Processa Pharmaceuticals, Inc. 2019 Omnibus Incentive Plan, having a weighted-average exercise price of $17.19 per share, of which 12,950 options have vested, having a weighted-average exercise price of $16.80 per share;
- 362,967 shares of common stock reserved for issuance pursuant to future awards under the Processa Pharmaceuticals, Inc. 2019 Omnibus Incentive Plan;
- 47,772 shares of our common stock issuable upon the exercise of outstanding non-qualified stock options granted to our Chief Financial Officer on September 1, 2018, having an exercise price of $19.88 per share, of which 13,872 shares have vested with an exercise price of $19.88 per share;
- 52,171 shares of common stock issuable upon the conversion of $745,000 principal amount of outstanding 8% Senior Convertible Notes, assuming a conversion price of $14.28 per share;
- 477,579 shares of common stock issuable upon exercise of the outstanding stock purchase warrants, all of which are exercisable, having a weighted average exercise price of $18.27 per share; and
- ● shares of our common stock that may be issued upon exercise of the underwriters' warrants at an exercise price of $●, which represents ●% of the shares of common stock being offered hereby and 125% of an assumed public offering price of $●.

Unless otherwise indicated, all share and per share information contained in this prospectus has been adjusted for the one for seven reverse stock split of our common stock completed on December ●, 2019. All share amounts (and corresponding exercise and conversion prices of derivative securities) in this prospectus have been retroactively adjusted to give effect to this reverse stock split (subject to rounding up fractional shares), except for the financial statements and notes thereto.

## SUMMARY HISTORICAL CONSOLIDATED FINANCIAL DATA

The following tables summarize our historical consolidated financial data for the periods and as of the dates indicated. The summary consolidated financial data as of December 31, 2018 and 2017 and for each of the years in the two-year period ended December 31, 2018 have been derived from our audited consolidated financial statements included herein. The summary unaudited condensed consolidated financial data as of September 30, 2019 and the nine-month period ended September 30, 2019 and 2018 has been derived from our unaudited condensed consolidated financial statements included herein The unaudited interim financial statements have been prepared on the same basis as our annual audited financial statements and, in the opinion of management, reflect all adjustments, which include only normal, recurring adjustments that are necessary to state fairly the unaudited interim financial statements. Our historical results are not necessarily indicative of results that may be expected in the future, and the results for the nine months ended September 30, 2019 are not necessarily indicative of results to be expected for the full year or any other period.

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.

| | Year Ended December 31, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2019 | 2018 |
| **Statements of Operations and Comprehensive Loss Data:** | | | | |
| Operating expenses: | | | | |
| Research and development | $ 3,085,317 | $ 964,164 | $ 1,804,169 | $ 2,477,481 |
| General and administrative | 1,439,623 | 838,269 | 1,219,329 | 1,305,511 |
| Loss from operations | (4,524,940) | (1,802,433) | (3,023,498) | (3,782,992) |
| Other income (expense): | | | | |
| Interest income | 18,297 | 5,181 | 10,886 | 10,163 |
| Interest expense | (161,205) | (59,063) | (12,973) | (154,377) |
| Net Operating Loss Before Income Tax Benefit | (4,667,848) | (1,856,315) | (3,025,585) | (3,927,206) |
| Income Tax Benefit | 902,801 | - | 442,152 | 771,332 |
| Net loss and comprehensive loss | $ (3,765,047) | $ (1,856,315) | $ (2,583,433) | $ (3,155,874) |
| Net loss per share attributable to common stockholders - basic and diluted, adjusted for the one for seven reverse stock split. | $ (0.71) | $ (0.40) | $ (0.47) | $ (0.60) |
| Weighted average common shares outstanding - basic and diluted, adjusted for the one for seven reverse stock split. | 5,332,038 | 4,656,526 | 5,530,864 | 5,267,046 |

| | As of December 31, 2018 | As of December 31, 2017 |
|---|---|---|
| | Actual | Actual |
| **Balance Sheet Data:** | | |
| Cash and cash equivalents | $ 1,740,961 | $ 2,847,429 |
| Total Assets | 12,481,068 | 2,982,940 |
| Working Capital[3] | 1,374,672 | 351,771 |
| Total Liabilities | 2,780,050 | 2,609,776 |
| Total Stockholders' Equity | 9,701,018 | 2,982,940 |

| | As of September 30, 2019 - Unaudited | |
|---|---|---|
| | Actual | Pro Forma [1][2] |
| **Balance Sheet Data:** | | |
| Cash and cash equivalents | $ 504,302 | $ ● |
| Total Assets | 10,821,293 | ● |
| Working Capital[3] | 433,564 | ● |
| Total Liabilities | 2,150,614 | ● |
| Total Stockholders' Equity | 8,670,679 | ● |

(1) Reflects the issuance and sale of shares of common stock in this offering at the assumed public offering price of $ ● per share, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(2) Each $1.00 increase (decrease) in the assumed public offering price of $● per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets, and total stockholders' equity by approximately $● million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us at the assumed public offering price after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us would increase (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately $● million. The pro forma information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of our public offering determined at pricing.

(3) We define working capital as current assets less current liabilities.

## RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, the section of this prospectus entitled "Management's Discussion and Analysis of Financial Condition and Results of Operation" and our financial statements and related notes, before investing in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or that we currently deem immaterial may also adversely affect our business operations. If any of the following risks occur, our business, operating results and prospects could be materially harmed. In that event, the price of our common stock could decline, and you could lose part or all of your investment.*

### Risks Related to Our Financial Position and Need for Capital

***We have a history of losses and we may never become profitable.***

We are a clinical stage biopharmaceutical company with a limited operating history. Processa itself as an organization has never had a drug approved by the FDA or any regulatory agency. The likelihood of success of our business plan must be considered in light of the challenges, substantial expenses, difficulties, complications and delays frequently encountered in connection with developing and expanding early-stage businesses and the regulatory and competitive environment in which we operate. Biopharmaceutical product development is a highly speculative undertaking, involves a substantial degree of risk, and is a capital-intensive business. If we cannot successfully execute our plan to develop our pipeline of drug(s), our business may not succeed.

Promet Therapeutics, LLC, whose assets were acquired by Processa, had an accumulated deficit of $3.3 million incurred since its inception on August 31, 2015 through the date of acquisition on October 4, 2017. Subsequent to the date of acquisition, the accumulated deficit increased to $10.2 million at September 30, 2019. We will incur additional losses as we continue our research and development activities, seek regulatory approvals for our product candidates and engage in clinical trials. These losses will cause, among other things, our stockholders' equity and working capital to decrease. Any future earnings and cash flow from operations of our business are dependent on our ability to further develop our products and on revenues and profitability from sales of products or successful joint venture relationships.

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

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

***We have limited cash resources and will require additional financing.***

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

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

We recently entered into two line of credit agreements providing a revolving commitment of an aggregate of up to $1.4 million but have not drawn any amounts as of the date hereof. On November 30, 2019 we closed our bridge financing and issued $745,000 of 8% Senior Convertible Notes (“8% Senior Notes”) to accredited investors. We have not had any revenue since our inception and we do not currently have any revenue under contract or any immediate sales prospects. As part of our effort to conserve cash, beginning on August 1, 2019 we have also delayed some of our cash outflows, primarily through the deferred payment of salaries ($48,840, which has been accrued and included in accrued expenses during the three and nine months ended September 30, 2019) until such time as we have raised sufficient funding.

We may seek additional capital through a combination of private and public equity offerings, debt financings and strategic collaborations. If we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly issued securities may have rights, preferences or privileges senior to those of existing stockholders. Debt financing, if obtained, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, could increase our expenses and require that our assets secure such debt. Moreover, any debt we incur must be repaid regardless of our operating results. If we choose to pursue additional indications and/or geographies for our product candidates, in-license additional development assets, or otherwise expand more rapidly than we presently anticipate, we may also need to raise additional capital sooner than expected.

As a result, substantial doubt exists about our ability to continue as a going concern as of the date hereof and our auditors included a going concern paragraph in their Report of Independent Registered Public Accounting Firm accompanying our audited financial statements for the year ended December 31, 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 we be unable to continue as a going concern based on the outcome of these uncertainties described above.

***Raising additional capital may cause dilution to our existing shareholders, including purchasers of common stock in this offering, restrict our operations or require us to relinquish rights to our technology or product candidates.***

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

**Risks Relating to Clinical Development and Commercialization of Our Product Candidates**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- demonstration of clinical safety and efficacy;
- relative convenience, dosing burden and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe our product candidates, and the target patient population to try new therapies;

- efficacy of our product candidates compared to competing products;
- the introduction of any new products that may in the future become available targeting indications for which our product candidates may be approved;
- new procedures or therapies that may reduce the incidences of any of the indications in which our product candidates may show utility;
- pricing and cost-effectiveness;
- the inclusion or omission of our product candidates in applicable therapeutic and vaccine guidelines;
- the effectiveness of our own or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in approved labeling from regulatory authorities;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors or to receive the necessary pricing approvals from government bodies regulating the pricing and usage of therapeutics; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement or government pricing approvals.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as (i) the drug's orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant's product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. If a drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity. While the FDA granted orphan-drug designation to PCS-499 for the treatment of NL on June 22, 2018 there can be no assurance that we will receive orphan drug designation for any additional product candidates in the indications for which we think they might qualify, if we elect to seek such applications.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**Risks Relating to Our Intellectual Property Rights**

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

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

Our current patent portfolio consists of patents licensed from CoNCERT Pharmaceuticals for PCS-499 and related compounds. The portfolio includes approximately 29 allowed or issued patents (of which 9 are in the United States), which are directed to claims for composition of matter, methods of use, and certain chemical processes. Of these, 3 allowed or issued patents in the U.S. and Europe, as well as 2 in each of Australia, Canada, China, Japan and Mexico and 1 in each of Taiwan, Hong Kong, Russia, South Korea, the Philippines, South Africa, and Brazil cover the composition of matter of PCS-499. The allowed or issued U.S. and European patents are expected to expire between 2029 and 2031, excluding any extension or adjustment of patent term that may be available.

In addition, we do not own any intellectual property rights, including any patents that underlie our drug candidates. These drugs are in-licensed from other biotech or pharmaceutical companies and our rights to develop and commercialize the product candidates we license are subject to the validity of the owner's intellectual property rights. All of our product candidates are either in the early stages of clinical development or late stages of preclinical development and we have only recently initiated a clinical trial and significant additional research and development activity and clinical testing are required before we will have a chance to achieve a viable product for licensing or commercialization from our drug candidates. Most drug candidates never reach the clinical development stage and even those that do commence clinical development have only a small chance of successfully completing clinical development and gaining regulatory approval. Therefore, our business currently depends entirely on the successful development, regulatory approval, and licensing or commercialization of our product candidates, which may never occur.

Our rights to develop and commercialize the product candidates we license are subject to the validity of the owner's intellectual property rights. Enforcement of our licensed patents or defense or any claims asserting the invalidity of these patents is often subject to the control or cooperation of our licensors. Legal action could be initiated against the owners of the intellectual property that we license and an adverse outcome in such legal action could harm our business because it might prevent such companies or institutions from continuing to license intellectual property that we may need to operate our business. In addition, such licensors may resolve such litigation in a way that benefits them but adversely affects our ability to develop and commercialize our product candidates.

In addition, our rights to practice the inventions claimed in the licensed patents and patent applications are subject to our licensors abiding by the terms of those licenses and not terminating them. Our licenses may be terminated by the licensor if we are in material breach of certain terms or conditions of the license agreement or in certain other circumstances. Our license agreements with CoNCERT Pharmaceuticals include provisions that allow the licensor to terminate the license if (i) we breach any payment obligation or other material provision under the agreement and fail to cure the breach within a fixed time following written notice of termination, (ii) we or any of our affiliates, licensees or sublicensees directly or indirectly challenge the validity, enforceability, or extension of any of the licensed patents, or (iii) we declare bankruptcy or dissolve. Our rights under the licenses are subject to our continued compliance with the terms of the license, including the payment of royalties due under the license. Termination of these licenses could prevent us from marketing some or all of our products. Because of the complexity of our products and the patents we have licensed, determining the scope of the license and related royalty obligations can be difficult and can lead to disputes between us and the licensor. An unfavorable resolution of such a dispute could lead to an increase in the royalties payable pursuant to the license. If a licensor believed we were not paying the royalties due under the license or were otherwise not in compliance with the terms of the license, the licensor might attempt to revoke the license. If such an attempt were successful, we might be barred from producing and selling some or all of our products.

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

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

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

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

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

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

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

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

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

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

**General Company-Related Risks**

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

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

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

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

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

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

- decreased demand for any of our product candidates or any future products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- substantial costs to defend the related litigation;
- a diversion of management's time and our resources;

- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- the inability to commercialize some or all of our product candidates; and
- a decline in the value of our stock.

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

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

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

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

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

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

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

To induce valuable personnel to remain at our Company, in addition to salary and cash incentives, we expect that we will provide stock options, restricted stock units or other equity securities that vest over time from our 2019 Omnibus Incentive Plan or a subsequent plan. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we expect to have employment agreements with our key employees, these employment agreements may still allow these employees to leave our employment at any time, for or without cause. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical and scientific personnel.

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

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

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

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

We plan to implement a number of measures to address the material weaknesses we have identified, including hiring additional accounting personnel or consultants with appropriate expertise as necessary. We intend to complete the implementation of our remediation plan during late 2019 and/or early 2020. However, we cannot assure you that we will be successful in remediating the material weaknesses we identified or that our internal control over financial reporting, as modified, will enable us to identify or avoid material weaknesses in the future.

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

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

***We are exposed to cyber-attacks and data breaches, including the risks and costs associated with protecting our systems and maintaining integrity and security of our business information, as well as personal data of our guests, employees and business partners.***

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

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

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

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

**Risks Related to Ownership of Our Common Stock and This Offering**

***If you purchase shares of common stock in this offering, you will suffer substantial and immediate dilution of your investment.***

You will suffer immediate and substantial dilution in the net tangible book value of the common stock you purchase in this offering. The public offering price of our common stock will be substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our net tangible book value per share after this offering. Based on an assumed public offering price of $● per share, you will experience immediate dilution of $● per share, representing the difference between our pro forma as adjusted net tangible book value per share as of September 30, 2019, after giving effect to this offering. In addition, investors purchasing common stock in this offering will contribute ● % of the total amount invested by stockholders since inception but will only own ● % of the shares of common stock outstanding, assuming no exercise of the underwriters' option to acquire additional common stock in this offering and assuming we issue the number of shares of common stock as set forth on the cover page of this prospectus. To the extent these outstanding securities are ultimately exercised, investors purchasing common stock in this offering will sustain further dilution. See the "Dilution" section of this prospectus for a more detailed description of the dilution to investors participating in the offering.

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

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

- the introduction of technological innovations or new commercial products by our competitors;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- future sales of our common stock by us, our insiders or our other stockholders;
- a negative outcome in any litigation or potential legal proceeding.
- additions and departures of key personnel;
- negative publicity or announcements regarding regulatory developments relating to our products;
- actual or anticipated fluctuations in our financial condition and operating results, including our cash and cash equivalents balance, operating expenses, cash burn rate or revenue levels;
- our filing for protection under federal bankruptcy laws; or
- the other factors described in this "Risk Factors" section.

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

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

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

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

Upon the closing of this offering, our executive officers and directors, combined with our stockholders who owned more than 5% of our outstanding common stock before this offering and their respective affiliates, will, in the aggregate, beneficially own shares representing approximately •% of our outstanding capital stock, assuming no exercise of the underwriters' option to acquire additional common stock in this offering and assuming we issue the number of shares of common stock as set forth on the cover page of this prospectus. As a result, if these stockholders were to choose to act together, they would be able to influence our management and affairs and potentially control the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our assets. These stockholders acquired their shares of common stock (including shares of common stock issuable upon the conversion of preferred stock) for less than the price of the shares of common stock being acquired in this offering, and these stockholders may have interests, with respect to their common stock, that are different from those of investors in this offering and the concentration of voting power among these stockholders may have an adverse effect on the price of our common stock. This concentration of ownership control may adversely affect the market price of our common stock by:

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

See the "Principal Stockholders" section of this prospectus for more information regarding the ownership of our outstanding common stock by our executive officers, directors, principal stockholders and their affiliates.

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

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

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

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. There is no guarantee that our valuation will appreciate in value or even maintain the valuation at which our stockholders have purchased their shares.

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

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

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

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

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

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

***We have broad discretion in the use of the net proceeds from this offering and may not use them effectively, which could affect our results of operations and cause our stock price to decline.***

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the “Use of Proceeds” section of this prospectus and you will not have the opportunity to assess whether the net proceeds are being used appropriately as part of your investment decision. Our management could spend the net proceeds from this offering in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical facts contained in this prospectus are forward-looking statements. In some cases, you can identify forward-looking statements by words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would," or the negative of these words or other comparable terminology. We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in "Risk Factors." In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our use of the net proceeds from this offering;
- our liquidity and working capital requirements, including cash requirements over the next 12 months;
- our ability to obtain funding for our operations;
- our ability to obtain and maintain regulatory approval of PCS-499 and/or our other product candidates;
- our ability to successfully commercialize and market PCS-499 and/or our other product candidates, if approved;
- our ability to contract with third-party suppliers, manufacturers and other service providers and their ability to perform adequately;
- the potential market size, opportunity and growth potential for PCS-499 and/or our other product candidates, if approved;
- our ability to build our own sales and marketing capabilities, or seek collaborative partners, to commercialize PCS-499 and/or our other product candidates, if approved;
- the initiation, timing, progress and results of our pre-clinical studies and clinical trials, and our research and development programs;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- our ability to recruit and enroll suitable patients in our clinical trials; the timing or likelihood of the accomplishment of various scientific, clinical, regulatory filings and approvals and other product development objectives;
- the pricing and reimbursement of our product candidates, if approved;
- the degree of market acceptance of PCS-499 and/or our other product candidates by physicians, patients, third-party payors and others in the medical community;
- the rate and degree of market acceptance of our product candidates, if approved;

- the implementation of our business model, strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- developments relating to our competitors and our industry;
- the accuracy of our estimates regarding expenses, capital requirements and needs for additional financing; and
- our financial performance.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the "Risk Factors" section and elsewhere in this prospectus. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable as of the date of this prospectus, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to new information, actual results or to changes in our expectations, except as required by law.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the Securities and Exchange Commission, or SEC, as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance, and events and circumstances may be materially different from what we expect.

## USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately $● million from the sale of the shares of our common stock in this offering, or approximately $● million, if the underwriters exercise their option to purchase additional shares of common stock in full, based on an assumed public offering price of $ ● per share, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase (decrease) in the assumed public offering price of $● per share, would increase (decrease) the net proceeds to us from this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, by approximately $ ● million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. We may also increase or decrease the number of shares we are offering. An increase (decrease) of 1,000,000 in the number of shares we are offering would increase (decrease) the net proceeds to us from this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, by approximately $● million, assuming no change in the assumed initial public offering price.

We intend to use the net proceeds from this offering as follows:

- approximately $● million to advance the development PCS-499 and to conduct clinical trials for PCS-499 in additional indications;
- approximately $● million to continue the development of HT-100 and/or other product candidates;
- the balance for working capital and other general corporate purposes.

We believe opportunities may exist from time to time to expand our current business through acquisitions or in-licenses of complementary companies, medicines or technologies. While we have no current agreements, commitments or understandings for any specific acquisitions or in-licenses at this time, we may use a portion of the net proceeds for these purposes.

We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements through 2021. With our existing cash and cash equivalents and the net proceeds of this offering, we expect to be able to complete our Phase 2a trial and begin development of HT-100. We have based these estimates on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect. We may satisfy our future cash needs through the sale of equity securities, debt financings, working capital lines of credit, corporate collaborations or license agreements, grant funding, interest income earned on invested cash balances or a combination of one or more of these sources.

Although we currently anticipate that we will use the net proceeds from this offering as described above, there may be circumstances where a reallocation of funds is necessary. Due to the uncertainties inherent in the product development process, it is difficult to estimate with certainty the exact amounts of the net proceeds from this offering that may be used for the above purposes. The amounts and timing of our actual expenditures will depend upon numerous factors, including our sales and marketing and commercialization efforts, demand for our products, if approved, our operating costs and the other factors described under the “Risk Factors” section of this prospectus. Accordingly, our management will have flexibility in applying the net proceeds from this offering. In addition, we might decide to postpone or not pursue clinical trials or pre-clinical activities if the net proceeds from this offering and the other sources of cash are less than expected. An investor will not have the opportunity to evaluate the economic, financial or other information on which we base our decisions on how to use the proceeds.

Pending their use as described above, we plan to invest the net proceeds in short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or guaranteed obligations of the U.S. government.

## MARKET FOR COMMON EQUITY AND DIVIDEND POLICY

**Market Information**

Our common stock is currently traded on the OTCQB tier of the over-the-counter market under the symbol PCSA. Upon the closing of this offering our shares of common stock will be listed for trading on the Nasdaq Market.

**Holders of our Common Stock**

As of December 10, 2019, we had 5,486,362 shares of common stock issued and outstanding (adjusted for the one for seven reverse stock split completed on December ●, 2019) and 195 holders of record of our common stock.

**Transfer Agent**

Corporate Stock Transfer, Inc., Denver, Colorado, is the transfer agent for our common stock.

**Dividend Policy**

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and future earnings, if any, for use in the operation of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any future determination to declare and pay dividends will be made at the discretion of our board of directors and will depend on various factors, including applicable laws, our results of operations, our financial condition, our capital requirements, general business conditions, our future prospects and other factors that our board of directors may deem relevant. Our ability to pay cash dividends on our capital stock in the future may also be limited by the terms of any preferred securities we may issue or agreements governing any additional indebtedness we may incur. Investors should not purchase our common stock with the expectation of receiving cash dividends.

## CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of September 30, 2019 as follows:

- on an actual basis;
- on pro forma bases to reflect the issuance of $745,000 of principal amount of 8% Senior Convertible Notes to accredited investors on November 30, 2019 for aggregate net proceeds of $745,000;
- on a pro forma as adjusted basis to give further effect to the sale by us of ● shares of our common stock in this offering, at an assumed public offering price of $● per share and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Our capitalization following the completion of this offering will be adjusted based on the actual public offering price and other terms of the offering determined at pricing. You should read this information together with our audited financial statements and related notes appearing elsewhere in this prospectus and the information set forth under the "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections.

| | Actual | Pro forma | Pro forma, as adjusted |
|---|---|---|---|
| Cash and cash equivalents | $ 504,302 | $ 1,249,302 | $ ●(1) |
| 8% Senior Convertible Notes | - | 745,000 | ● |
| Preferred stock, $0.0001 par value: 1,000,000 shares authorized, no shares issued or outstanding | - | - | - |
| Common stock $0.0001 par value: 100,000,000 shares authorized, 5,486,362 shares issued and outstanding, actual; 5,486,362 shares issued and outstanding, pro forma; and ● shares issued and outstanding pro forma, as adjusted (2) | 549 | ● | ● |
| Additional paid-in capital(2) | 18,877,697 | ● | ● |
| Accumulated equity | (10,207,567) | ● | ● |
| Total stockholders' equity | (8,670,679) | ● | ● |
| Total capitalization | $ 10,821,293 | $ ● | ● |

(1) The pro forma as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing. A $1.00 increase (decrease) in the assumed public offering price of $● per share would increase (decrease) the amount of cash and cash equivalents, additional paid-in capital, total stockholders' equity and total capitalization on a pro forma as adjusted basis by approximately $● million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each increase (decrease) of 1,000,000 shares offered by us would increase (decrease) cash and cash equivalents, total stockholders' equity (deficit) and total capitalization on a pro forma as adjusted basis by approximately $● million, assuming the assumed public offering price of $● per share, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(2) The number of shares of our common stock outstanding as of September 30, 2019 has been adjusted for the one for seven reverse stock split completed on December ●, 2019 and excludes, as of September 30, 2019, the following, which has also been adjusted for the one for seven reverse stock split:

- 137,033 shares of our common stock issuable upon the exercise of outstanding stock options issued under the Processa Pharmaceuticals, Inc. 2019 Omnibus Incentive Plan, having a weighted-average exercise price of $17.19 per share, of which 12,950 options have vested, having a weighted-average exercise price of $16.80 per share;
- 362,967 shares of common stock reserved for issuance pursuant to future awards under the Processa Pharmaceuticals, Inc. 2019 Omnibus Incentive Plan;
- 47,772 shares of our common stock issuable upon the exercise of outstanding non-qualified stock options granted to our Chief Financial Officer on September 1, 2018, having an exercise price of $19.88 per share, of which 13,872 shares have vested with an exercise price of $19.88 per share;
- 52,171 shares of common stock issuable upon the conversion of $745,000 in principal amount of outstanding 8% Senior Convertible Notes, assuming a conversion price of $14.28 per share, and;
- 477,579 shares of common stock issuable upon exercise of the outstanding stock purchase warrants, all of which are exercisable, having a weighted average exercise price of $18.27 per share.

## DILUTION

If you invest in our common stock in this offering, your interest will immediately be diluted to the extent of the difference between the public offering price per share of our common stock in this offering and the as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book value is the amount of our total tangible assets less our total liabilities. Our historical net tangible book value per share is our historical net tangible book value divided by the number of shares of common stock outstanding as of September 30, 2019 (adjusted for the one for seven reverse stock split completed on December ●, 2019). Our historical net tangible book value as of September 30, 2019, was $521,587, or $0.10 per share of common stock.

Our pro forma net tangible book value as of September 30, 2019 gives effect to the conversion of all the 8% Senior Convertible Notes into an aggregate of ● shares of our common stock. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding at September 30, 2019, after giving effect to the conversion of all the 8% Senior Convertible Notes into an aggregate of ● shares of our common stock on completion of this offering.

Our as adjusted net tangible book value is our net tangible book value after giving further effect to the sale of ● shares of our common stock in this offering at an assumed public offering price of $● per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

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

| | | |
|---|---|---|
| Assumed public offering price per share | $ | ● |
| Historical net tangible book value per share as of September 30, 2019 | $ | 0.10 |
| Pro forma change in net tangible book value per share as of September 30, 2019 | $ | ● |
| Pro forma net tangible book value per share as of September 30, 2019 | $ | ● |
| Increase in net tangible book value per share from new investors participating in this offering | $ | ● |
| Pro forma As adjusted net tangible book value per share after this offering | $ | ● |
| Dilution in net tangible book value per share to new investors participating in this offering | $ | ● |

The information discussed above is illustrative only, and the dilution information following this offering will be adjusted based on the actual public offering price and other terms of this offering determined at pricing. A $1.00 increase (decrease) in the assumed public offering price of $● per share would increase (decrease) the net tangible book value by $● per share and the dilution to investors participating in this offering by $● per share, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated expenses payable by us.

We may also increase or decrease the number of shares we are offering. An increase of 1,000,000 shares offered by us would increase the net tangible book value by $● per share and decrease the dilution to investors participating in this offering by $● per share, assuming the assumed public offering price of $● per share, remains the same and after deducting the estimated underwriting discounts and commissions and estimated expenses payable by us. Similarly, a decrease of 1,000,000 shares offered by us would decrease the net tangible book value by $● per share and increase the dilution to investors participating in this offering by $● per share, assuming the assumed public offering price of $● per share, remains the same and after deducting the estimated underwriting discounts and commissions and estimated expenses payable by us.

If the underwriters exercise their option to purchase additional shares of common stock in full, the net tangible book value as of September 30, 2019, will increase to $●, or $ ● per share, representing an increase to existing stockholders of $● per share, and there will be an immediate dilution of $● per share to investors participating in this offering.

The following table summarizes as of September 30, 2019, on the net tangible book value basis as described above, the differences between the number of shares of common stock purchased from us, the total consideration and the average price per share paid by existing stockholders and by investors participating in this offering, before deducting the estimated underwriting discounts and commissions and estimated offering expenses, at an assumed initial public offering price of $● per share.

| | Shares Purchased | | Total Consideration | | Average Price/ Share |
|---|---|---|---|---|---|
| | Number | Percent | Amount | Percent | |
| Existing stockholders | ● | ●% | $ ● | ●% | $ ● |
| Investors participating in this offering | ● | ●% | $ ● | ●% | $ ● |
| Total | ● | ●% | $ ● | ●% | $ ● |

Each $1.00 increase (decrease) in the assumed public offering price of $● per share would increase (decrease) the total consideration paid by investors participating in this offering by $●, and increase (decrease) the percentage of total consideration paid by investors participating in this offering by approximately ●%, assuming that the number of shares offered by us, as listed on the cover page of this prospectus, remains the same. Similarly, each increase (decrease) of 1,000,000 shares in the number of shares of common stock offered by us would increase (decrease) the total consideration paid by investors participating in this offering by $● and increase (decrease) the percentage of total consideration paid by investors participating in this offering by approximately ●% assuming that the assumed public offering price of $● per share price remains the same.

The table above assumes no exercise of the underwriters' option to purchase additional shares of common stock in this offering. If the underwriters' option to purchase additional shares is exercised in full, the number of shares of our common stock held by existing stockholders would be reduced to ●% of the total number of shares of our common stock outstanding after this offering, and the number of shares of our common stock held by investors participating in the offering would be increased to ●% of the total number of shares of our common stock outstanding after this offering.

The number of shares of common stock to be outstanding after this offering has been adjusted for the one for seven reverse stock split completed on December ●, 2019, is based on an aggregate of 5,468,362 shares of common stock outstanding as of September 30, 2019 and excludes the following:

- 137,033 shares of our common stock issuable upon the exercise of outstanding stock options issued under the Processa Pharmaceuticals, Inc. 2019 Omnibus Incentive Plan, having a weighted-average exercise price of $17.19 per share, of which 12,950 options have vested, having a weighted-average exercise price of $16.80 per share;
- 362,967 shares of common stock reserved for issuance pursuant to future awards under the Processa Pharmaceuticals, Inc. 2019 Omnibus Incentive Plan;
- 47,772 shares of our common stock issuable upon the exercise of outstanding non-qualified stock options granted to our Chief Financial Officer on September 1, 2018, having an exercise price of $19.88 per share, of which 13,872 shares have vested with an exercise price of $19.88 per share;
- 52,171 shares of common stock issuable upon the conversion of $745,000 of outstanding 8% Senior Convertible Notes, assuming a conversion price of $14.28 per share, and;
- 477,579 shares of common stock issuable upon exercise of the outstanding stock purchase warrants, all of which are exercisable, having a weighted average exercise price of $18.27 per share.

To the extent that any options are exercised, new options or other securities are issued under our equity incentive plans, or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of such securities could result in further dilution to our stockholders.

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

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

*We completed a one for seven reverse stock split of our common stock on December ●, 2019. Unless otherwise indicated, all share amounts (and corresponding exercise and conversion prices of derivative securities) in this prospectus have been retroactively adjusted to give effect to this reverse stock split (subject to rounding up fractional shares), except for the financial statements and notes thereto.*

**Overview**

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

On October 4, 2017, we acquired all the net assets of Promet Therapeutics, LLC ("Promet"), a private Delaware limited liability company, including the rights to the CoNCERT Agreement, in exchange for 4,535,035 shares of our common stock. Immediately following the transaction, the former equity holders of Promet owned approximately 84% and held approximately 6% of the shares for the benefit of CoNCERT in relation to the CoNCERT contribution of the license to Processa as part of the Section 351 transaction, and our stockholders immediately prior to the transaction owned approximately 10% of our common stock. On ●, Promet distributed 4,236,420 shares of the common stock it held to its partners. We traded on the OTC Pink Marketplace until December 8, 2018 when we listed our common stock on the OTCQB.

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

We have a limited operating history as we were formed on March 29, 2011. Since that date, our operations have focused on acquiring the rights to PCS-499, organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and conducting clinical trials. We do not have any drug candidates approved for sale and have not yet generated any revenue from drug sales. We have funded our operations through the private sale of equity and equity-linked securities to accredited investors. Since inception, we have incurred operating losses. As of September 30, 2019, we had an accumulated deficit of $10.2 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will continue to increase in connection with our ongoing activities, as we:

- continue to invest in the development of PCS-499 for the treatment of NL;
- manufacture our drug candidate;
- begin developing HT-100;
- hire additional research and development and general and administrative personnel;
- maintain, expand and protect our intellectual property portfolio;
- evaluate opportunities for the development of additional drug candidates; and
- incur additional costs associated with operating as a public company.

**Going Concern and Management's Plan**

Our condensed consolidated financial statements are prepared using U.S. GAAP and are based on the assumption that we will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. We face certain risks and uncertainties that are present in many emerging growth companies regarding product development and commercialization, limited working capital, recurring losses and negative cash flow from operations, future profitability, ability to obtain future capital, protection of patents, technologies and property rights, competition, rapid technological change, navigating the domestic and major foreign markets' regulatory and clinical environment, recruiting and retaining key personnel, dependence on third party manufacturing organizations, third party collaboration and licensing agreements, lack of sales and marketing activities and no customers or pharmaceutical products to sell or distribute. Without consideration of the closing of our $745,000 8% Senior Notes bridge financing and the successful close of this offering, these risks and other factors raise substantial doubt about our ability to continue as a going concern.

We have relied exclusively on private placements with a small group of accredited investors to finance our business and operations. As described in more detail below, we recently entered into two line of credit agreements providing a revolving commitment of an aggregate of up to $1.4 million but have not drawn any amounts as of the date of this report. We have not had any revenue since our inception and we do not currently have any revenue under contract or any immediate sales prospects. For the nine months ended September 30, 2019, we incurred a net loss from continuing operations of $2.6 million and used $1.2 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. At September 30, 2019, we had cash and cash equivalents totaling $504,302.

On September 20, 2019, we entered into two separate Line of Credit Agreements ("LOC Agreements") with DKBK Enterprises, LLC ("DKBK") and current shareholder CorLyst, LLC ("CorLyst"), both related parties ("Lenders"), which provide a revolving commitment of up to $700,000 each ($1.4 million total). Under the LOC Agreements, all funds borrowed will bear an 8% annual interest rate. The lenders have the right to convert all or any portion of the debt and interest into Processa common shares. Our Chief Executive Officer (CEO) is also the Chief Executive Officer and Managing Member of both Lenders. CorLyst beneficially owns 401,401 shares of Processa common stock, representing approximately 7.2% of the Company's outstanding shares of voting capital stock. We have not drawn any amounts under these LOC agreements.

In connection with the LOC Agreements, we amended the existing pledge agreement with PoC Capital on September 30, 2019 to reduce the committed funds from $1.8 million to $900,000, which has now been paid in full. As part of the original pledge agreement, we issued 113,279 shares of common stock and 113,279 warrants to purchase shares of common stock to PoC Capital but held 56,639 shares and warrants to purchase 56,639 shares as collateral until certain payment milestones were met. PoC Capital forfeited the pledged collateral in the amended agreement and the shares have been reissued to Processa and will be retired.

On November 30, 2019 we closed our bridge financing and issued $745,000 of 8% Senior Convertible Notes ("8% Senior Notes") to accredited investors. In order to preserve cash, we have also delayed some of our cash outflows, primarily through the deferred payment of salaries ($48,840 which has been accrued and included in accrued expenses during the three and nine months ended September 30, 2019) until such time as we have raised sufficient funding.

We believe that the net proceeds from this offering, together with our existing cash, will enable us to fund our operating expenses and capital expenditure requirements through 2021. With our existing cash and the net proceeds of this offering, we expect to be able to complete our Phase 2a trial and begin development of HT-100. We have based these estimates on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect.

**Status of our Phase 2a Clinical Trial in Necrobiosis Lipoidica**

Our lead product, PCS-499 is an oral tablet that is a deuterated analog of one of the major metabolites of pentoxifylline (Trental®). The advantage of PCS-499 is that it potentially may work in many conditions because it has multiple pharmacological targets it affects that are important in the treatment of these conditions. Based on its pharmacological activity, we have identified multiple unmet medical need conditions where the use of PCS-499 may result in clinical efficacy. The lead indication currently under development for PCS-499 is Necrobiosis Lipoidica (NL). NL is a chronic, disfiguring condition affecting the skin and the tissue under the skin typically on the lower extremities with no currently approved FDA treatments. NL presents more commonly in women than in men and ulceration can occur in approximately 30% of NL patients. More severe complications can occur, such as deep tissue infections and osteonecrosis threatening life of the limb. Approximately 74,000 - 185,000 people in the United States and more than 200,000 – 500,000 people outside the United States are affected by NL.

On June 22, 2018, the FDA granted orphan-drug designation to PCS-499 for the treatment of NL. On September 28, 2018, the FDA cleared our IND for PCS-499 in NL such that we could move forward with the Phase 2a safety-dose tolerability trial. We dosed our first NL patient in this Phase 2a clinical trial on January 29, 2019. On August 23, 2019, our study was fully enrolled as the twelfth patient was dosed. The main objective of the trial is to evaluate the safety and tolerability of PCS-499 in patients with NL. We expect the safety and efficacy data collected to provide information for the design of future clinical trials. Based on toxicology studies and healthy human volunteer studies, Processa and the FDA agreed that a PCS-499 dose of 1.8 grams/day would be the highest dose administered to NL patients in this Phase 2 trial. As anticipated, the PCS-499 dose of 1.8 grams/day, 50% greater than the maximum tolerated dose of pentoxifylline, appears to be well tolerated with no serious adverse events reported. Twelve patients have been dosed with nine patients on treatment for at least four months, seven patients on treatment for at least six months, and two patients on treatment for at least nine months. Currently, nine patients remain in the study. To date, six patients dosed at 1.8 g/day have reported only mild adverse events related to the treatment, which occurred mostly in the first month of treatment and were quickly resolved. As expected, gastrointestinal or central nervous system (CNS) adverse events were reported most often.

Our findings as of December 4, 2019, based on our early efficacy data, showed that the two patients in the trial with more severe ulcerated NL (both ulcerated patients had ulcers for more than two months prior to dosing) had the ulcers fully closed after two and nine months after starting the trial, respectively. In addition, while in the trial, one of the ulcerated patients developed small ulcers at other sites as a result of contact trauma to the site and these ulcers resolved within one month. Ten patients presented with mild to moderate NL and no ulceration. These patients have shown a slight improvement but not as dramatic as the more serious ulcerated patients. Based on the literature and clinical experience, approximately 30% of the patients with NL are expected to have open ulcers with the ulceration naturally healing in less than 20% of these patients.

The degeneration of tissue occurring at the NL lesion site is caused by a number of pathophysiological changes, which has made it extremely difficult to develop effective treatments for this condition. PCS-499 may provide a solution since PCS-499 and its metabolites affect a number of biological pathways, several of which contribute to the pathophysiology associated with NL. We are continually evaluating the data we receive.

We plan to request a meeting with the FDA before the end of 2019 to further discuss the development of PCS-499, including the next clinical trial.

**License Agreement for HT-100**

On August 29, 2019, we entered into an exclusive license agreement with Akashi Therapeutics, Inc. (“Akashi”) to develop and commercialize an anti-fibrotic, anti-inflammatory drug, HT-100. As partial consideration for the licenses, we paid $10,000 to Akashi upon full execution of the license agreement. This upfront payment was expensed as a research and development cost. As additional consideration, we will pay Akashi development and regulatory milestone payments upon the achievement of certain milestones, which primarily consist of having a drug indication approved by a regulatory authority in the United States or another country. In addition, we must pay Akashi one-time sales milestone payments based on the achievement during a calendar year of one or more thresholds for annual sales made and pay royalties based on annual licensed sales. We are also required to split any milestone payments we receive with Akashi based on any sub-license agreement we may enter into.

In previous clinical trials in Duchenne Muscular Dystrophy (DMD), HT-100 showed promising improvement in the muscle strength of non-ambulant pediatric patients. Although the FDA placed a clinical hold on the DMD trial after a serious adverse event in a pediatric patient, FDA has removed the drug off clinical hold and defined how HT-100 can resume clinical trials in DMD. Once we have obtained adequate funding, we plan to develop HT-100 in rare adult fibrotic related diseases such as focal segmental glomerulosclerosis, idiopathic pulmonary fibrosis or Scleroderma.

**Results of Operations**

***Comparison of the Three and Nine Months Ended September 30, 2019 and 2018***

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

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|---|---|---|---|---|---|---|
| | 2019 | 2018 | Change | 2019 | 2018 | Change |
| Operating Expenses | | | | | | |
| Research and development expenses | $ 584,979 | $ 611,612 | $ (26,633) | $ 1,804,169 | $ 2,477,481 | $ (673,312) |
| General and administrative expenses | 419,028 | 451,359 | (32,331) | 1,219,329 | 1,305,511 | (86,182) |
| Total operating expenses | 1,004,007 | 1,062,971 | (58,964) | 3,023,498 | 3,782,992 | (759,494) |
| Other Income (Expense) | | | | | | |
| Interest Expense | (2,271) | (8,323) | 6,052 | (12,973) | (154,377) | 141,404 |
| Interest Income | 1,503 | 6,457 | (4,954) | 10,886 | 10,163 | 723 |
| Total other income (expense) | (768) | (1,866) | 1,098 | (2,087) | (144,214) | 142,127 |
| Net Operating Loss Before Income Tax Benefit | 1,004,775 | 1,064,837 | (60,062) | 3,025,585 | 3,927,206 | (901,621) |
| Income Tax Benefit | (141,251) | (212,015) | 70,764 | (442,152) | (771,332) | 329,180 |
| Net Loss | $ 863,524 | $ 852,822 | $ 10,702 | $ 2,583,433 | $ 3,155,874 | $ (572,441) |

*Revenues*.

We had no revenue during the three and nine months ended September 30, 2019 and 2018. We do not currently have any revenue under contract or any immediate sales prospects.

*Research and Development Expenses.*

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

During the three months ended September 30, 2019 and 2018, we incurred total research and development expenses of approximately $585,000 and $612,000 respectively, for the continued development and testing of our lead product, PCS-499. Research and development expenses were approximately $1.8 million and $2.5 million for the nine months ended September 30, 2019 and 2018, respectively. Costs for the three and nine months ended September 30, 2019 and 2018 were as follows:

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Amortization of intangible assets | $ 198,832 | $ 200,256 | $ 596,496 | $ 422,814 |
| Research and development salaries and benefits | 245,053 | 156,098 | 564,935 | 494,274 |
| Preclinical, clinical trial and other costs | 141,094 | 255,258 | 642,738 | 1,560,393 |
| Total | $ 584,979 | $ 611,612 | $ 1,804,169 | $ 2,477,481 |

Overall, during the three months ended September 30, 2019, our research and development costs decreased by $26,633 when compared to the three months ended September 30, 2018. As a result of exercising the CoNCERT license and option agreement for PCS-499 in March 2018, and the purchase of a software license, we recognized $198,832 and $200,256 of amortization expense during the three months ended September 30, 2019 and 2018, respectively. The decrease in amortization expense of approximately $1,400 was from the software license purchased in the second quarter of 2018, which began recognition in the third quarter of 2018. Our research and development salaries, stock-based compensation and benefits increased by approximately $89,000 for the three months ended September 30, 2019 when compared to the same period in 2018 due to the stock-based compensation expense. Much of the reduction related to lower research and development expenses for preclinical, clinical trial and other costs of $117,000 during the three months ended September 30, 2019 when compared to the same period in 2018. During the three months ended September 30, 2019, our focus was on enrolling patients in our trial, along with other trial costs, including providing doses of PCS-499 to participants in our Phase 2a clinical trial in NL. In contrast, during the same period in 2018, we experienced significantly higher costs related to a Phase 1 trial for PCS-499 and costs related to having to establishing a new site to contract manufacture the tablets of PCS-499 needed for our clinical trial since the original CoNCERT tablet manufacturing site could no longer be used.

During the nine months ended September 30, 2019, our research and development costs decreased by $673,312 as compared to the nine months ended September 30, 2018. The decrease is due to a reduction of approximately $918,000 in preclinical, clinical trial, and other costs. The decrease was offset by an increase of approximately $71,000 in salaries, benefits, and other related payroll costs and an increase of approximately $174,000 in amortization expense for the software license and CoNCERT license agreement when comparing the nine months ended September 30, 2019 to the same period in 2018.

During the year ended December 31, 2018, we made payments to our CRO related to our Phase 2a trial of approximately $239,000. We have accounted for these payments as either a prepaid expense or a research and development expense depending on whether the related service has been provided. During the nine months ended September 30, 2019, PoC Capital made payments directly to our CRO totaling $689,168 for amounts invoiced. PoC Capital also repaid us $210,832 for clinical trial expenses we previously paid to our CRO, $180,119 of which is included in Prepaid and Other on our condensed consolidated balance sheet at September 30, 2019. We amended the existing pledge agreement with PoC Capital on September 30, 2019 to reduce the committed funds from $1.8 million to $900,000, which has now been paid in full. As part of the original pledge agreement, we issued 113,279 shares of common stock and warrants to purchase 113,279 shares of common stock to PoC Capital but held 56,639 shares and warrants to purchase 56,639 shares as collateral until certain payment milestones were met. PoC Capital forfeited the pledged collateral in the amended agreement and the shares have been reissued to Processa and will be retired.

We incurred $435,544 in costs related to our Phase 2a trial during the nine months ended September 30, 2019 and expect to spend approximately an additional $113,400 during the remainder of 2019 and approximately $711,000 thereafter through 2021 to complete our current trial. We believe, based on our estimates, the cost of our current Phase 2a trial to be approximately $1.5 to 1.6 million. PoC Capital paid for $900,000 of the clinical trial costs, and we will cover the remaining $600,000 to $700,000 with funds received from the sale of our 8% Senior Notes and our LOC Agreements, as necessary. The funding necessary to bring a drug candidate to market is, however, subject to numerous uncertainties. Once a drug candidate is identified, the further development of that drug candidate can be halted or abandoned at any time due to a number of factors. These factors include, but are not limited to, funding constraints, safety or a change in market demand. For each of our drug candidate programs, we periodically assess the scientific progress and merits of the programs to determine if continued research and development is economically viable. Certain of our programs may be terminated due to the lack of scientific progress and lack of prospects for ultimate commercialization. We anticipate our research and development costs to increase in the future as we continue our Phase 2a clinical trial activities for NL in 2019 and into 2020.

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

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

*General and Administrative Expenses.*

Our general and administrative expenses for the three months ended September 30, 2019 decreased by $32,331 to $419,028 from $451,359 for the three months ended September 30, 2018. The decrease related mostly to a reduction in professional fees of approximately $198,000 and in office and travel expenses of approximately $8,000. The decrease was offset by increased payroll and related costs of approximately $143,000 (including stock-based compensation of $180,422) as we built our finance team and hired our Chief Financial Officer and Director of Finance and Accounting in the second half of 2018 to support our growth and public company reporting and compliance requirements. We also experienced increases of approximately $25,000 in other administrative costs such as insurance, rent and repairs and maintenance expenses. Our tax expense also increased by approximately $6,000 due to our 2018 and estimated 2019 Delaware franchise taxes. Franchise tax in Delaware is calculated using the number of shares of Common Stock and Preferred Stock that the Company is authorized to issue. We were authorized to issue 350,000,000 shares of Common Stock and 10,000,000 shares of Preferred Stock, which is disproportionately large in relation to our outstanding shares. This resulted in a high tax bill for 2018 and requires us to pay quarterly estimated taxes for 2019. We have amended our Certificate of Incorporation to reduce our authority to issue 100,000,000 shares of Common Stock and 1,000,000 shares of Preferred Stock, thereby reducing our future Delaware franchise tax.

For the nine months ended September 30, 2019, general and administrative expenses decreased by $86,182 to $1,219,329 from $1,305,511 for the nine months ended September 30, 2018. The decrease related to a cybersecurity fraud loss of approximately $144,000, for which we did not have insurance coverage, which occurred during the nine months ended September 30, 2018. We also saw reductions in professional fees for legal, accounting, advisory and consulting costs of approximately $400,000. The overall decrease in our general and administrative expenses during the nine months ended September 30, 2019 was also offset by increases of approximately $352,000 in payroll and related costs (including stock-based compensation of $302,053) and approximately $106,000 in administrative costs such as insurance, rent, office, taxes and travel expenses.

Reimbursable expenses from CorLyst of $26,594 and $79,058 for rent and other costs during the three and nine months ended September 30, 2019 were comparable for the same periods in 2018.

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

*Interest Expense.*

Interest expense was $2,271 and $8,323 for the three months ended September 30, 2019 and 2018, respectively, and $12,973 and $154,377 for the nine months ended September 30, 2019 and 2018, respectively, related to our $2.58 million of Senior Convertible Notes sold in 2017. In May 2018, $2.35 million of these Senior Convertible Notes were converted into shares of our common stock and stock purchase warrants. On July 2, 2019, the remaining $230,000 was converted into shares of common stock and stock purchase warrants. Included in interest expense is the amortization of debt issuance costs totaling $0 and $3,709 for the three months ended September 30, 2019 and 2018, respectively, and $0 and $64,841 for the nine months ended September 30, 2019 and 2018, respectively.

*Interest Income.*

Interest income was $1,503 and $6,457 for the three months ended September 30, 2019 and 2018, respectively, and $10,886 and $10,163 for the nine months ended September 30, 2019 and 2018, respectively. Interest income represents interest earned on money market funds and certificates of deposit.

*Income Tax Benefit.*

An income tax benefit of $141,251 and $212,015 was recognized for the three months ended September 30, 2019 and 2018, respectively, and $442,152 and $771,332 for the nine months ended September 30, 2019 and 2018, respectively. When we acquired CoNCERT's license and "Know-How" in exchange for Processa Stock, we created a deferred tax liability. Each year, the deferred tax liability is decreased by the amortization of the intangible asset for the current period. Additionally, the liability is being offset for the deferred tax assets resulting from our net taxable operating losses. Our taxable net operating loss for 2019 is expected to be $1.3 million less than that of 2018 as we focus on the Phase 2a clinical trial study and decrease administrative costs such as professional fees. As a result, the income tax benefit recognized in the three and nine months ended September 30, 2019 is $70,764 and $329,180 less than the comparable periods in 2018, respectively.

***Comparison of the year ended December 31, 2018 and 2017***

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

| | Years Ended December 31, | |
|---|---|---|
| | 2018 | 2017 |
| Operating expenses: | | |
| Research and development | $ 3,085,317 | $ 964,164 |
| General and administrative | 1,439,623 | 838,269 |
| Loss from operations | (4,524,940) | (1,802,433) |
| Other income (expense): | | |
| Interest expense, net | (142,908) | (53,882) |
| Net loss before income tax benefit | (4,677,848) | (1,856,315) |
| Income tax benefit | 902,801 | — |
| Net loss | $ (3,765,047) | $ (1,856,315) |

*Revenues*.

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

*Research and Development Expenses.*

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

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

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

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

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

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

As we noted above, we have had significant events related to our continued development of PCS-499, including:

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

As a result of exercising the CoNCERT license and option agreement for PCS-499 in March 2018, and the purchase of a software license, we recognized $621,647 of amortization expense during the year ended December 31, 2018. We had no similar expense in 2017. During 2018, we completed a Phase 1 study to evaluate the safety and pharmacokinetics of single and optional multiple dosing regimens of modified release ("MR") formulations of PCS-499 compared to Trental® (pentoxifylline) administered to healthy subjects. We also incurred costs to establish a new site to contract manufacture the tablets of PCS-499 needed for our clinical trial since the original CoNCERT tablet manufacturing site could no longer be used. Our research and development salaries and benefits increased by $129,968 for the year ended December 31, 2018 when compared to the same period in 2017 related to an increase in full-time equivalent staff and related staff costs. We recognized higher research and development expenses for preclinical, clinical trial and other costs of $1,369,538 during the year ended December 31, 2018 when compared to the same period in 2017 due to the completion of our Phase 1 pharmacokinetics study described above, the scaling up of the manufacture of clinical trial material we will need for the Phase 2a clinical trial for NL, beginning our Phase 2a clinical study in fourth quarter of 2018, and for other research and development costs that we incurred.

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

We anticipate our research and development costs to increase in the future as we continue our Phase 2a clinical trial activities for NL in 2019 and 2020. We incurred $519,531 during the year ended December 31, 2018 and $435,544 during the nine months ended September 30, 2019 in costs related to our Phase 2a trial. We expect to spend approximately an additional $113,400 during the remainder of 2019 and approximately $711,000 through 2021 to complete our current trial. We anticipate the cost of our current Phase 2a trial to be approximately $1.5 to $1.6 million. PoC Capital paid $900,000 of the clinical trial costs, and we will cover the remaining $600,000 to $700,000 with funds received from the sale of our 8% Senior Notes and our LOC Agreements, as necessary. The funding necessary to bring a drug candidate to market is, however, subject to numerous uncertainties. Once a drug candidate is identified, the further development of that drug candidate can be halted or abandoned at any time due to a number of factors. These factors include, but are not limited to, funding constraints, safety or a change in market demand. For each of our drug candidate programs, we periodically assess the scientific progress and merits of the programs to determine if continued research and development is economically viable. Certain of our programs may be terminated due to the lack of scientific progress and lack of prospects for ultimate commercialization.

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

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

*General and Administrative Expenses.*

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

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

*Interest Expense.*

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

*Interest Income.*

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

*Income Tax Benefit.*

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

Prior to the asset purchase transaction on October 4, 2017, Promet was treated as a partnership for federal income tax purposes and thus was not subject to income taxes at the entity level. Therefore, no provision/benefit or liability for income taxes was included in the consolidated financial statements through October 4, 2017.

**Financial Condition**

At September 30, 2019, we had $504,302 in cash. Net cash used in our operating activities during the nine months ended September 30, 2019 totaled $1,236,659 compared to $3,243,938 for the nine months ended September 30, 2018.

Our total assets decreased by approximately $1.7 million to $10.8 million at September 30, 2019 compared to $12.5 million at December 31, 2018. This decrease is a result of the operating costs we have incurred during the nine months ended September 30, 2019, net of operating costs funded through the stock subscription receivable, offset by the recording of right of use assets in conjunction with the adoption of ASC 842.

At September 30, 2019, our total liabilities, not including the impact of deferred income taxes, decreased by $187,284 to $458,420 when compared to $645,704 at December 31, 2018. This decrease is due primarily to the conversion of Senior Convertible Notes and changes in accounts payable, offset by the recognition of operating lease liabilities in accordance with the adoption of ASC 842 and prepaid reimbursements.

We had $0 and $230,000 of Senior Convertible Notes outstanding at September 30, 2019 and 2018, respectively. The Senior Convertible Notes outstanding at September 30, 2018 were held by Canadian investors that, although qualifying for automatic and mandatory conversion, could not be converted until the Alberta Securities Commission released us from a cease trade order, which predated our merger with HeatWurx, and permitted us to issue common stock units (consisting of shares of our common stock and stock purchase warrants) to these Canadian investors. In June 2019, the Alberta Securities Commission released the cease trade order and assessed us a $10,000 fine. On July 2, 2019, we converted the principal and related accrued interest of approximately $259,000 into 18,106 shares of common stock and 18,106 stock purchase warrants.

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

**Liquidity and Capital Resources**

To date, we have funded our business and operations primarily through the private placement of equity securities and senior secured convertible notes. On November 30, 2019, we closed our bridge financing and issued $745,000 of 8% Senior Convertible Notes (“8% Senior Notes”) to accredited investors. In order to preserve cash, we have also delayed some of our cash outflows, primarily through the deferred payment of salaries ($48,840 which has been accrued and included in accrued expenses during the three and nine months ended September 30, 2019) until such time as we have raised sufficient funding.

At September 30, 2019, we had $504,302 in cash and cash equivalents compared to $1.7 million at December 31, 2018. During the nine months ended September 30, 2019, PoC Capital made payments directly to our CRO totaling $689,168 for amounts invoiced. PoC Capital also repaid us $210,832 for clinical trial expenses we previously paid to our CRO, $180,119 of which is included in Prepaid and Other on our condensed consolidated balance sheet at September 30, 2019.

On September 20, 2019, we entered into two separate LOC Agreements” with DKBK and current shareholder CorLyst, both related parties, which provide a revolving commitment of up to $700,000 each ($1.4 million total). Under the LOC Agreements, all funds borrowed will bear an 8% annual interest rate. We have not drawn any amounts under these LOC Agreements.

In connection with the LOC Agreements, we amended the existing pledge agreement with PoC Capital on September 30, 2019 to reduce the amount committed from $1.8 million to $900,000, which has now been paid in full. As part of the original pledge agreement, we issued 113,279 shares of common stock and warrants to purchase 113,279 shares of common stock to PoC Capital but held 56,639 shares and warrants to purchase 56,639 shares as collateral until certain payment milestones were met. PoC Capital forfeited the pledged collateral in the amended agreement. We anticipate the total cost to fund our current Phase 2a clinical trial of PCS-499 for patients with NL to be between $1.5 to $1.6 million. We will fund the remaining $600,000 to $700,000 with funds received from the sale of our 8% Senior Notes and our LOC Agreements, as necessary.

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

- the timing and extent of spending on our research and development efforts, including with respect to 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.

We believe that the net proceeds from this offering, together with our existing cash, will enable us to fund our operating expenses and capital expenditure requirements through 2021. With our existing cash and depending on the amount of the net proceeds from this offering, we expect to be able to complete our Phase 2a trial and begin development of HT-100 and/or other product candidates. We have based these estimates on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect.

**Cash Flows**

The following table sets forth our sources and uses of cash and cash equivalents for the nine months ended September 30, 2019 and 2018:

| | Nine months ended September 30, | |
|---|---|---|
| | 2019 | 2018 |
| Net cash provided by (used in): | | |
| Operating activities | $ (1,236,659) | $ (3,243,938) |
| Investing activities | - | (22,282) |
| Financing activities | - | 2,843,014 |
| Net increase in cash and cash equivalents | $ (1,236,659) | $ (423,206) |

*Net cash used in operating activities*

We used net cash in our operating activities of $1,236,659 and $3,243,938 during the nine months ended September 30, 2019 and 2018, respectively. The decrease in cash used in operating activities in 2019 compared to the comparable period in 2018 was related to a decreased amount of direct cash costs incurred. Our net loss for the nine months ended September 30, 2019 was $572,441 less than the comparable period in 2018. This was due primarily to our focus on PCS-499 leading to an overall reduction in our research and development expenses. The cash used in operating activities for the nine months ended September 30, 2019 was further reduced as PoC Capital made payments directly to our CRO totaling $689,168 for amounts invoiced. PoC Capital also repaid us $210,832 for clinical trial expenses we previously paid to our CRO. We also incurred amortization expense of $596,496 (versus $422,814 for the comparable period in 2018) and $394,164 of stock-based compensation (versus $50,528 for the comparable period in 2018) during the nine months ended September 30, 2019. During the nine months ended September 30, 2018, we incurred a one-time cybersecurity fraud loss of $144,200 in January 2018, which was recognized in general and administrative expenses.

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

*Net cash used in investing activities*

We had no cash sources or uses for investing activities during the nine months ended September 30, 2019. Net cash used during the nine months ended September 30, 2018 was $22,282 for transaction costs related to the exercise of the option agreement with CoNCERT and for the purchase of a software license.

*Net cash provided by financing activities*

We had no cash sources or uses for financing activities during the nine months ended September 30, 2019. Net cash provided from financing activities was approximately $2.8 million for the nine months ended September 30, 2018.

**Funding Requirements**

We believe that the net proceeds from this offering, together with our existing cash, will enable us to fund our operating expenses and capital expenditure requirements through 2021. With our existing cash and the net proceeds of this offering, we expect to be able to complete our Phase 2a trial and begin development of HT-100 We have based these estimates on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect.

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

- the cost of future trials for PCS-499 and the cost of manufacturing;
- the initiation, progress, timing, costs and results of drug discovery, pre-clinical studies and clinical trials of HT-100 any other future product candidates;
- the number and characteristics of product candidates that we pursue;
- the outcome, timing and costs of seeking regulatory approvals;
- the costs associated with hiring additional personnel and consultants as our pre-clinical and clinical activities increase;
- the emergence of competing therapies and other adverse market developments;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the extent to which we in-license or acquire other products and technologies; and
- the costs of operating as a public company.

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

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

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

**Contractual Obligations and Commitments**

The following table summarizes our contractual obligations at September 30, 2019:

| | Payments Due by Period | | | | |
|---|---|---|---|---|---|
| | Total | Less than 1 Year | 1-3 Years | 3-5 Years | More than 5 Years |
| | (in thousands) | | | | |
| Operating lease obligations | $ 276,234 | $ 93,582 | $ 182,652 | $ - | $ - |
| Total | $ 276,234 | $ 93,582 | $ 182,652 | $ - | $ - |

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

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

**Off Balance Sheet Arrangements**

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

**Quantitative and Qualitative Disclosures about Market Risk**

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate risks and inflation risks. Periodically, we maintain deposits in accredited financial institutions in excess of federally insured limits. We deposit our cash in financial institutions that we believe have high credit quality and have not experienced any losses on such accounts and do not believe we are exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

***Interest Rate Risk***

Our cash consists of cash in readily-available checking accounts and short-term money market fund investments. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant.

***Effects of Inflation***

Inflation generally affects us by increasing our cost of labor and research and development contract costs. We do not believe inflation has had a material effect on our results of operations during the periods presented.

**Critical Accounting Policies and Use of Estimates**

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

While our significant accounting policies are described in more detail in Note 2 to our December 31, 2018 audited consolidated financial statements included elsewhere in this prospectus, we believe the following accounting policies are the most critical to the judgments and estimates used in the preparation of our financial statements.

**Valuation of Intangible Assets**

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

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

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

**Clinical Trial Accruals / Research and Development**

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

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

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

**Stock-Based Compensation**

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

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

We estimate the fair value of stock option grants using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. The Black-Scholes option-pricing model requires the use of subjective assumptions that include the expected stock price volatility and the fair value of the underlying common stock on the date of grant. See Notes 4 and 9 to our September 30, 2019 and December 31, 2018 consolidated financial statements, respectively, included elsewhere in this prospectus for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted during the years ended December 31, 2018 and 2017 and for the nine months ended September 30, 2019 and 2018.

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

**Income Taxes**

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

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

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

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

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

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

**Recently Issued Accounting Pronouncements**

A description of recently issued and adopted accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 1 to the unaudited condensed consolidated financial statements included elsewhere in this prospectus.

**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.

## BUSINESS

## DESCRIPTION OF BUSINESS

**Overview**

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

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

Part of our business strategy is:

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

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

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

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

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

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

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

**Processa Portfolio: PCS-499**

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. 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 is tolerated at higher doses than the maximum recommended FDA dose of PTX based on animal toxicology studies as well healthy human volunteer trials.

Based on the pharmacological activity of PCS-499 and the off-label use of PTX, we have identified multiple unmet medical need conditions where the use of PCS-499 may result in clinical efficacy. The lead indication currently under development for PCS-499 is Necrobiosis Lipoidica (NL). NL is a chronic, disfiguring condition affecting the skin and the tissue under the skin typically on the lower extremities with no currently approved FDA treatments. NL presents more commonly in women than in men and ulceration can occur in approximately 30% of NL patients. More severe complications can occur, such as deep tissue infections and osteonecrosis threatening life of the limb. Approximately 74,000 - 185,000 people in the United States and more than 200,000 – 500,000 people outside the United States are affected by NL

The degeneration of tissue occurring at the NL lesion site is caused by a number of pathophysiological changes which has made it extremely difficult to develop effective treatments for this condition. PCS-499 may provide a solution since PCS-499 and its metabolites affect a number of the biological pathways which contribute to the pathophysiology associated with NL.

On June 22, 2018, the FDA granted orphan-drug designation to PCS-499 for the treatment of NL. On September 28, 2018, the FDA cleared our IND for PCS-499 in NL such that we could move forward with the Phase 2a safety-dose tolerability trial. We dosed our first NL patient in this Phase 2a clinical trial on January 29, 2019 and completed enrollment on August 23, 2019. The main objective of the trial is to evaluate the safety and tolerability of PCS-499 in patients with NL, and expect to use the collected safety and efficacy data to design of future clinical trials. Based on toxicology studies and healthy human volunteer studies, Processa and the FDA agreed that a PCS-499 dose of 1.8 grams/day would be the highest dose administered to NL patients in this Phase 2 trial. As anticipated, the PCS-499 dose of 1.8 grams/day, 50% greater than the maximum tolerated dose of PTX, appears to be well tolerated with no serious adverse events reported. To date, six of the patients dosed at 1.8 g/day have reported only mild adverse events related to the treatment, which occurred mostly in the first month of treatment and were quickly resolved. As expected, gastrointestinal or CNS adverse events were reported most often.

Our findings as of December 4, 2019, based on our early efficacy data, showed that the two patients in the trial with more severe ulcerated NL (both ulcerated patients had ulcers for more than two months prior to dosing) had the ulcers fully closed after two and nine months after starting the trial, respectively. In addition, while in the trial, one of the ulcerated patients developed small ulcers at other sites as a result of contact trauma to the site and these ulcers resolved within one month. Ten patients presented with mild to moderate NL and no ulceration. These patients have shown a slight improvement but not as dramatic as the more serious ulcerated patients. Based on the literature and clinical experience, approximately 30% of the patients with NL are expected to have open ulcers with the ulceration naturally healing in less than 20% of these patients.

One patient after 3 months of treatment and after altering her hypertension medication had a transient prolonged QTc interval 4 days after adding a beta blocker to her hypertension regimen. Her PCS-499 regimen was decreased to 1.2 grams/day even though her QTc prolongation was only transient. The safety and tolerability of a dose 50% greater than the maximum tolerated dose of PTX is in part what Processa plans to demonstrate in this trial.

In our evaluation of the efficacy, after 9 months of treatment we have seen significant changes in the two patients with more severe NL, one patient having a single ulcer and the second having multiple ulcers. In both patients, all of these ulcers have completely closed. Historically, less than 20% of the patients with ulcers have a natural progression to complete closure and it is even less likely when multiple ulcers exist. In those patients without ulcers, we have only seen a slight change in the NL lesion.

Given the positive side effect profile of PCS-499 and the efficacy seen in the severe NL patients, Processa will be requesting a meeting with the FDA before the end of 2019 to discuss the design of a pivotal adaptive design trial as a Special Protocol Assessment (SPA). A SPA is an advanced declaration from the FDA that a Phase III trial's design, clinical endpoints, and statistical analyses are acceptable for FDA approval if the agreed upon approval endpoints are met within the study.

The FDA 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 PTX, we were able to define a development and regulatory strategy for PCS-499 based on the previous PCS-499 data and our findings in the literature that PTX has some pharmacological effects and clinical evidence that could be relevant to the treatment of NL.

The development program to date, including the studies performed by Processa and CoNCERT, has included five Phase 1 studies, which were conducted to support the clinical pharmacology program for PCS-499, one Phase 2 study in patients with chronic kidney disease (CKD) with Type 2 diabetes, and one Phase 2 study in NL patients. 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). Also, 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 PCS499 oral tablets. No serious adverse events related to PCS-499 have been experienced during the conduct of these studies.

Two Phase 1 studies to note are CP505.1004 and PCS499.1005. CP505.1004 was designed to assess the effect of food on the bioavailability and tolerability 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. 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 at 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.

Processa is also evaluating other unmet medical need conditions for PCS-499 such as primary glomerulonephritis and other conditions which would benefit from the diverse pharmacological properties associated with PCS-499 and its active metabolites. Although our evaluation to date has identified numerous conditions which are likely to benefit from the use of PCS-499, we are presently evaluating which indications meet our portfolio requirement of high potential return on investment and lower risk of development failure.

**Processa Portfolio: HT-100**

Processa recently entered into a license agreement for an anti-fibrotic, anti-inflammatory drug which affects collagen expression and the TGF-β pathway. HT-100 was previously developed for Duchenne Muscular Dystrophy (DMD) in pediatric patients but an incomplete toxicology package and a mismanaged DMD pediatric trial resulted in a serious adverse event, placing the drug temporarily on clinical hold. Since efficacy was observed in some DMD pediatric patients and FDA has removed the clinical hold, Processa plans to better define the therapeutic window and develop HT-100 in an adult unmet medical need condition (e.g., idiopathic pulmonary fibrosis, primary glomerulonephritis) and then move back to the pediatric focused indications at a later time.

**Processa Portfolio: Additional Drugs**

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

**Manufacturing**

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

We anticipate that these CMOs will have the capacity to support both clinical supply and commercial-scale production, but we do not have any formal agreements at this time with any of these CMOs to cover commercial production. We believe that we have or will have sufficient quantities of drug substance and drug product to supply our current Phase 2a trial of PCS0499 for patients with NL.

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

**Competition**

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

The key competitive factors affecting the success of PCS-499, if approved, are likely to include its efficacy, safety, convenience and price. There are currently no FDA-approved drugs for the treatment of patients with NL.

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

**Intellectual Property**

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

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

Although we rely extensively on licensing patents from third parties, we intend to seek appropriate patent protection for product candidates in our research and development programs, where applicable, and their uses by filing patent applications in the United States and other selected countries. We intend for these patent applications to cover, where possible, claims for composition of matter, medical uses, processes for preparation and formulations. Our current patent portfolio consists of patents licensed from CoNCERT Pharmaceuticals for PCS-499 and related compounds. The portfolio includes approximately 29 allowed or issued patents (of which 9 are in the United States), which are directed to claims for composition of matter, methods of use, and certain chemical processes. Of these, 3 allowed or issued patents in the U.S. and Europe, as well as 2 in each of Australia, Canada, China, Japan and Mexico and 1 in each of Taiwan, Hong Kong, Russia, South Korea, the Philippines, South Africa, and Brazil cover the composition of matter of PCS-499. The allowed or issued U.S. and European patents are expected to expire between 2029 and 2031, excluding any extension or adjustment of patent term that may be available.

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

**License Agreement with CoNCERT Pharmaceuticals, Inc.**

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

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

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

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

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

**License Agreement with Akashi Therapeutics, Inc.**

On August 29, 2019, we entered into an exclusive license agreement with Akashi Therapeutics, Inc. ("Akashi") to develop and commercialize an anti-fibrotic, anti-inflammatory drug (HT-100) that also promotes healthy muscle fiber regeneration. In previous clinical trials in Duchenne Muscular Dystrophy (DMD), HT-100 showed promising improvement in the muscle strength of non-ambulant pediatric patients. Although the FDA placed a clinical hold on the DMD trial after a serious adverse event in a pediatric patient, FDA has removed the drug off clinical hold and defined how HT-100 can resume clinical trials in DMD. Once we have obtained adequate funding, we plan to develop HT-100 in rare adult fibrotic related diseases such as focal segmental glomerulosclerosis, idiopathic pulmonary fibrosis or Scleroderma.

The Akashi Agreement provides us with a worldwide license to research, develop, make and commercialize products comprising or containing HT-100. As partial consideration for the licenses, we paid $10,000 to Akashi upon full execution of the agreement. This upfront payment was expensed as a research and development cost. As additional consideration, we will pay Akashi development and regulatory milestone payments (up to $3.0 million per milestone) upon the achievement of certain milestones, which primarily consist of having a drug indication approved by a regulatory authority in the United States or another country. In addition, we must pay Akashi one-time sales milestone payments based on the achievement during a calendar year of one or more thresholds for annual sales for products made and pay royalties based on annual licensing sales. We are also required to split any milestone payments we receive with Akashi based on any sub-license agreement we may enter into.

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

**Government Regulation**

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

***U.S. Government Regulation***

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

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

- completion of pre-clinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND application, which must become effective before human clinical trials may begin;

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

***Pre-clinical studies***

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

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

***Clinical trials***

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

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

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

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

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

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

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

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

***Marketing Approval***

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

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

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

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

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

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

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

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

***Orphan drug designation***

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

***Expedited review and approval***

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

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

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

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

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

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

***Post-approval requirements***

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

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

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

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

- restrictions on the marketing or manufacturing of the product;
- complete withdrawal of the product from the market or product recalls;

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

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

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

***Other Regulatory Matters***

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

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

- the federal Anti-Kickback Statute, which makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Moreover, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA), provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal civil and criminal false claims and civil monetary penalties laws, including the civil False Claims Act that can be enforced by private citizens through civil whistleblower or qui tam actions, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

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

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

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

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

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

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

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

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

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

***U.S. Patent-Term Restoration and Marketing Exclusivity***

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

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

***European Union Drug Development***

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

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

***European Union Drug Review and Approval***

In the European Economic Area (EEA), which is comprised of the 27 Member States of the European Union (including Norway and excluding Croatia), Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization (MA). There are two types of marketing authorizations:

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

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

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

***Coverage and Reimbursement***

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

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

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

***Healthcare Reform***

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

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

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

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

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

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

**Employees**

As of November 30, 2019, we had 14 employees. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good.

**Facilities**

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

**Legal Proceedings**

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

## MANAGEMENT

### Executive Officers and Directors

The following table provides information regarding our executive officers and directors as of September 30, 2019:

| Name | Age | Position |
|---|---|---|
| **Executive Officers:** | | |
| David Young, Pharm.D, Ph.D. | 67 | Chairman of the Board of Directors and Chief Executive Officer |
| Patrick Lin | 54 | Chief Business and Strategy Officer and Director |
| Sian Bigora, Ph.D. | 59 | Chief Development Officer |
| James Stanker | 61 | Chief Financial Officer |
| Wendy Guy | 55 | Chief Administrative Officer |
| **Non-Employee Directors:** | | |
| Justin Yorke | 53 | Director |
| Virgil Thompson | 80 | Director |

***Executive Officers***

*David Young, Pharm.D., Ph.D.* - Dr. Young has served as our Chairman and Chief Executive Officer since October 4, 2017 and has over 30 years of pharmaceutical research, drug development, and corporate experience. He was a Founder and CEO of Promet Therapeutics, LLC ("Promet") since its formation in August 2015. He served as our interim CFO from October 4, 2017 to September 1, 2018. From 2006 to 2009, prior to joining the Questcor executive management team, Dr. Young served as an independent Director on the Questcor Board of Directors. As an independent director, Dr. Young, representing Questcor, worked with the FDA in developing a process to obtain approval for Acthar (the only commercial product owned by Questcor) in Infantile Spasms (IS), a deadly and debilitating very rare orphan indication. In 2009, Dr. Young joined the Questcor executive management team as Chief Scientific Officer (CSO) in order to obtain IS FDA approval and market exclusivity by completing the New Drug Application (NDA) process, working with FDA on modernizing the label, and leading all aspects of approval including the Advisory Committee Meeting that voted to approve the NDA for IS. During the eight years that Dr. Young was involved with Questcor as an independent director and as its CSO, Questcor transitioned to an orphan drug specialty pharmaceutical company, moving from an outdated Acthar label and near bankruptcy in 2007 to a modernized Acthar label that helped it to achieve sales greater than $750 million per year and the ultimate sale of the company for approximately $5.6 billion in 2014. While serving on Questcor's Board of Directors, Dr. Young was Executive Director & President, U.S. Operations of AGI Therapeutics plc. Dr. Young has also served as the Executive Vice President of the Strategic Drug Development Division of ICON plc, an international CRO, and was the Founder and CEO of GloboMax LLC, a CRO specializing in FDA drug development, purchased by ICON plc in 2003. Prior to forming GloboMax, Dr. Young was a Tenured Associate Professor at the School of Pharmacy, University of Maryland, 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 Scale-up and Post-Approval Changes (SUPAC) and in-vitro in-vivo correlation (IVIVC) FDA Guidances, taught FDA reviewers as part of the UMAB-FDA contract for 5 years, has served on National Institutes of Health (NIH) grant review committees, and was Co-Principal Investigator on a National Cancer Institute contract to evaluate new oncology drugs. Dr. Young has met more than 100 times with the FDA on more than 50 drug products and has been a key team member on more than 30 NDA/supplemental NDA approvals. Dr. Young has more than 150 presentations-authored publications-book chapters, including formal presentations to the FDA, FDA Advisory Committees, and numerous invited presentations at both scientific and investment meetings. Dr. Young received his B.S. in Physiology from the University of California at Berkeley, his M.S. in Medical Physics from the University of Wisconsin at Madison, and his Pharm.D. - Ph.D. with emphasis in Pharmacokinetics and Pharmaceutical Sciences from the University of Southern California.

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

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

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

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

***Non-Employee Directors***

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

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

***Board Composition***

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

***Director Independence***

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

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

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

***Committees of the Board of Directors***

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

***Audit Committee***

Effective upon completion of this offering, our audit committee will be comprised of [●] and [●] with [●] serving as chairman of the committee. Our board of directors has determined that each member of the audit committee meets the independence requirements of Rule 10A-3 under the Exchange Act and the applicable Nasdaq Listing Rules and has sufficient knowledge in financial and auditing matters to serve on the audit committee. Our board of directors has determined that [●] is an "audit committee financial expert" within the meaning of the SEC regulations and the applicable Nasdaq Listing Rules. The audit committee's responsibilities upon completion of this offering will include:

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

***Compensation Committee***

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

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

***Nominating and Governance Committee***

Effective upon completion of this offering, our nominating and governance committee will be comprised of [●] and [●] with [●] as the chairman of the committee. Our board of directors has determined that each member of the nominating and corporate governance committee is "independent" as defined in the applicable Nasdaq Listing Rules. The nominating and corporate governance committee's responsibilities upon completion of this offering will include:

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

***Leadership Structure and Risk Oversight***

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

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

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

***Compensation Committee Interlocks and Insider Participation***

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

***Code of Business Conduct and Ethics***

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

## EXECUTIVE AND DIRECTOR COMPENSATION

***Summary Compensation Table***

The following table shows the total compensation paid or accrued during the years ended December 31, 2018 and 2017, to our Chairman and Chief Executive Officer, our three next most highly compensated executive officers and our Chief Financial Officer, none of whom earned more than $100,000 of cash compensation during the fiscal years ended December 31, 2018 and 2017, and was serving as an executive officer as of such date.

| Name and Principal Position | Year | Salary | Option Awards[2] | Total |
|---|---|---|---|---|
| David Young | 2018 | $ - | $ - | $ - |
| Chairman and Chief Executive Officer | 2017 | $ - | $ - | $ - |
| Patrick Lin | 2018 | $ 44,479 | $ - | $ 44,479 |
| Chief Business and Strategy Officer | 2017 | $ 25,000 | $ - | $ 25,000 |
| Sian Bigora | 2018 | $ 50,750 | $ - | $ 50,750 |
| Chief Development Officer | 2017 | $ 52,500 | $ - | $ 52,500 |
| Wendy Guy | 2018 | $ 87,500 | $ - | $ 87,500 |
| Chief Administrative Officer | 2017 | $ 87,500 | $ - | $ 87,500 |
| James Stanker | 2018 | $ 29,167 | $ 700,440 | $ 729,607 |
| Chief Financial Officer [1] | | | | |

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

(2) Reflects the aggregate grant date fair value of equity awards to each named executive officer during 2018, calculated in accordance with FASB ASC Topic 718. Refer to "Note 9 – Stock-Based Compensation" in our December 31, 2018 audited consolidated financial statements included elsewhere in this prospectus for a discussion of the assumptions used in calculating the award amount.

We have do not currently have any executive employment agreements with any of our named executive officers in connection with their employment with us.

***Equity Incentive Plan***

*Outstanding Equity Awards at Fiscal Year End 2018*

The following table lists the outstanding equity awards held by each of our named executive officers as of December 31, 2018 (and is adjusted for the one for seven reverse stock split completed on December ●, 2019):

| Name | Grant Date | Number of Securities Underlying Unexercised Options (#) Exercisable | Number of Securities Underlying Unexercised Options (#) Unexercisable | Option Exercise Price ($) | Option Expiration Date |
|---|---|---|---|---|---|
| James Stanker | 09/01/2018 | 11,300 | 33,900[1] | $ 19.88 | 08/31/2028 |
| | 09/01/2018 | 2,571 | | $ 19.88 | 08/31/2028 |

(1) This option vests 25% on September 1, 2019 and 1/48$^{th}$ of such options shall vest each month thereafter.

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

As of December ●, 2019 there were stock options outstanding for the purchase of 137,033 shares of our common stock outstanding under the Plan with an average exercise price of $17.19 (adjusted for the one for seven reverse stock split completed on December ●, 2019), of which 12,950 shares have vested with a weighted-average exercise price of $16.80 per share.

## DIRECTOR COMPENSATION

Our non-employee directors do not currently receive any compensation for their service on the Board. They are however reimbursed for any reasonable out-of-pocket expenses incurred in connection with service as a director.

**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 and DKDB Enterprises, LLC**

CorLyst was a related party to Promet as one of the largest investors in Promet. As a result of the transaction with Heatwurx, all of Promet's assets were purchased in exchange for equity in the company and CorLyst is now considered a related party to Processa by association. CorLyst and Processa share certain administrative expenses (salaries, healthcare and office space). David Young, our Chief Executive Officer and Chairman of our Board of Directors, is also the Chief Executive Officer and Managing Member of CorLyst. David Young spends less than 1 hour per week on CorLyst activity, while averaging more than 40 hours per week on Processa activities. CorLyst beneficially owns 401,401 shares of Processa common stock, representing approximately 7.2% of the Company's outstanding shares of voting capital stock.

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

**License Agreement with CoNCERT Pharmaceuticals, Inc.**

On October 4, 2017, Promet entered into the CoNCERT Agreement with CoNCERT. On March 19, 2018, we, Promet, and CoNCERT entered into an Amended Option Licensing Agreement ("March Amendment") that, among other things, assigned the CoNCERT Agreement from Promet to us and we exercised the exclusive commercial license option for the PCS-499 compound from CoNCERT. The CoNCERT Agreement provides us with an exclusive (including to CoNCERT) royalty-bearing license to CoNCERT's patent rights and know-how to develop, manufacture, use, sub-license and commercialize compounds (PCS-499 and each metabolite thereof) and pharmaceutical products with such compounds worldwide. We are required to pay CoNCERT royalties, on a product by product basis, on worldwide net sales

## PRINCIPAL STOCKHOLDERS

The following table sets forth certain information with respect to the beneficial ownership of our common stock at December [●], 2019, and as adjusted to reflect the sale of our common stock in this offering, for:

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

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

The percentage of shares beneficially owned is computed on the basis of 5,486,362 shares of our common stock outstanding as of December ●, 2019 (and adjusted for the one for seven reverse stock split completed on December ●, 2019). Shares of our common stock that a person has the right to acquire within 60 days of December ●, 2019, are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group.

| | Shares beneficially owned prior to this offering | | Shares beneficially owned after this offering | |
|---|---|---|---|---|
| | Shares | Percent | Shares | Percent |
| **Name and address of beneficial owner[1]** | | | | |
| **Officers and Directors** | | | | |
| David Young[2], [9] | 1,286,491 | 23.1% | ● | ●% |
| Sian Bigora[3] | 486,980 | 8.8% | ● | ●% |
| Patrick Lin[7] | 341,447 | 6.1% | ● | ●% |
| Wendy Guy[4] | 302,148 | 5.4% | ● | ●% |
| Virgil Thompson[8] | 87,625 | 1.6% | ● | ●% |
| Justin Yorke[5] | 446,809 | 8.0% | ● | ●% |
| James Stanker[12] | 15,604 | * | ● | * |
| **Total for all Officers and Directors** | 2,967,104 | 53.3% | ● | ●% |
| | | | | |
| **More than 5% Stockholders:** | | | | |
| Young-Plaisance Revoc. Trust [9], [10] | 533,409 | 9.6% | ● | ●% |
| CorLyst, LLC [6], [9], [11] | 401,401 | 7.2% | ● | ●% |
| CoNCERT Pharmaceuticals, Inc. | 298,614 | 5.4% | ● | ●% |

* - represents less than 1%

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

(2) Consists of (i) 346,801 shares of common stock held directly by Dr. Young; (ii) 1,733 shares of common stock issuable pursuant to options held directly by Dr. Young exercisable within 60 days of December ●, 2019; (iii) 533,409 shares held by the Young-Plaisance Revoc. Trust; (iv) 401,401 shares held by CorLyst, LLC ("CorLyst"); and (v) 3,147 shares that Dr. Young will receive on the exercise of stock purchase warrants. Dr. Young is the Trustee of the Young-Plaisance Revoc. Trust and the Chief Executive Officer and Managing Member of CorLyst. Dr. Young disclaims beneficial ownership of a portion of CorLyst shares.

(3) Consists of (i) 485,248 shares of common stock held directly by Dr. Bigora and (ii) 1,733 shares of common stock issuable pursuant to options held directly by Dr. Bigora exercisable within 60 days of December ●, 2019.

(4) Consists of (i) 300,416 shares of common stock held directly by Ms. Guy and (ii) 1,733 shares of common stock issuable pursuant to options held directly by Ms. Guy exercisable within 60 days of December ●, 2019.

(5) Justin Yorke, a member of our Board of Directors, is a manager of the San Gabriel Fund, LLC, JMW Fund, LLC and the Richland Fund, LLC. 446,613 shares of common stock reported for Mr. Yorke include the shares held by these Funds. Also included are 196 shares of common stock issuable pursuant to options held directly by Mr. Yorke exercisable within 60 days of December ●, 2019.

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

(7) Consists of (i) 335,246 shares of common stock held directly by Mr. Lin; (ii) 1,733 shares of common stock issuable pursuant to options held directly by Mr. Lin exercisable within 60 days of December ●, 2019; and (iii) 4,468 shares that Mr. Lin will receive on the exercise of stock purchase warrants.

(8) Consists of (i) 87,429 shares of common stock held directly by Mr. Thompson and (ii) 196 shares of common stock issuable pursuant to options held directly by Mr. Thompson exercisable within 60 days of December ●, 2019.

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

(10) Includes 30,464 shares of common stock that will be issued upon the exercise of stock purchase warrants.

(11) Includes 18,880 shares of common stock that will be issued upon the exercise of stock purchase warrants.

(12) Consists of 15,604 options to purchase shares of common stock that are exercisable as of December ●, 2019 or will become exercisable within 60 days after such date held by Mr. Stanker.

## 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 100,000,000 shares of $0.0001 par value common stock and 1,000,000 shares of $0.0001 par value preferred stock. As of September 30, 2019, there are 5,486,362 shares of common stock outstanding (adjusted for the one for seven reverse stock split completed on December ●, 2019) and no shares of preferred stock outstanding.

### Common Stock

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

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

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

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

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

### Preferred Stock

Our Board is authorized, subject to certain limitations prescribed by law, without further stockholder approval, to issue from time to time up to an aggregate of 1,000,000 shares of preferred stock in one or more series and to fix or alter the designations, preferences, rights and any qualifications, limitations or restrictions of the shares of each such series thereof, including the dividend rights, dividend rates, conversion rights, voting rights and terms of redemption of shares constituting any series or designations of such series. The rights of holders of our common stock may be subject to, and adversely affected by, the rights of the holders of any preferred stock that may be issued in the future. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change of control and may adversely affect the voting and other rights of holders of our common stock.

### Warrants

As of the date of this prospectus we have issued warrants to purchase shares of our common stock to various persons and entities, under which we could be obligated to issue up to 477,579 shares of common stock, including:

(a) 277,710 shares of common stock issuable upon exercise of warrants allowing the holders to purchase shares of common stock at an exercise price of $19.07 per share through June 29, 2021; of which warrants for 20,722 shares of common stock contain cashless exercise provisions; and

(b) 199,869 shares of common stock issuable upon exercise of warrants allowing the holders to purchase shares of common stock at an exercise price of $17.16 per share through June 29, 2021; of which warrants for 9,443 shares of common stock contain cashless exercise provisions.

**Debt**

The Company recognizes debt issuance costs incurred on $745,000 principal amount of 8.0% Senior Convertible Notes ("Senior Notes") issued on November 30, 2019 as a reduction of the carrying amount of the Senior 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 Notes.

Upon completion of listing our common stock on either the Nasdaq Capital Market or the New York Stock Exchange, our 8% Senior Notes are mandatorily convertible into shares of our common stock at a conversion price equal to the lower of (i) $14.28 per share or (ii) a price per share equal to a 10% discount to the pre-money valuation of a Qualified Financing or an Equity State Transaction, both as defined in the 8% Senior Note agreement, occurring after the closing of the 8% Senior Note financing. Upon maturity (December 15, 2020), the 8% Senior Note holders have the option to convert the 8% Senior Note into shares of our common stock at the lower of $14.28 per share or an adjusted price as set forth in the 8% Senior Note agreement. Upon either mandatory conversion or conversion at the holder's option, the holder will also receive stock purchase warrants on a 1:1 basis to the number of shares of common stock received that have an exercise price equal to the greater of (i) the closing price of our common stock on the date of conversion or (ii) $19.04 per share.

**Indemnification of Directors and Officers**

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

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

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

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

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

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

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

**Certain Anti-Takeover Effects**

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

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

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

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

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

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

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

## SHARES ELIGIBLE FOR FUTURE SALE

Assuming our application for the listing of our shares of common stock is accepted by Nasdaq. upon the closing of this offering, our common stock will be listed on Nasdaq under the symbol "PCSA". We cannot assure investors that there will continue to be an active public market for our common stock following this offering. We cannot predict what effect, if any, sales of our shares of common stock in the public market or the availability of shares for sale will have on the market price of our common stock. Future sales of substantial amounts of shares of common stock in the public market, including shares issued upon exercise of outstanding warrants and options, or the perception that such sales may occur, however, could adversely affect the market price of our common stock and also could adversely affect our future ability to raise capital through the sale of our common stock or other equity-related securities at times and prices we believe appropriate.

As of ● 2020, upon completion of this offering and assuming the sale of all shares of common stock pursuant to this offering, ● shares of Common Stock will be outstanding, excluding an aggregate of ● shares of common stock issuable upon the exercise of outstanding warrants and options.

Of these shares, all of the shares of common stock sold in this offering will be freely tradable without restrictions or further registration under the Securities Act, except for any shares held by our "affiliates," as that term is defined under Rule 144 under the Securities Act. The remaining outstanding shares of common stock held by existing stockholders are "restricted securities," as that term is defined in Rule 144 under the Securities Act. Restricted securities may be sold in the public market only if the offer and sale is registered under the Securities Act or if the offer and sale of those securities qualifies for exemption from registration, including exemptions provided by Rules 144 and 701 promulgated under the Securities Act.

As a result of lock-up agreements that all of our directors and executive officers and certain holders of more than 10% of the outstanding equity securities have entered into, market standoff provisions described below and the provisions of Rules 144 and 701, the restricted securities will be available for sale in the public market as follows:

- no shares will be eligible for immediate sale upon the completion of this offering; and
- ● shares of common stock, ● shares of common stock issuable upon exercise of warrants, and ● shares of common stock issuable upon exercise of options will be eligible for sale upon expiration of lock-up agreements and market standoff provisions described below, beginning 91 days after the date of this prospectus, subject in certain circumstances to the volume, manner of sale and other limitations under Rule 144 and Rule 701.

We may issue shares of common stock from time to time for a variety of corporate purposes, including in capital-raising activities through future public offerings or private placements, in connection with exercise of options and warrants, vesting of restricted shares and other issuances relating to our future employee benefit plans and as consideration for future acquisitions, investments or other purposes. The number of shares of Common Stock that we may issue may be significant, depending on the events surrounding such issuances. In some cases, the shares of common stock that we issue may be freely tradable without restriction or further registration under the Securities Act; in other cases, we may grant registration rights covering the shares of common stock issued in connection with these issuances, in which case the holders of the shares of common stock will have the right, under certain circumstances, to cause us to register any resale of such shares to the public.

**Rule 144**

Rule 144, as currently in effect, generally provides that, as we have been subject to the public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, a stockholder who is not deemed to have been one of our affiliates at any time during the preceding 90 days and who has beneficially owned the shares of our capital stock proposed to be sold for at least six months is entitled to sell such our securities in reliance upon Rule 144 without complying with the volume limitation, manner of sale or notice conditions of Rule 144. As the Company was previously a "shell company", as such term is defined in Rule 12b-2 of the Exchange Act, our stockholders, whether affiliates or non-affiliates, may never sell shares of our securities under Rule 144, unless current public information is available about us at the time of the sale of such shares.

Rule 144 also provides that a stockholder who is deemed to have been one of our affiliates at any time during the preceding 90 days and who has beneficially owned our securities that are proposed to be sold for at least six months is entitled to sell such securities in reliance upon Rule 144 within any three month period beginning 90 days after the date of this prospectus a number of shares that does not exceed the greater of the following:

- 1% of the number of shares of our capital stock then outstanding, which will equal ● shares immediately after the completion of this offering; or
- the average weekly trading volume of our Common Stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales of our securities made in reliance upon Rule 144 by a stockholder who is deemed to have been one of our affiliates at any time during the preceding 90 days are also subject to the current public information, manner of sale and notice conditions of Rule 144.

**Restrictions on the Use of Rule 144 by Shell Companies or Former Shell Companies**

Rule 144 is not available for the resale of securities initially issued by shell companies (other than business combination related shell companies) or issuers that have been at any time previously a shell company. However, Rule 144 also includes an important exception to this prohibition if the following conditions are met:

- the issuer of the securities that was formerly a shell company has ceased to be a shell company;
- the issuer of the securities is subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act;
- the issuer of the securities has filed all Exchange Act reports and materials required to be filed, as applicable, during the preceding 12 months (or such shorter period that the issuer was required to file such reports and materials), other than Current Reports on Form 8-K; and
- at least one year has elapsed from the time that the issuer filed current Form 10 type information with the SEC reflecting its status as an entity that is not a shell company.

As a result, our stockholders are able to sell shares pursuant to Rule 144, provided that there is current public information available on us and there has been compliance will other applicable requirements of Rule 144.

**Rule 701**

Rule 701 generally allows a stockholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been one of our affiliates during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation, or notice provisions of Rule 144. Rule 701 also permits our affiliates to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144.

**Registration Rights**

Upon the completion of this offering, the holders of approximately ● shares of our common stock, other than such shares offered in connection with this offering, or their respective transferees, will be entitled to specified rights with respect to the registration of the offer and sale of their respective shares under the Securities Act. Registration of the offer and sale of such shares under the Securities Act would result in such shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration statement that is filed with the SEC which registers such shares. See “Description of Securities—Registration Rights” for additional information.

## UNDERWRITING

We are offering the shares of common stock described in this prospectus through the underwriter, ●, which is acting as lead managing underwriter of the offering.

We have agreed to enter into an underwriting agreement with the underwriter prior to the closing of this offering. Subject to the terms and conditions of the underwriting agreement, we will agree to sell to the underwriter, and the underwriter will agree to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, as it may be supplemented, shares of common stock.

The underwriter is committed to purchase all of the common shares offered by us, other than those covered by the option to purchase additional shares described below, if they purchase any shares. The underwriting agreement provides that the underwriter's obligations to purchase shares of our common stock are subject to conditions contained in the underwriting agreement. A copy of the underwriting agreement has been filed, or will be filed by amendment, as an exhibit to the registration statement of which this prospectus forms a part.

We have been advised by the underwriter that the underwriter proposes to offer shares of our common stock directly to the public at the public offering price set forth on the cover page of this prospectus and to certain dealers that are members of the Financial Industry Regulatory Authority, or FINRA. Any securities sold by the underwriter to such securities dealers will be sold at the public offering price less a selling concession not in excess of $● per share. After the public offering of the shares, the offering price and other selling terms may be changed by the underwriter.

None of our securities included in this offering may be offered or sold, directly or indirectly, nor may this prospectus and any other offering material or advertisements in connection with the offer and sales of any of our common stock, be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons who receive this prospectus are advised to inform themselves about and to observe any restrictions relating to this offering of our common stock and the distribution of this prospectus. This prospectus is neither an offer to sell nor a solicitation of any offer to buy any of our common stock included in this offering in any jurisdiction where that would not be permitted or legal.

The underwriter has advised us that it does not intend to confirm sales to any accounts over which they exercise discretionary authority.

### Underwriting Discount and Expenses

The following table summarizes the underwriting discount and commission to be paid to the underwriter by us.

| | Without Over-Allotment | With Over-Allotment |
|---|---|---|
| Public offering price | $ ● | $ ● |
| Underwriting discount to be paid to the underwriter | $ ● | $ ● |
| Net proceeds, before other expenses | $ ● | $ ● |

In addition to the discount set forth in the above table, we have agreed to issue to the underwriter and its designees a warrant to purchase up to 4.0% of the shares of common stock sold in this offering and to pay $75,000 for certain of their out-of-pocket expenses. The terms of the underwriter's warrant are more fully described in this section under the caption, "Underwriter Warrants."

### Over-Allotment Option

In addition to the discount set forth in the above table, we have granted to the underwriter an option, exercisable not later than 45 days after the date of this prospectus, to purchase up to an additional ● shares of our common stock (up to 15% of the shares firmly committed in this offering) at the public offering price, less the underwriting discount, set forth on the cover page of this prospectus. The underwriter may exercise the option solely to cover over-allotments, if any, made in connection with this offering. If any additional shares of our common stock are purchased pursuant to the over-allotment option, the underwriter will offer these additional shares of our common stock on the same terms as those on which the other shares of common stock are being offered hereby.

**Determination of Offering Price Listing**

We have applied to list our common stock on the NASDAQ Capital Market under the symbol "TFFP". In order to meet the requirements for listing on that exchange, the underwriters have undertaken to sell a minimum number of shares to a minimum number of beneficial owners as required by that exchange.

Before this offering, there has been a limited trading market for our common stock, which is quoted on the OTCQB Marketplace. Our underwriter, ●, is not obligated to make a market in our securities, and even if it chooses to make a market, can discontinue at any time without notice. Neither we nor the underwriter can provide any assurance that an active and liquid trading market in our securities will develop or, if developed, that the market will continue.

The public offering price of the shares offered by this prospectus has been determined by negotiation between us and the underwriter. Among the factors considered in determining the public offering price of the shares were:

- our history and our prospects;
- the industry in which we operate;
- our past and present operating results;
- the previous experience of our executive officers; and
- the general condition of the securities markets at the time of this offering.

The offering price stated on the cover page of this prospectus should not be considered an indication of the actual value of the shares. Upon the commencement of trading, the price of our shares will be subject to change as a result of market conditions and other factors, and we cannot assure you that the shares can be resold at or above the public offering price.

**Underwriter Warrants**

In connection with this offering, we have agreed to issue to ● and its designees a warrant to purchase shares of our common stock equal to 4.0% of the shares of common stock sold in this offering. This warrant is exercisable at $● per share (125% of the price of the common stock sold in this offering), expiring five years from the effective date of this offering. The warrant and the shares of common stock underlying the warrant have been deemed compensation by FINRA and are therefore subject to a six-month lock-up pursuant to Rule 5110(g)(1) of FINRA. Additionally, ● has contractually agreed that it (or its permitted assignees under the Rule) will not sell, transfer, assign, pledge, or hypothecate this warrant or the securities underlying this warrant, nor will it engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of this warrant or the underlying securities for a period of twelve months from the effective date of the offering.

**Lock-Up Agreements**

In connection with our issuance of the underwriter warrant to be issued to ● upon the completion of this offering, ● and ● have agreed not to sell, transfer or pledge, or offering to do any of the same, directly or indirectly, the shares of common stock issuable upon exercise of such warrants for a period of ● days following the close of this offering. We, all of our directors and officers and their affiliates have agreed in connection with the present offering, that, without the prior written consent of ●, not to sell, transfer, pledge, lend or offer to do any of the same, directly or indirectly, any of our securities for a period of 90 days following the close of this offering.

The number of shares of common stock outstanding upon the completion of this offering subject to the ●-day lock-up totals ● shares.

Other than in respect of the warrants issued or to be issued to ●, the underwriter may consent to an early release from the lock-up period if, in its opinion, the market for the common stock would not be adversely impacted by sales and in cases of a financial emergency of an officer, director or other stockholder. We are unaware of any security holder who intends to ask for consent to dispose of any of our equity securities during the relevant lock-up periods.

**Indemnification**

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act relating to losses or claims resulting from material misstatements in or omissions from this prospectus, the registration statement of which this prospectus is a part, certain free writing prospectuses that may be used in the offering and in any marketing materials used in connection with this offering and to contribute to payments the underwriters may be required to make in respect of those liabilities.

**Short Positions and Penalty Bids**

The underwriter may engage in over-allotment, syndicate covering transactions, and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of the common stock, in accordance with Regulation M under the Exchange Act.

- Over-allotment involves sales by the underwriter of shares in excess of the number of shares the underwriter is obligated to purchase, which creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by an underwriter is not greater than the number of shares that it may purchase in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriter may close out any short position by either exercising its over-allotment option and/or purchasing shares in the open market.

- Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriter will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which it may purchase shares through the over-allotment option. If an underwriter sells more shares than could be covered by the over-allotment option, a naked short position, the position can only be closed out by buying shares in the open market. A naked short position is more likely to be created if an underwriter is concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.

- Penalty bids permit an underwriter to reclaim a selling concession from a syndicate member when the shares originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of the common stock. As a result, the price of the common stock may be higher than the price that might otherwise exist in the open market. These transactions may be effected on the NASDAQ Capital Market, and if commenced, they may be discontinued at any time.

Neither we nor the underwriter make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of the common stock. In addition, neither we nor the underwriter make any representation that the underwriter will engage in these transactions or that any transaction, once commenced, will not be discontinued without notice.

**Electronic Distribution**

A prospectus in electronic format may be made available on the Internet sites or through other online services maintained by the underwriter, or by its affiliates. In those cases, prospective investors may view offering terms online and, depending upon the underwriter, prospective investors may be allowed to place orders online. The underwriter may agree with us to allocate a specific number of shares for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriter on the same basis as other allocations.

Other than the prospectus in electronic format, the information on the underwriter's website and any information contained in any other website maintained by the underwriter is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the underwriter in its capacity as underwriter and should not be relied upon by investors.

The underwriter's compensation in connection with this offering is limited to the fees and expenses described above under "Underwriting Discount and Expenses."

## LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Foley & Lardner, Jacksonville, Florida. Certain legal matters in connection with this offering will be passed upon for the underwriters by ●.

## EXPERTS

The financial statements of Processa Pharmaceuticals, Inc. as of December 31, 2018 and 2017, and for the years then ended have been included herein and in the registration statement in reliance on the report of BD & Company, an independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1, including exhibits and schedules, under the Securities Act that registers the shares of our common stock to be sold in this offering. This prospectus does not contain all the information contained in the registration statement and the exhibits and schedules filed as part of the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and the exhibits and schedules filed as part of the registration statement. Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, we refer you to the copies of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit.

We file annual, quarterly and current reports, proxy statements and other information with the SEC under the Exchange Act. You can read our SEC filings, including the registration statement, at the SEC's website at www.sec.gov.

Our website address is www.processapharmaceuticals.com. The information contained in, and that can be accessed through, our website is not incorporated into and shall not be deemed to be part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

**INDEX TO FINANCIAL STATEMENTS**

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Processa Pharmaceuticals, Inc. (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations, stockholders' equity, and cash flows, for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The Company's Ability to Continue as a Going Concern

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

Basis for Opinion

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

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

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

*/s/ BD & Company*

Owings Mills, MD
April 5, 2019

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

Processa Pharmaceuticals, Inc.
Consolidated Balance Sheets

| | December 31, 2018 | December 31, 2017 |
|---|---|---|
| **ASSETS** | | |
| **Current Assets** | | |
| Cash and cash equivalents | $ 1,740,961 | $ 2,847,429 |
| Due from related party | 21,583 | 62,709 |
| Prepaid expenses and other | 257,832 | 41,446 |
| Total Current Assets | 2,020,376 | 2,951,584 |
| Property and equipment, net | 17,375 | 25,821 |
| Intangible assets, net | 10,437,782 | - |
| Security deposit | 5,535 | 5,535 |
| **Total Assets** | $ 12,481,068 | $ 2,982,940 |
| | | |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| **Current Liabilities** | | |
| Senior convertible notes, net of debt issuance costs | $ 230,000 | $ 2,448,570 |
| Accrued interest | 20,343 | 35,693 |
| Accounts payable | 292,102 | 50,686 |
| Due to related parties | - | 436 |
| Accrued expenses | 103,259 | 64,428 |
| Total Current Liabilities | 645,704 | 2,599,813 |
| **Non-current Liabilities** | | |
| Accrued rent liability | - | 9,963 |
| Net deferred tax liability | 2,134,346 | - |
| **Total Liabilities** | 2,780,050 | 2,609,776 |
| | | |
| Commitments and Contingencies | - | - |
| | | |
| **Stockholders' Equity** | | |
| Preferred stock, par value $0.0001, 10,000,000 shares authorized; no shares issued and outstanding | - | - |
| Common stock, par value $0.0001, 350,000,000 and 43,261,049 shares authorized; 38,674,265 and 35,272,626 issued and outstanding at December 31, 2018 and 2017, respectively | 3,867 | 3,527 |
| Additional paid-in capital | 19,121,285 | 4,228,723 |
| Stock subscription receivable | (1,800,000) | - |
| Accumulated deficit | (7,624,134) | (3,859,086) |
| **Total Stockholders' Equity** | 9,701,018 | 373,164 |
| **Total Liabilities and Stockholders' Equity** | $ 12,481,068 | $ 2,982,940 |

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

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

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

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

Processa Pharmaceuticals, Inc.
Consolidated Statement of Changes in Stockholders' Equity
Years Ended December 31, 2018 and 2017

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

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

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

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

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

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

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

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

**Note 1 – Organization and Description of the Business**

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

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

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

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

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

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

**Note 2 – Going Concern and Management's Plans**

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

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

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

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

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

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

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

*Basis of Presentation*

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

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

*Use of Estimates*

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

*Cash and Cash Equivalents*

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

*Property and Equipment*

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

*Intangible Assets*

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

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

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

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

*Impairment of Long-Lived Assets and Intangibles Other Than Goodwill*

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

*Fair Value Measurements and Disclosure*

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

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

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

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

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

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

*Stock-based Compensation*

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

*Net Loss Per Share*

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

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

*Segments*

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

*Fair Value of Financial Instruments*

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

*Debt Issuance Costs*

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

*Research and development*

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

*Income Taxes*

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

The net deferred tax assets of Heatwurx were principally federal and state net operating loss carry forwards. The Heatwurx net deferred tax assets were significantly limited following an ownership change as defined by Internal Revenue Code Section 382 and were fully reserved with a valuation allowance. Promet determined that it was not required to record a liability related to uncertain tax positions as a result of the requirements of ASC 740-10-25 *Income Taxes.*

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

The provision for income taxes includes federal and state income taxes currently payable and deferred taxes resulting from temporary differences between the financial statement and tax basis of assets and liabilities at the enacted tax rates. Changes in deferred income tax assets and liabilities are included as a component of income tax expense. The effect on deferred income tax assets and liabilities attributable to changes in enacted tax rates are charged or credited to income tax expense in the period of enactment. Valuation allowances are recorded to reduce deferred tax assets when it is more-likely-than-not that a tax benefit will not be realized. A full valuation allowance was recorded against our deferred tax assets at December 31, 2018 and 2017.

With respect to uncertain tax positions, we would recognize the tax benefit from an uncertain tax position only if it is more-likely-than-not that the tax position will be sustained upon examination by the taxing authorities, based on the technical merits of the position. Estimated interest and penalties related to uncertain tax positions are included as a component of interest expense and general and administrative expense, respectively. We had no unrecognized tax benefits or uncertain tax positions at December 31, 2018 or 2017.

*Recent Accounting Pronouncements*

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

*Recently issued accounting pronouncements not yet adopted*

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

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

*Recently adopted accounting pronouncements*

From May 2014 through December 31, 2018, the FASB issued several ASUs related to ASU 2014-09,*Revenue from Contracts with Customers.* The new guidance is effective for interim and annual periods beginning after December 15, 2017, although entities may adopt one year earlier if they choose. The two permitted transition methods under the new standard are the full retrospective method, in which case the standard would be applied to each prior reporting period presented and the cumulative effect of applying the standard would be recognized at the earliest period shown, or the modified retrospective method, in which case the cumulative effect of applying the standard would be recognized at the date of initial application. We are currently in the pre-revenue stages of operations. As such, the adoption of this standard did not have a material impact on our results of operations, financial condition or cash flows.

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

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

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

**Note 4 – Acquisition**

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

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

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

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

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

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

**Note 5 – Intangible Assets**

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

*Acquisition of the CoNCERT License*

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

The negotiation of the modification to the Agreement was in process as of October 4, 2017 and was finalized in mid-February 2018 and the legal documents were thereafter executed and the option was exercised on March 19, 2018 in exchange for CoNCERT receiving: (i) $8 million of our common stock that was held by Promet LLC for the benefit of CoNCERT; (ii) royalties, on a product-by-product basis, on worldwide net sales of products during each year as follows: (a) four percent (4%) of sales less than or equal to $100 million; (b) five percent (5%) of sales greater than $100 million and less than or equal to $500 million; (c) six percent (6%) of sales greater than $500 million and less than or equal to $1 billion; and, (d) for that portion greater than $1 billion, (i) with respect to net sales made by Promet or any of its affiliates, ten percent (10%) of net sales, and (ii) with respect to net sales made by any sub-licensee, the greater of (1) 6% of such net sales or (2) 50% of all payments received by Promet or any of its affiliates with respect to such net sales; and (iii) 15% of any sublicense revenue earned by us for a period equivalent to the royalty term (as defined in the Agreement) until the earliest of (a) our raising $8 million of gross proceeds and (b) CoNCERT being able to sell its shares of our common stock without restrictions pursuant to the terms of the amended Agreement. All other terms of the Agreement remained unchanged. The license agreement was assigned to and exercised by us. As a result of the transaction, we recognized an intangible asset for the fair value of the common stock consideration paid of $8 million with an offsetting amount in additional paid-in capital resulting from Promet releasing the shares to CoNCERT in satisfaction of our obligation to CoNCERT under the Agreement.

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

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

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

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

**Note 6 – Notes Payable**

**Notes Payable**

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

**Senior Convertible Notes**

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

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

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

*Issuance of the Senior Notes*

As of October 4, 2017, certain entities affiliated with current shareholders purchased $1.25 million of our Senior Notes in a bridge financing undertaken by us to support our operations. On November 21, 2017, additional third-party accredited investors contributed $1.33 million in financing proceeds. On May 25, 2018, $2,350,000 of Senior Notes were converted, as described below, leaving $230,000 of Senior Notes outstanding at December 31, 2018.

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

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

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

We retained a placement agent and agreed to pay the placement agent (i) six percent (6%) of gross proceeds received by us and (ii) warrants to purchase securities in the amount of three percent (3%) of the equity issued or issuable in connection with the Senior Notes bridge financing upon their conversion. As a result of the Senior Notes conversion, warrants to purchase a total of 72,375 shares of common stock were issued, with a three-year term, at an exercise price equal to $2.452.

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

*Conversion of Our Senior Notes*

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

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

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

**Note 7 – Stockholders' Equity**

*Preferred Stock*

As of December 31, 2018, we have authorized 10,000,000 shares of Preferred Stock with a $0.0001 par value. No shares were issued and outstanding.

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

*Common Stock*

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

*2018 Private Placement Transactions*

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

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

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

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

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

**Note 8 – Income Taxes**

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

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

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

As a result of the asset purchase transaction, Promet was issued 90 percent of the total issued and outstanding common stock of Heatwurx (including the approximate 6% of shares issued in the Section 351 transaction for CoNCERT and held by Promet for the benefit of CoNCERT until the CoNCERT transaction could be concluded). The overall transaction resulted in an ownership change as defined by Internal Revenue Code Section 382. Promet also determined that it was not required to record a liability related to any uncertain tax positions as a result of the requirements of ASC 740-10-25 *Income Taxes.* The net deferred tax assets of Heatwurx were principally federal and state net operating loss carry forwards, which are significantly limited following an ownership change as defined by Internal Revenue Code Section 382.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**Note 9 - Stock-based Compensation**

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

The Plan provides for the grant of options to purchase shares of our common stock. Options may be incentive stock options, designed to satisfy the requirements of Section 422 of the U.S. Internal Revenue Code, or non-statutory stock options, which do not meet those requirements. We can grant incentive stock options only to our employees, however, we can grant non-statutory stock options to our employees, nonemployee directors, advisors, and consultants.

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

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

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

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

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

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

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

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

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

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

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

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

**Note 10 – Net Loss per Share of Common Stock**

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

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

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

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

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

**Note 11 – Related Party Transactions**

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

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

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

**Note 12 – Commitments and Contingencies**

*Operating Lease Obligations*

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

Our office lease commenced on October 1, 2016 and expires September 30, 2019 with monthly rent at inception of $5,535 that escalates $1,107 annually on each October. Rent expense under our current office lease for the years ended December 31, 2018 and 2017 was $79,704 and $83,025, respectively. We also incurred common area maintenance and real estate tax reimbursements of $23,648 and $22,929 for the years ended December 31, 2018 and 2017, respectively. At December 31, 2018 and 2017, we included the current portion of our deferred rent liability of $9,963 and $3,321 in accrued expenses.

Our equipment lease commenced in June 2017 and expires in August 2020. Monthly rent of $586 over the 39-month lease term includes a monthly operating usage cost allowance of $125. Additional charges for excess usage, as defined in the agreement, are charged quarterly. The lessor charges monthly sales tax of 6 percent. Rent expense under the equipment lease for the years ended December 31, 2018 and 2017 was $8,533 and $6,626, respectively.

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

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

*Purchase Obligations*

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

**Note 13 – Concentration of Credit Risk**

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

**Note 14 – Subsequent Event**

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

Processa Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)

| | September 30, 2019 | December 31, 2018 |
|---|---|---|
| **ASSETS** | | |
| **Current Assets** | | |
| Cash and cash equivalents | $ 504,302 | $ 1,740,961 |
| Due from related party | 663 | 21,583 |
| Prepaid expenses and other | 220,280 | 257,832 |
| Total Current Assets | 725,245 | 2,020,376 |
| **Property And Equipment** | | |
| Software | 19,740 | 19,740 |
| Office equipment | 9,327 | 9,327 |
| Total Cost | 29,067 | 29,067 |
| Less: accumulated depreciation | 18,026 | 11,692 |
| Property and equipment, net | 11,041 | 17,375 |
| **Other Assets** | | |
| Operating lease right of use assets, net of accumulated amortization | 238,186 | - |
| Intangible assets, net of accumulated amortization | 9,841,286 | 10,437,782 |
| Security deposit | 5,535 | 5,535 |
| Total Other Assets | 10,085,007 | 10,443,317 |
| **Total Assets** | $ 10,821,293 | $ 12,481,068 |
| | | |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| **Current Liabilities** | | |
| Senior convertible notes | $ - | $ 230,000 |
| Current maturities of operating lease liability | 77,423 | - |
| Accrued interest | - | 20,343 |
| Accounts payable | 64,861 | 292,102 |
| Due to related parties | 25,727 | - |
| Accrued expenses | 123,670 | 103,259 |
| Total Current Liabilities | 291,681 | 645,704 |
| **Non-current Liabilities** | | |
| Noncurrent operating lease liability | 166,739 | - |
| Net deferred tax liability | 1,692,194 | 2,134,346 |
| **Total Liabilities** | 2,150,614 | 2,780,050 |
| | | |
| **COMMITMENTS AND CONTINGENCIES** | | |
| | | |
| **Stockholders' Equity** | | |
| Preferred stock, par value $0.0001, 1,000,000 shares authorized; no shares issued and outstanding | - | - |
| Common stock, par value $0.0001, 100,000,000 shares authorized; 38,404,530 and 38,674,265 issued and outstanding at September 30, 2019 and December 31, 2018, respectively | 3,840 | 3,867 |
| Additional paid-in capital | 18,874,406 | 19,121,285 |
| Subscription receivable | - | (1,800,000) |
| Accumulated deficit | (10,207,567) | (7,624,134) |
| **Total Stockholders' Equity** | 8,670,679 | 9,701,018 |
| **Total Liabilities and Stockholders' Equity** | $ 10,821,293 | $ 12,481,068 |

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

Processa Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
Three and Nine Months Ended September 30, 2019 and 2018
(Unaudited)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| **Operating Expenses** | | | | |
| Research and development expenses | $ 584,979 | $ 611,612 | $ 1,804,169 | $ 2,477,481 |
| General and administrative expenses | 419,028 | 451,359 | 1,219,329 | 1,305,511 |
| Total operating expenses | 1,004,007 | 1,062,971 | 3,023,498 | 3,782,992 |
| **Operating Loss** | (1,004,007) | (1,062,971) | (3,023,498) | (3,782,992) |
| **Other Income (Expense)** | | | | |
| Interest expense | (2,271) | (8,323) | (12,973) | (154,377) |
| Interest income | 1,503 | 6,457 | 10,886 | 10,163 |
| Total other income (expense) | (768) | (1,866) | (2,087) | (144,214) |
| **Net Operating Loss Before Income Tax Benefit** | (1,004,775) | (1,064,837) | (3,025,585) | (3,927,206) |
| **Income tax benefit** | 141,251 | 212,015 | 442,152 | 771,332 |
| **Net Loss** | $ (863,524) | $ (852,822) | $ (2,583,433) | $ (3,155,874) |
| **Net Loss per Common Share - Basic and Diluted** | $ (0.02) | $ (0.02) | $ (0.07) | $ (0.09) |
| **Weighted Average Common Shares Used to Compute Net Loss Applicable to Common Shares - Basic and Diluted** | 38,798,251 | 38,674,265 | 38,716,048 | 36,869,323 |

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

Processa Pharmaceuticals, Inc.
Condensed Consolidated Statement of Changes in Stockholders' Equity
Nine Months Ended September 30, 2019
(Unaudited)

| | Common Stock | | Additional Paid-In | Subscription | Accumulated | |
|---|---|---|---|---|---|---|
| | Shares | Amount | Capital | Receivable | Deficit | Total |
| Balance, January 1, 2019 | 38,674,265 | $ 3,867 | $ 19,121,285 | $ (1,800,000) | $ (7,624,134) | $ 9,701,018 |
| Stock-based compensation | - | - | 58,559 | - | - | 58,559 |
| Payments made directly by investor for clinical trial costs | - | - | - | 115,000 | - | 115,000 |
| Net loss | - | - | - | - | (750,832) | (750,832) |
| Balance, March 31, 2019 | 38,674,265 | 3,867 | 19,179,844 | (1,685,000) | (8,374,966) | 9,123,745 |
| Stock-based compensation | - | - | 66,476 | - | - | 66,476 |
| Payments made directly by investor for clinical trial costs | - | - | - | 280,927 | - | 280,927 |
| Net loss | - | - | - | - | (969,077) | (969,077) |
| Balance, June 30, 2019 | 38,674,265 | 3,867 | 19,246,320 | (1,404,073) | (9,344,043) | 8,502,071 |
| Conversion of Senior Convertible Debt for common stock and stock purchase warrants | 126,741 | 13 | 258,917 | - | - | 258,930 |
| Payments made by investor for clinical trial costs | - | - | - | 504,073 | - | 504,073 |
| Pledge shares of common stock forfeited upon revised research funding commitment | (396,476) | (40) | (899,960) | 900,000 | - | - |
| Stock-based compensation | - | - | 269,129 | - | - | 269,129 |
| Net loss | - | - | - | - | (863,524) | (863,524) |
| | 38,404,530 | $ 3,840 | $ 18,874,406 | $ - | $ (10,207,567) | $ 8,607,679 |

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

Processa Pharmaceuticals Inc.
Condensed Consolidated Statement of Changes in Stockholders' Equity
Nine Months Ended September 30, 2018
(Unaudited)

| | Common Stock | | Additional Paid-In | Subscription | Accumulated | |
|---|---|---|---|---|---|---|
| | Shares | Amount | Capital | Receivable | Deficit | Total |
| Balance, January 1, 2018 | 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 held by Promet | - | - | 8,000,000 | - | - | 8,000,000 |
| Net loss | - | - | - | - | (1,096,798) | (1,096,798) |
| Balance, March 31, 2018 | 35,272,626 | 3,527 | 12,228,723 | - | (4,955,884) | 7,276,366 |
| 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 $218,422 | 1,402,442 | 140 | 2,964,955 | - | - | 2,965,095 |
| 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 | - | - | - | - | (1,206,255) | (1,206,255) |
| Balance, June 30, 2018 | 38,674,265 | 3,867 | 19,266,508 | (1,800,000) | (6,162,139) | 11,308,236 |
| Stock-based compensation | - | - | 50,528 | - | - | 50,528 |
| Net loss | - | - | - | - | (852,822) | (852,822) |
| Balance, September 30, 2018 | 38,674,265 | $ 3,867 | $ 19,317,036 | $ (1,800,000) | $ (7,014,961) | $ 10,505,942 |

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

Processa Pharmaceuticals, Inc.
Condensed Consolidated Statements of Cash Flows
Nine Months Ended September 30, 2019 and 2018
(Unaudited)

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2019 | 2018 |
| **Cash Flows From Operating Activities** | | |
| Net Loss | $ (2,583,433) | $ (3,155,874) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 6,334 | 6,334 |
| Amortization of right-of-use assets | 55,012 | - |
| Amortization of debt issuance costs | - | 64,841 |
| Amortization of intangible asset | 596,496 | 422,814 |
| Deferred income tax benefit | (442,152) | (771,332) |
| Stock-based compensation | 394,164 | 50,528 |
| Payments/Reimbursements made directly by an investor in partial satisfaction of their stock subscription receivable | 900,000 | - |
| Net changes in operating assets and liabilities: | | |
| Prepaid expenses | 37,552 | (240,872) |
| Operating lease liability | (58,999) | - |
| Accrued interest | 8,587 | 89,522 |
| Accounts payable | (227,241) | 29,334 |
| Due (from)/to related parties | 46,647 | (32,393) |
| Accrued expenses | 30,374 | 293,160 |
| Net cash used in operating activities | (1,236,659) | (3,243,938) |
| | | |
| **Cash Flows From Investing Activities** | | |
| Purchase of intangible asset | - | (1,782) |
| Purchase of software license | - | (20,500) |
| Net cash used in investing activities | - | (22,282) |
| | | |
| **Cash Flows From Financing Activities** | | |
| Net proceeds from issuance of common stock | - | 2,965,095 |
| 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 | - | 2,843,014 |
| | | |
| **Net (Decrease)/Increase in Cash and Cash Equivalents** | (1,236,659) | (423,206) |
| **Cash and Cash Equivalents – Beginning of Period** | 1,740,961 | 2,847,429 |
| **Cash and Cash Equivalents – End of Period** | $ 504,302 | $ 2,424,223 |

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

Processa Pharmaceuticals, Inc.
Condensed Consolidated Statements of Cash Flows (continued)
Nine Months Ended September 30, 2019 and 2018
(Unaudited)

| | Nine Months Ended September 30, 2019 | |
|---|---|---|
| | 2019 | 2018 |
| **Non-Cash Investing and Financing Activities:** | | |
| Right-of-use asset obtained in exchange for operating lease liability | (293,198) | - |
| Reduction in deferred lease liability | (9,963) | - |
| Operating lease liability | 303,161 | - |
| Recognize the 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 released by Promet to CoNCERT for Processa | - | 8,000,000 |
| Net | $ - | $ - |
| Conversion of Senior Convertible Debt and related accrued interest into shares of common stock and warrants | $ 258,930 | $ 2,395,111 |
| Common stock and stock purchase warrants issued in connection with a clinical trial funding commitment | $ (900,000) | $ 1,800,000 |

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

**Note 1 – Organization and Summary of Significant Accounting Policies**

*Business Activities and Organization*

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

Our lead product, PCS-499, is an oral tablet that is a deuterated analog of one of the major metabolites of pentoxifylline (Trental®). The advantage of PCS-499 is that it potentially may work in many conditions due to the multiple pharmacological targets it affects that are important in the treatment of these conditions. Based on its pharmacological activity, we have identified multiple unmet medical need conditions where the use of PCS-499 may result in clinical efficacy. The lead indication currently under development for PCS-499 is Necrobiosis Lipoidica (NL). NL is a chronic, disfiguring condition affecting the skin and the tissue under the skin typically on the lower extremities with no currently approved FDA treatments. NL presents more commonly in women than in men and ulceration can occur in approximately 30% of NL patients. More severe complications can occur, such as deep tissue infections and osteonecrosis threatening life of the limb. Approximately 74,000 - 185,000 people in the United States and more than 200,000 – 500,000 people outside the United States are affected by NL.

On June 22, 2018, the FDA granted orphan-drug designation to PCS-499 for the treatment of NL. On September 28, 2018, the FDA cleared our IND for PCS-499 in NL such that we could move forward with the Phase 2a safety-dose tolerability trial. We dosed our first NL patient in this Phase 2a clinical trial on January 29, 2019. On August 23, 2019, our study was fully enrolled as the twelfth patient was dosed. The main objective of the trial is to evaluate the safety and tolerability of PCS-499 in patients with NL. We expect the safety and efficacy data collected to provide information for the design of future clinical trials. Based on toxicology studies and healthy human volunteer studies, Processa and the FDA agreed that a PCS-499 dose of 1.8 grams/day would be the highest dose administered to NL patients in this Phase 2 trial. As anticipated, the PCS-499 dose of 1.8 grams/day, 50% greater than the maximum tolerated dose of pentoxifylline, appears to be well tolerated with no serious adverse events reported. Twelve patients have been dosed with nine patients on treatment for at least four months, seven patients on treatment for at least six months, and two patients on treatment for at least nine months. Currently, nine patients remain in the study. To date, six patients dosed at 1.8 g/day have reported only mild adverse events related to the treatment, which occurred mostly in the first month of treatment and were quickly resolved. As expected, gastrointestinal or central nervous system (CNS) adverse events were reported most often.

The degeneration of tissue occurring at the NL lesion site is caused by a number of pathophysiological changes, which has made it extremely difficult to develop effective treatments for this condition. PCS-499 may provide a solution since PCS-499 and its metabolites affect a number of biological pathways, several of which contribute to the pathophysiology associated with NL. As expected, we have not yet seen any significant change in the NL lesion of the trial participants. We are continually evaluating the data we receive.

We plan to request a meeting with the FDA before the end of 2019 to further discuss the development of PCS-499, including the next clinical trial.

On August 29, 2019, we entered into an exclusive license agreement with Akashi Therapeutics, Inc. (“Akashi”) to develop and commercialize an anti-fibrotic, anti-inflammatory drug (HT-100) that also promotes healthy muscle fiber regeneration. In previous clinical trials in Duchenne Muscular Dystrophy (DMD), HT-100 showed promising improvement in the muscle strength of non-ambulant pediatric patients. Although the FDA placed a clinical hold on the DMD trial after a serious adverse event in a pediatric patient, FDA has removed the drug off clinical hold and defined how HT-100 can resume clinical trials in DMD. Once we have obtained adequate funding, we plan to develop HT-100 in rare adult fibrotic related diseases such as focal segmental glomerulosclerosis, idiopathic pulmonary fibrosis or Scleroderma.

*Basis of Presentation*

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

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

*Going Concern and Management's Plans*

Our condensed consolidated financial statements have been prepared using U.S. GAAP and are based on the assumption that we will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. We face certain risks and uncertainties that are present in many emerging 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. We currently have no customers or pharmaceutical products to sell or distribute. These risks and other factors raise substantial doubt about our ability to continue as a going concern.

We have relied exclusively on private placements with a small group of accredited investors to finance our business and operations. As described in more detail below, we recently entered into two line of credit agreements providing a revolving commitment of an aggregate up to $1.4 million but have not drawn any amounts as of the date of this report. We have not had any revenue since our inception. We are looking at ways to add a revenue stream to offset some of our expenses but do not currently have any revenue under contract or any immediate sales prospects. During the nine months ended September 30, 2019, we had an accumulated deficit of $10.2 million, incurred a net loss of $2.6 million and used $1.2 million in net cash from operating activities from continuing operations. At September 30, 2019, we had cash and cash equivalents totaling $504,302. During the nine months ended September 30, 2019, PoC Capital (our clinical trial funding commitment investor) made payments directly to our CRO totaling $689,168 for amounts invoiced. PoC Capital also repaid us $210,832 for clinical trial expenses we previously paid to our CRO, $180,119 of which is included in Prepaid and Other on our condensed consolidated balance sheet at September 30, 2019.

On September 20, 2019, we entered into two separate Line of Credit Agreements ("LOC Agreements") with DKBK Enterprises, LLC ("DKBK") and current shareholder CorLyst, LLC ("CorLyst"), both related parties ("Lenders"), which provide a revolving commitment of up to $700,000 each ($1.4 million total). Under the LOC Agreements, all funds borrowed will bear an 8% annual interest rate. The lenders have the right to convert all or any portion of the debt and interest into shares of our common stock at a conversion price equal to the lower of (i) $2.04 per share (ii) a price per share equal to a 10% discount to the pre-money valuation of a Qualified Financing or an Equity State Transaction or (iii) at an adjusted price; all as defined in the 8% Senior Note agreement. The lenders will also receive stock purchase warrants on a 1:1 basis to the number of shares of common stock received that have an exercise price equal to the greater of (i) the closing price of our common stock on the date of conversion or (ii) $2.72 per share. Our Chief Executive Officer (CEO) is also the Chief Executive Officer and Managing Member of both Lenders. CorLyst beneficially owns 6,859,527 shares of Processa common stock, representing approximately 17.7% of the Company's outstanding shares of voting capital stock. We have not drawn any amounts under these LOC agreements.

In connection with the LOC Agreements, we amended the existing pledge agreement with PoC Capital on September 30, 2019 to reduce the committed funds from $1.8 million to $900,000, which has now been paid in full. As part of the original pledge agreement, we issued 792,952 shares of common stock and 792,952 warrants to purchase shares of common stock to PoC Capital but held 396,476 shares and 396,476 warrants as collateral until certain payment milestones were met. PoC Capital forfeited the pledged collateral in the amended agreement and the shares have been reissued to Processa and will be retired.

We are currently in the process of raising additional funds through the private sale of 8% Senior Convertible Notes ("8% Senior Notes") to accredited investors. As of November 5, 2019, $745,000 from the sale of 8% Senior Notes to both new and existing investors has been received in escrow. We have not recorded these amounts in the accompanying condensed consolidated financial statements at September 30, 2019 since these investors, in connection with the revision of our agreement with PoC Capital and our entering into the LOC agreements, had the opportunity through October 18, 2019 to rescind their investment. No investors indicated any intention to rescind any investment and we plan to close the escrow account in the fourth quarter of 2019, at which time we will record the proceeds. We have also delayed some of our cash outflows, primarily through the deferred payment of salaries ($48,840 has been accrued and included in accrued expenses during the three and nine months ended September 30, 2019) until such time as we have raised sufficient funding.

Based on our current plan, we likely need to raise additional capital to fund our future operations. While we believe our current resources are adequate to complete our current Phase 2a trial for NL, we do not currently have resources to conduct other future trials or develop HT-100 without raising additional capital. As noted above, the timing and extent of our spending will depend on the costs associated with, and the results of our Phase 2a trial for NL. Our anticipated spending and our cash flow needs could change significantly as the trial progresses. There may be costs we incur during our trial that we do not currently anticipate in order to complete the trial, requiring us to need additional capital sooner than currently expected.

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

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

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

*Use of Estimates*

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

*Intangible Assets*

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

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

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

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

*Impairment of Long-Lived Assets and Intangibles Other Than Goodwill*

We account for the impairment of long-lived assets in accordance with ASC 360, *Property, Plant and Equipment* and ASC 350, *Intangibles – Goodwill and Other,* which require that long-lived assets and certain identifiable intangibles be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to its expected future undiscounted net cash flows generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amounts of the assets exceed the fair value of the assets based on the present value of the expected future cash flows associated with the use of the asset. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. Based on management's evaluation, there was no impairment loss recorded during the nine months ended September 30, 2019.

*Stock-based Compensation*

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

*Net Loss Per Share*

Basic loss per share is computed by dividing our net loss available to common shareholders by the weighted average number of shares of common stock outstanding during the period. Diluted loss per share is computed by dividing our net loss available to common shareholders by the diluted weighted average number of shares of common stock during the period. Since we experienced a net loss for all periods presented, basic and diluted net loss per share are the same. As such, diluted loss per share for the three and nine months ended September 30, 2019 and 2018 excludes the impact of potentially dilutive common shares related to outstanding stock options, warrants and the conversion of our Senior Convertible Notes since those shares would have an anti-dilutive effect on loss per share.

*Research and Development*

Research and development costs are expensed as incurred and consisted of direct and overhead-related expenses.

*Recently Adopted Accounting Pronouncements*

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

The adoption of the new guidance did not have a material impact on the condensed consolidated statement of operations. For further details regarding the adoption of this standard, see Note 9, “Operating Leases.”

**Note 2 – Intangible Assets**

Intangible assets at September 30, 2019 and December 31, 2018 consisted of the following:

| | September 30, 2019 | December 31, 2018 |
|---|---|---|
| Gross intangible assets | $ 11,059,429 | $ 11,059,429 |
| Less: Accumulated amortization | (1,218,143) | (621,647) |
| Total intangible assets, net | $ 9,841,286 | $ 10,437,782 |

Amortization expense was $198,832 and $200,256 for the three months ended September 30, 2019 and 2018, respectively, and $596,496 and $422,814 for the nine months ended September 30, 2019 and 2018, respectively. This expense is included within research and development expense in the accompanying condensed consolidated statements of operations. Our estimated amortization expense for the next year will be approximately $795,000 and approximately $788,000 per year for annual periods thereafter.

The capitalized costs for the license rights to PCS-499 included the $8 million purchase price, $1,782 in transaction costs and $3,037,147 associated with the initial recognition of an offsetting deferred tax liability related to the acquired temporary difference for an asset purchased that is not a business combination and has a tax basis of $1,782 in accordance with ASC 740-10-25-51 *Income Taxes*. In accordance with ASC Topic 730, *Research and Development*, we capitalized the costs of acquiring the exclusive license rights to PCS-499, as the exclusive license rights represent intangible assets to be used in research and development activities that management believes has future alternative uses.

**Note 3 – Income Taxes**

We account for income taxes in accordance with ASC Topic 740, *Income Taxes.* Deferred income taxes are recorded for the expected tax consequences of temporary differences between the tax basis of assets and liabilities for financial reporting purposes and amounts recognized for income tax purposes. As of September 30, 2019, and December 31, 2018, we recorded a valuation allowance equal to the full recorded amount of our net deferred tax assets related to deferred start-up costs and other minor temporary differences since it is more-likely-than-not that such benefits will not be realized. The valuation allowance is reviewed quarterly and is maintained until sufficient positive evidence exists to support its reversal.

A deferred tax liability was recorded on March 19, 2018 when Processa received CoNCERT’s license and “Know-How” in exchange for Processa stock that had been issued in an Internal Revenue Code Section 351 Transaction. The Section 351 Transaction treats the acquisition of the license and Know-How for stock as a tax-free exchange. As a result, under ASC 740-10-25-51 *Income Taxes*, Processa recorded a deferred tax liability of $3,037,147 for the acquired temporary difference between intangible assets (see Note 2) for the financial reporting basis of $11,038,929 and the tax basis of $1,782. The deferred tax liability will be reduced for the effect of non-deductibility of the amortization of the intangible asset and may be offset by the deferred tax assets resulting from net operating tax losses.

Under ACS 740-270 *Income Taxes – Interim Reporting*, we are required to project our annual federal and state effective income tax rate and apply it to the year to date ordinary operating tax basis loss before income taxes. Based on the projection, we expect to recognize the tax benefit from our projected ordinary tax loss, which can be used to offset the deferred tax liabilities related to the intangible assets and resulted in the recognition of a deferred tax benefit shown in the condensed consolidated statements of operations for three and nine months ended September 30, 2019 and 2018. No current income tax expense is expected for the foreseeable future as we expect to generate net operating tax losses.

**Note 4 - Stock-based Compensation**

On June 20, 2019, our Board of Directors granted stock options for the purchase of 909,230 shares of our common stock to employees. The stock options awarded contained either service or performance vesting conditions, as described below, have a contractual term of five years and an exercise price equal to the closing price of our common stock on the OTCQB on the date of grant of $2.40. We granted 334,400 stock options to employees and non-employees during the nine months ended September 30, 2018.

Stock options representing the purchase of 456,000 shares of common stock (of the 909,230 stock options granted on June 20, 2019) contained service vesting conditions. The service condition related solely to employees rendering service over a three-year period. These awards vest one-third on the first anniversary of the grant date, and then vest ratably over the remaining twenty-four months, $1/36^{th}$ of the original award each month.

Stock options representing the purchase of 453,230 shares of common stock (of the 909,230 stock options granted on June 20, 2019) vest upon meeting the following performance criteria: (i) 90,646 shares vest when we in-license one new or additional drug; (ii) 90,646 shares vest when our current Phase 2a clinical trial for PCS-499 is complete; and (iii) 271,938 shares vest when we up-list from the OTCQB to either the Nasdaq or NYSE markets. As of September 30, 2019, we are recognizing compensation cost for the awards related to completion of our current clinical trial and for in-licensing a new drug. The clinical trial is progressing as planned with no significant adverse events, is fully enrolled, and fully funded. Management does not foresee any reasons why this study will not be completed as planned and believes it is probable that this performance condition will be met in mid-2020. On August 29, 2019, we reached a license agreement with Akashi Therapeutics for HT-100 and as such, the performance condition related to the award for in-licensing one new or additional drug has been met. As for the last award with performance conditions related to up-listing on Nasdaq or NYSE markets, management has determined that until we complete the performance related condition, it is not probable to conclude the performance condition will be achieved. As such, no stock-based compensation expense is being recorded for those awards.

We had outstanding options to purchase 334,400 and 1,293,630 shares of our common stock at September 30, 2018 and 2019, respectively, of which options for the purchase of 187,746 shares of our common stock have been vested. We recorded $50,528 and $269,129 for the three months ended September 30, 2018 and 2019, respectively, and $50,528 and $394,164 of stock-based compensation expense for the nine months ended September 30, 2018 and 2019, respectively. The allocation of stock-based compensation expense between research and development and general and administrative expense was as follows:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2019** | **2018** | **2019** | **2018** |
| Research and Development | $ 88,707 | $ - | $ 92,111 | $ - |
| General and Administrative | 180,422 | 50,528 | 302,053 | 50,528 |
| | $ 269,129 | $ 50,528 | $ 394,164 | $ 50,528 |

**Note 5 – Debt**

Line of Credit Agreements

On September 20, 2019, we entered into two separate Line of Credit Agreements (“LOC Agreements”) with DKBK Enterprises, LLC (“DKBK”) and current shareholder CorLyst, LLC (“CorLyst”), both related parties (“Lenders”), which provide a revolving commitment of up to $700,000 each ($1.4 million total). Under the LOC Agreements, all funds borrowed will bear an 8% annual interest rate. The lenders have the right to convert all or any portion of the debt and interest into shares of our common stock at a conversion price equal to the lower of (i) $2.04 per share, (ii) a price per share equal to a 10% discount to the pre-money valuation of a Qualified Financing or an Equity State Transaction, or (iii) at an adjusted price; all as defined in the 8% Senior Note agreement. The lenders will also receive stock purchase warrants on a 1:1 basis to the number of shares of common stock received that have an exercise price equal to the greater of (i) the closing price of our common stock on the date of conversion or (ii) $2.72 per share. Our Chief Executive Officer (CEO) is also the Chief Executive Officer and Managing Member of both Lenders. CorLyst beneficially owns 6,859,527 shares of Processa common stock, representing approximately 17.7% of the Company’s outstanding shares of voting capital stock.

We have not drawn any amounts under these LOC agreements.

Senior Convertible Notes

At September 30, 2019 and December 31, 2018, we had $0 and $230,000 of Senior Convertible Notes outstanding. The $230,000 outstanding at December 31, 2018 were held by Canadian investors that, although qualifying for automatic and mandatory conversion, could not be converted until the Alberta Securities Commission released us from a cease trade order, which predated our merger with HeatWurx, and permitted us to issue common stock units (consisting of shares of our common stock and stock purchase warrants) to these Canadian investors. In June 2019, the Alberta Securities Commission released the cease trade order and assessed us a $10,000 fine, which was expensed. On July 2, 2019, we converted the principal and related accrued interest of $258,930 into 126,741 shares of common stock and 126,741 stock purchase warrants.

We are currently in the process of raising additional funds through the private sale of 8% Senior Convertible Notes ("8% Senior Notes") to accredited investors. As of November 5, 2019, we have received into escrow $745,000 from the sale of 8% Senior Notes. We have not recorded these amounts in the accompanying condensed consolidated financial statements at September 30, 2019 since these investors, in connection with the revision of our agreement with PoC Capital and our entering into the LOC agreements, had the opportunity through October 18, 2019 to rescind their investment. No investors indicated their plan to rescind any investment and we plan to close the escrow account in the fourth quarter of 2019, at which time we will record the proceeds.

**Note 6 – License Agreement for HT-100**

As described in Note 1 – Business Activities and Organization, on August 29, 2019, we entered into an exclusive license agreement with Akashi to develop and commercialize an anti-fibrotic, anti-inflammatory drug, HT-100. As partial consideration for the licenses, we paid $10,000 to Akashi upon full execution of the license agreement. This upfront payment was expensed as a research and development cost. As additional consideration, we will pay Akashi up to $12 million over the period of achieving certain future development and regulatory milestones related to the drug. The expense related to these milestone payments will be recorded as research and development expense over the period from when achieving the milestone is probable to when the milestone is actually achieved. The agreement also contains provisions for sales milestone payments and royalty payments.

**Note 7 – Stockholders' Equity**

During the nine months ended September 30, 2019 and 2018, there were no sales of our preferred stock. At September 30, 2019 and December 31, 2018, there were no issued or outstanding shares of preferred stock. During the nine months ended September 30, 2019, PoC Capital (our clinical trial funding commitment investor), made payments directly to our CRO totaling $689,168 for amounts invoiced. PoC Capital also repaid us $210,832 for clinical trial expenses we previously paid to our CRO, $180,119 of which is included in Prepaid and Other on our condensed consolidated balance sheet at September 30, 2019. As explained in Note 1 – Going Concern, we amended the existing pledge agreement with PoC Capital on September 30, 2019 to reduce the committed funds from $1.8 million to $900,000, which has now been paid in full. As part of the original pledge agreement, we issued 792,952 shares of common stock and 792,952 warrants to purchase shares of common stock to PoC Capital but held 396,476 shares and 396,476 warrants as collateral until certain payment milestones were met. PoC Capital forfeited the pledged collateral in the amended agreement and the shares have been reissued to Processa and will be retired.

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

**Note 8 – 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, which includes potentially dilutive effect of stock options, warrants and senior convertible notes. Since we experienced a loss for all periods presented, including any dilutive common shares outstanding would have an anti-dilutive impact on diluted net loss per share, and as shown below, were excluded from the computation. The treasury-stock method is used to determine the dilutive effect of our stock options and warrants grants, and the if-converted method is used to determine the dilutive effect of the Senior Notes.

The computation of net loss per share for the three and nine months ended September 30, 2019 and 2018 was as follows:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| **Basic and diluted net loss per share:** | | | | |
| Net loss from continuing operations | $ (863,524) | (852,822) | $ (2,583,433) | $ (3,155,874) |
| Weighted average number of common shares-basic and diluted | 38,798,251 | 38,674,265 | 38,716,048 | 36,869,323 |
| Basic and diluted net loss per share | $ (0.02) | $ (0.02) | $ (0.07) | $ (0.09) |

The following potentially dilutive securities were excluded from the computation of diluted net income per share as their effect would have been anti-dilutive for the periods presented.

| | September 30, 2019 | December 31, 2018 |
|---|---|---|
| Stock options and purchase warrants | 4,636,682 | 3,997,187 |
| Senior convertible notes and related accrued interest | - | 122,717 |

**Note 9 - Operating Leases**

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

Lease costs included in our condensed consolidated statement of operations totaled $73,621 and $66,712 for the nine months ended September 30, 2019 and 2018, respectively. The weighted average remaining lease terms and discount rate for our operating leases were as follows at September 30, 2019:

| | |
|---|---|
| Weighted average remaining lease term (years) for our facility and equipment leases | 2.6 |
| Weighted average discount rate for our facility and equipment leases | 8% |

Maturities of our lease liabilities for all operating leases were as follows as of September 30, 2019:

| | |
|---|---|
| 2019 | $ 23,396 |
| 2020 | 92,603 |
| 2021 | 90,495 |
| 2022 | 69,741 |
| Total lease payments | 276,235 |
| Less: Interest | (32,073) |
| Present value of lease liabilities | 244,162 |
| Less: current maturities | (77,423) |
| Non-current lease liability | $ 166,739 |

**Note 10 – Related Party Transactions**

A shareholder, CorLyst, LLC, reimburses us for shared costs related to payroll, health care insurance and rent based on actual costs incurred, which are recognized as a reduction of our general and administrative operating expenses being reimbursed in our condensed consolidated statements of operations. Reimbursable expenses from CorLyst totaled $79,058 and $80,447 for rent and other costs during the nine months ended September 30, 2019 and 2018, respectively. In August 2019, CorLyst prepaid us for Q3 and Q4 shared expenses. At September 30, 2019, we recognize $25,727 in prepaid reimbursements as due to related parties in the accompanying condensed consolidated balance sheet. Amounts due from CorLyst at September 30, 2019 and December 31, 2018 were $0 and $21,583, respectively.

As described further in Note 1 – Going Concern and Note 5, we also entered into two separate Line of Credit Agreements with CorLyst, LLC and DKBK Enterprises, LLC, both related parties, on September 20, 2019.

**Note 11 – Commitments and Contingencies**

*Purchase Obligations*

We enter into contracts in the normal course of business with contract research organizations and subcontractors to further develop our products. The contracts are cancellable, with varying provisions regarding termination. If a contract with a specific vendor were to be terminated, we would only be obligated for products or services that we received as of the effective date of the termination and any applicable cancellation fees. We had a purchase obligation of approximately $16,000 and $35,000 at September 30, 2019 and December 31, 2018, respectively.

**Note 12 – Subsequent Events**

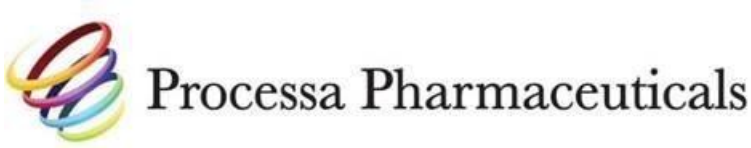
Senior Convertible Notes

As of November 5, 2019, we have received into escrow $745,000 from the sale of 8% Senior Convertible Notes (8% Senior Notes). We have not recorded these amounts in the accompanying condensed consolidated financial statements at September 30, 2019 since these investors, in connection with the revision of our agreement with PoC Capital and our entering into the LOC agreements, had the opportunity through October 18, 2019 to rescind their investment. No investors indicated their plan to rescind any investment and we plan to close the escrow account in the fourth quarter of 2019, at which time we will record the proceeds.

Upon completion of listing our common stock on either the Nasdaq Capital Market or the New York Stock Exchange, our 8% Senior Notes are mandatorily convertible into shares of our common stock at a conversion price equal to the lower of (i) $2.04 per share or (ii) a price per share equal to a 10% discount to the pre-money valuation of a Qualified Financing or an Equity State Transaction, both as defined in the 8% Senior Note agreement, occurring after the closing of the 8% Senior Note financing. Upon maturity (December 15, 2020), the 8% Senior Note holders have the option to convert the 8% Senior Note into shares of our common stock at the lower of $2.04 per share or an adjusted price as set forth in the 8% Senior Note agreement. Upon either mandatory conversion or conversion at the holder's option, the holder will also receive stock purchase warrants on a 1:1 basis to the number of shares of common stock received that have an exercise price equal to the greater of (i) the closing price of our common stock on the date of conversion or (ii) $2.72 per share.

Reverse Stock Split

On October 31, 2019, our Board of Directors authorized management to effect a reverse stock split of our common stock in a ratio between four for one share to ten to one share, subject to regulatory approval and at the discretion of the Board of Directors. The accompanying condensed consolidated financial statements have not been adjusted to reflect the effect of any future reverse stock split.




**Processa Pharmaceuticals, Inc.**

- **Shares of Common Stock**

- **, 2019**

**Through and including ●, 2019 (the 25th day after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.**

**PART II**

## INFORMATION NOT REQUIRED IN PROSPECTUS

**Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, paid or payable by the Registrant in connection with the sale of the common stock being registered. All amounts shown are estimates except for the SEC registration fee and the FINRA filing fee:

| | | Amount |
|---|---|---|
| SEC registration fee | $ | 2,044.35 |
| FINRA filing fee | | 1,000.00 |
| Initial Nasdaq Global Market listing fee | | ● |
| Blue sky qualification fees and expenses | | ● |
| Printing and engraving expenses | | ● |
| Legal fees and expenses | | ● |
| Accounting fees and expenses | | ● |
| Transfer agent and registrar fees and expenses | | ● |
| Miscellaneous expenses | | ● |
| Total | $ | ● |

**Item 14. Indemnification of Directors and Officers.**

Processa Pharmaceuticals, Inc. is incorporated under the laws of the State of Delaware.

Section 102(b)(7) of the General Corporation Law of the State of Delaware, or the "DGCL," permits a Delaware corporation to include a provision in its certificate of incorporation eliminating or limiting the personal liability of directors to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. This provision, however, may not eliminate or limit a director's liability (1) for breach of the director's duty of loyalty to the corporation or its stockholders, (2) for acts or omissions not in good faith or involving intentional misconduct or a knowing violation of law, (3) under Section 174 of the DGCL, or (4) for any transaction from which the director derived an improper personal benefit. The amended and restated certificate of incorporation of Processa contains such a provision.

Section 145(a) of the DGCL provides that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation), by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's conduct was unlawful.

Section 145(b) of the DGCL provides that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Delaware Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Delaware Court of Chancery or such other court shall deem proper.

Section 145(c) of the DGCL provides that to the extent that a present or former director or officer of a corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding referred to in subsections (a) and (b) of Section 145 of the DGCL, or in defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith.

Section 145(e) of the DGCL permits a Delaware corporation to advance litigation expenses, including attorneys' fees, incurred by present and former directors and officers prior to the final disposition of the relevant proceedings. The advancement of expenses to a present director or officer is conditioned upon receipt of an undertaking by or on behalf of such director or officer to repay the advancement if it is ultimately determined that such director or officer is not entitled to be indemnified by the corporation. Advancement to former officers and directors may be conditioned upon such terms and conditions, if any, as the corporation may deem appropriate.

Section 145(g) of the DGCL specifically allows a Delaware corporation to purchase liability insurance on behalf of its directors and officers and to insure against potential liability of such directors and officers regardless of whether the corporation would have the power to indemnify such directors and officers under Section 145 of the DGCL.

The amended and restated certificate of incorporation and the amended and restated bylaws of Processa authorize the corporation to indemnify its directors and officers to the fullest extent permitted by law.

The foregoing summaries are necessarily subject to the complete text of the DGCL and Processa's amended and restated certificate of incorporation and amended and restated bylaws.

**Item 15. Recent Sales of Unregistered Securities.**

In the three years preceding the filing of this registration statement, we have issued the following securities that were not registered under the Securities Act (adjusted for the one for seven reverse stock split completed on December ●, 2019):

- On September 29, 2017, prior to the consummation of the Asset Purchase Agreement, Heatwurx converted 178,924 shares of Series D Preferred Stock and all accrued dividends in the amount of $118,658 into 102,786 shares of Common Stock.

- On October 4, 2017 and November 21, 2017, accredited investors purchased $1.25 million and $1.33 million of our senior secured convertible notes in a bridge financing undertaken by us to support our operations. The Notes were issued in reliance on the exemptions from registration under Regulation D and Securities Act Section 4(a)(2).

- On October 4, 2017, in connection with the Asset Purchase Agreement dated October 2, 2017, among the Company, Promet Therapeutics LLC ("Promet") and Processa Therapeutics LLC, the Company's wholly owned subsidiary ("Asset Purchase Agreement"), we issued 4,535,035 shares of the Company's Common Stock to Promet in exchange for all the assets of Promet. On December ●, 2019, Promet distributed these shares to the beneficial holders. The issuance of our shares was made in reliance on the exemption provided by Section 4(a)(2) of the Securities Act for the offer and sale of securities not involving a public offering, and Regulation D promulgated under the Securities Act.

- On May 15, 2018 and June 29, 2018, the Company entered into subscription and purchase agreements with certain accredited investors and conducted a closing pursuant to which the Company sold 157,378 shares of common stock and 42,972 shares of common stock at a purchase price of $15.89 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 $19.07, subject to adjustment thereunder. The Company received total gross proceeds of approximately $3.2 million from the closings, prior to deducting placement agent fees and estimated expenses payable by the Company associated with the closing. The common stock was 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. Boustead acted as placement agent. The placement agent received approximately $168,000 in connection with the closing and a warrant to purchase up to 12,021 shares of common stock at an exercise price equal to $19.07. We have used the proceeds to fund research and development of our lead product candidate, PCS-499, including clinical trial activities, and for general corporate purposes.

- On May 25, 2018, we entered into an agreement with an accredited investor to whom we sold 113,279 shares of common stock at a purchase price of $15.89 per share for $1.80 million of gross proceeds. 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 $19.07. The investor pledged 56,639 shares and warrants to purchase 56,639 shares to us to secure the investor's funding obligation. The $1.80 million private placement was applied to funding the Phase 2 Necrobiosis Lipoidica Trial, which began in the fourth quarter of 2018. The investor made payments totaling $689,168 directly to the CRO conducting our Phase 2 Necrobiosis Lipoidica Trial based on their invoicing. The investor also repaid us $210,832 for clinical trial expenses we previously paid to our CRO. On September 30, 2019, we amended the existing pledge agreement to reduce the committed funds from $1.8 million to $900,000, which has now been paid in full. The investor forfeited the pledged collateral in the amended agreement and the shares have been reissued to Processa and will be retired. Boustead Securities, placement agent, received as fees approximately $108,000 and a warrant to purchase up to 6,797 shares of common stock at an exercise price equal to $19.07. The Securities 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.

- In addition, on May 25, 2018 and July 2, 2019, we converted approximately $2.5 million of our mandatory convertible 8% Senior Notes and accrued interest of $119,178 into 190,427 shares of common stock, at a price of $14.30 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 $17.16. Boustead Securities, our placement agent, received as fees $154,800 and a warrant to purchase up to 11,347 shares of common stock at an exercise price equal to $17.16.

- On November 30, 2019, we sold $745,000 principal amount of 8.0% Senior Convertible Notes to accredited investors.

All sales of securities described above were exempt from the registration requirements of the Securities Act in reliance on Section 4(a)(2) of the Securities Act, Rule 701 promulgated under the Securities Act or Regulation D promulgated under the Securities Act, relating to transactions by an issuer not involving a public offering. All of the foregoing securities are deemed restricted securities for purposes of the Securities Act.

**Item 16. Exhibits and Financial Statement Schedules.**

(a) Exhibits.

The exhibits to the registration statement are listed in the Exhibit Index attached hereto and are incorporated by reference herein.

(b) Financial Statement Schedules.

All other schedules are omitted because they are not required, are not applicable, or the information is included in the financial statements or the related notes to financial statements thereto.

**Item 17. Undertakings.**

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the “Calculation of Registration Fee” table in the effective registration statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(5) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities: the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(6) Provide to the underwriter at the closing specified in the underwriting agreements certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

(7) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b) (1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(8) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

## EXHIBIT INDEX

In reviewing the agreements included as exhibits to this registration statement, please remember they are included to provide you with information regarding their terms and are not intended to provide any other factual or disclosure information about us, our subsidiaries or other parties to the agreements. The agreements contain representations and warranties by each of the parties to the applicable agreement. These representations and warranties have been made solely for the benefit of the other parties to the applicable agreement and:

- should not in all instances be treated as categorical statements of fact, but rather as a way of allocating the risk to one of the parties if those statements prove to be inaccurate;
- have been qualified by disclosures that were made to the other party in connection with the negotiation of the applicable agreement, which disclosures are not necessarily reflected in the agreement;
- may apply standards of materiality in a way that is different from what may be viewed as material to you or other investors; and
- were made only as of the date of the applicable agreement or such other date or dates as may be specified in the agreement and are subject to more recent developments.

Accordingly, these representations and warranties may not describe the actual state of affairs as of the date they were made or at any other time. We acknowledge that, notwithstanding the inclusion of the foregoing cautionary statements, we are responsible for considering whether additional specific disclosures of material information regarding material contractual provisions are required to make the statements in this registration statement not misleading. Additional information about us may be found elsewhere in the prospectus included in this registration statement.

| Exhibit Number | Description of the Exhibit |
|---|---|
| 1.1 | Form of Underwriting Agreement* |
| 2.1 | Asset Purchase Agreement. Dated October 2, 2017, among the Company, Promet Therapeutics LLC and Processa Therapeutics LLC (incorporated by reference to exhibit 2.1 accompanying Form 8-K filed on October 5, 2017) |
| 3.1 | Fourth Amended and Restated Certificate of Incorporation of Heatwurx, Inc. (incorporated by reference to exhibit 3.1 to Form 8-K/A filed on October 17, 2017) |
| 3.1.1 | Amendment to Fourth Amended and Restated Certificate of Incorporation of Heatwurx, Inc. (incorporated by reference to exhibit 3.1 to Form 8-K filed on October 30, 2017) |
| 3.1.2 | Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation (incorporated by reference to Appendix A to Information Statement filed on July 18, 2019) |
| 3.2 | Bylaws (incorporated by reference to exhibit 3.2 to Form 10-K filed on March 27, 2014) |
| 4.1 | Specimen of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Form S-1/A filed on May 15, 2013) |
| 4.2 | Warrant issued to PoC Capital, LLC (incorporated by reference from Form 8-K filed June 1, 2018) |
| 4.3 | Warrant issued to PoC Capital, LLC (incorporated by reference from Form 8-K filed June 1, 2018) |
| 4.4 | Warrant issued to PoC Capital, LLC (incorporated by reference from Form 8-K filed June 1, 2018) |
| 4.5 | Warrants issued to Boustead Securities (incorporated by reference from Form 8-K filed June 1, 2018) |
| 4.6 | Form of Warrant (incorporated by reference to exhibit 10.3 to Form 10-Q filed on May 21, 2018) |
| 4.7 | Form of Underwriters' Warrant* |
| 4.8 | Form of 8% Senior Convertible Notes (filed herewith) |
| 5.1 | Opinion of Foley & Lardner LLP* |
| 10.1 | Amended and Restated 2011 Equity Incentive Plan (incorporated by reference to exhibit 10.10 to Form S-1 filed on November 14, 2012)+ |
| 10.2 | License Option Agreement with CoNCERT (incorporated by reference to exhibit 10.4 to Form 10-K/A filed on April 17, 2018) |

| | |
|---|---|
| 10.3 | Amendment to License Agreement and Securities Purchase Agreement with CoNCERT Pharmaceuticals (incorporated by reference to exhibit 10.5 to Form 10-K/A filed on April 17, 2018) |
| 10.4 | Employment Agreement dated September 5, 2018, between Processa and James Stanker (incorporated by reference from Form 8-K filed September 10, 2018) |
| 10.5 | Processa Pharmaceuticals, Inc. 2019 Omnibus Incentive Plan (incorporated by reference to Annex A to Processa's definitive proxy statement filed April 26, 2019). |
| 10.6 | Line of Credit Agreement dated September 20, 2019 between Processa Pharmaceuticals and DKBK Enterprises, LLC (incorporated by reference to Form 8-K filed October 3, 2019) |
| 10.7 | Line of Credit Agreement dated September 20, 2019 between Processa Pharmaceuticals and CorLyst, LLC (incorporated by reference to Form 8-K filed October 3, 2019) |
| 10.8 | License Agreement with Akashi Therapeutics, Inc. dated August 29, 2019 (incorporated by reference to Form 8-K filed September 4, 2019) |
| 21.1 | List of Subsidiaries (incorporated by reference to exhibit 21.1 to Form 10-K filed on March 28, 2019) |
| 23.1 | Consent of Foley & Lardner LLP (included in Exhibit 5.1)* |
| 23.2 | Consent of Independent Registered Public Accounting Firm, BD & Co. Inc. (filed herewith) |
| 24.1 | Power of Attorney (included on signature page) |
| 99.1** | XBRL Files |

+ Indicates a management contract or compensatory plan or arrangement.
* To be filed by amendment.
** Furnished herewith. XBRL (eXtensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act is deemed not filed for purposes of Section 18 of the Exchange Act and otherwise is not subject to liability under these sections.

## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in Hanover, Maryland, on the 13th day of December, 2019.

**Processa Pharmaceuticals, Inc.**

*/s/ David Young, Pharm.D, Ph.D.*
David Young, Pharm. D, Ph.D.
Chairman and Chief Executive Officer

## SIGNATURES AND POWER OF ATTORNEY

We, the undersigned directors and officers of Processa Pharmaceuticals, Inc., hereby severally constitute and appoint David Young and James Stanker, and each of them, our true and lawful attorneys-in-fact and agents, with full power of substitution and re-substitution for him or her and in his or her name, place, and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement, and any subsequent registration statements pursuant to Rule 462 of the Securities Act of 1933, as amended and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as we might or could do in person, hereby ratifying and confirming all that each of said attorney-in-fact or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof. Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

| Signature | Title | Date |
|---|---|---|
| */s/ David Young, Pharm.D, Ph.D.*<br>David Young, Pharm.D, Ph.D. | Chairman and Chief Executive Officer<br>*(principal executive officer)* | December 13, 2019 |
| */s/ James Stanker*<br>James Stanker | Chief Financial Officer<br>*(principal accounting officer and principal financial officer)* | December 13, 2019 |
| */s/ Patrick Lin*<br>Patrick Lin | Director | December 13, 2019 |
| */s/ Justin Yorke*<br>Justin Yorke | Director | December 13, 2019 |
| */s/ Virgil Thompson*<br>Virgil Thompson | Director | December 13, 2019 |

NEITHER THIS SECURITY NOR THE SECURITIES INTO WHICH THIS SECURITY IS CONVERTIBLE HAVE BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCEWITH APPLICABLE STATE SECURITIES LAWS. THIS SECURITY AND THE SECURITIES ISSUABLE UPON CONVERSION OF THIS SECURITY MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT OR OTHER LOAN SECURED BY SUCH SECURITIES.

Original Issue Date: As of ___, 2019

$_____

**PROCESSA PHARMACEUTICALS, INC.**
**8.0% SENIOR CONVERTIBLE NOTE**

THIS NOTE is a duly authorized and validly issued Senior Convertible Note of Processa Pharmaceuticals, Inc., a Delaware corporation, and its subsidiaries (the "Company"), having its principal place of business at 7380 Coca Cola Drive, Suite 106, Hanover, MD 21076, designated as a 8.0% Senior Secured Convertible Note (this "Note" or the "Senior Note").

FOR VALUE RECEIVED, and in consideration of the principal amount of _____, (hereinafter "Principal Amount") as _____(the "Holder") has made hereunder, to the Company, the Company promises to pay to the Holder, or its permitted assigns, the aggregate of unpaid Principal Amount and all accrued but unpaid interest under this Note on the earlier of: 1) the conversion of the Senior Note into shares of Company common stock as set forth herein or 2) December 15, 2020 ("Maturity Date"), in each instance in accordance with the provisions hereof.

This Note is subject to the following additional provisions:

Section 1. Definitions. For the purposes hereof, in addition to the terms defined elsewhere in this Note (a) capitalized terms not otherwise defined herein shall have the meanings set forth in the Subscription Agreement and (b) the following terms shall have the following meanings:

"Bankruptcy Event" means any of the following events: (a) the Company or any Significant Subsidiary (as such term is defined in Rule 1-02(w) of Regulation S-X) thereof commences a case or other proceeding under any bankruptcy, reorganization, arrangement, adjustment of debt, relief of debtors, dissolution, insolvency or liquidation or similar law of any jurisdiction relating to the Company or any Significant Subsidiary thereof; (b) there is commenced against the Company or any Significant Subsidiary thereof any such case or proceeding that is not dismissed within sixty (60) days after commencement; (c) the Company or any Significant Subsidiary thereof is adjudicated insolvent or bankrupt or any order of relief or other order approving any such case or proceeding is entered; (d) the Company or any Significant Subsidiary thereof suffers any appointment of any custodian or the like for it or any substantial part of its property that is not discharged or stayed within sixty (60) calendar days after such appointment; (e) the Company or any Significant Subsidiary thereof makes a general assignment for the benefit of creditors; (f) the Company or any Significant Subsidiary thereof calls a meeting of its creditors with a view to arranging a composition, adjustment or restructuring of its debts; or (g) the Company or any Significant Subsidiary thereof, by any act or failure to act, expressly indicates its consent to, approval of or acquiescence in any of the foregoing or takes any corporate or other action for the purpose of effecting any of the foregoing.

"Business Day" means any day except any Saturday, any Sunday, any day which shall be a federal legal holiday in the United States or any day on which banking institutions in the State of Delaware are authorized or required by law or other governmental action to close.

"Common Stock Equivalents" means any securities of the Company or its subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, rights, options, warrants or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.
"Event of Default" shall have the meaning set forth in Section 5(a).

"Maryland Courts" shall have the meaning set forth in Section 6(d).

"Original Issue Date" means the date of the first issuance of this Note, regardless of any transfers of this Note and regardless of the number of instruments which may be issued to evidence this Note.

"Permitted Indebtedness" means (a) the indebtedness evidenced by this Note, (b) the indebtedness existing on the Closing Date, (c) lease obligations and purchase money and (e) indebtedness that is expressly subordinate to this Note pursuant to a written subordination agreement with the Holder that is acceptable to the Holder in its sole and absolute discretion.

"Permitted Lien" means the individual and collective reference to the following:
(a) Liens existing on the Closing Date, (b) Liens for taxes, assessments and other governmental charges or levies not yet due or Liens for taxes, assessments and other governmental charges or levies being contested in good faith and by appropriate proceedings for which adequate reserves (in the good faith judgment of the management of the Company) have been established in accordance with GAAP; (c) Liens imposed by law which were incurred in the ordinary course of the Company's business, such as carriers', warehousemen's and mechanics' Liens, statutory landlords' Liens, and other similar Liens arising in the ordinary course of the Company's business, and which (x) do not individually or in the aggregate materially detract from the value of such property or assets or materially impair the use thereof in the operation of the business of the Company and its consolidated Subsidiaries or (y) are being contested in good faith by appropriate proceedings, which proceedings have the effect of preventing for the foreseeable future the forfeiture or sale of the property or asset subject to such Lien; and (d) Liens incurred in connection with Permitted Indebtedness.

"Offering Documents" shall have the meaning set forth in the Subscription Agreement, excluding, however, the Annual Report and Form 10-Qs and other filings made by the Company with the Securities and Exchange Commission.

"Qualified Financing" means an equity financing where the Company sells shares of it's common stock for cash.

"Subscription Agreement" means the Subscription Agreement, dated as of __, 2019, among the Company and the original Holder, as amended, modified or supplemented from time to time in accordance with its terms.

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

"Subsidiary" shall mean a Significant Subsidiary, as such term is defined in Rule 1-02(w) of Regulation S-X.

Section 2. Interest; No Prepayment.

a) Interest Rate. Interest shall accrue daily on the outstanding principal amount of this Note at a rate per annum equal to 8.0%.

b) Payment of Interest. On the Maturity Date, the Company shall pay to the Holder any accrued but unpaid and unconverted interest hereunder on the aggregate unconverted and then outstanding principal amount of this Note. The amount of interest that has accrued on the principal hereof as of any date shall be added to and included with the principal amount being so converted on any date on which a conversion is affected under Section 3 below.

c) Interest Calculations. Interest shall be calculated on the basis of a three hundred sixty (360)-day year, consisting of twelve (12) thirty (30) calendar day periods, and shall accrue daily commencing on the Original Issue Date until payment or conversion in full of the outstanding principal, together with all accrued and unpaid interest and other amounts which may become due hereunder, has been made. Interest hereunder will be paid to the Person in whose name this Note is registered on the records of the Company regarding registration and transfers of this Note.

d) Prepayment. This note may be prepaid by the Company at any time following the Original Issuance Date on seven (7) day's prior written notice to the Holder.

Section 3. Conversion

a). Optional Conversion on the Up-listing of the Company's Common Stock. Each Holder will have the option to convert a Senior Note, and all accrued and unpaid interest, at any time following the completion of the Company listing its common stock on a national securities exchange at a conversion price per share equal to the lower of (i) $2.04 or (ii) a per share price equal to a 10% discount to the calculated market capitalization immediately prior to a Qualified Financing or an acquisition with net cash obtained after the closing of this Senior Note financing ((i) or (ii) the "Conversion Price").

b). Additional Optional Conversion for Offering Proceeds. Each Holder will have the option to convert a Senior Note, and all accrued and unpaid interest, at any time following the Company raising at

least $14.0 million prior to December 15, 2020 in one or more Qualified Financings or an acquisition with net cash obtained.

c). Mandatory Conversion. If the Senior Note not been paid or converted prior to the Maturity Date, the outstanding Principal Amount of the Senior Note, and all accrued and unpaid interest, will be automatically converted into shares of common stock of the Company at the Conversion Price. Mandatory conversion shall be automatic.

d). Payment on Change of Control. If prior to the Maturity Date, there is a Change of Control and the Senior Note has not previously been converted, a Holder may elect to have the Senior Note together with any accrued interest repaid in full at that time plus an additional 10% on the principal amount of the Senior Note.

e). Anti-Dilution Provision. The shares of Common Stock issued in this Offering, but not the Warrants, will have the following weighted-average anti-dilution protection.

Except as provided below, in the event that the Company issues additional equity securities or securities convertible into equity securities at a purchase price less than $2.27 per share of Common Stock, the Purchase Price shall be adjusted and new shares of Common stock issued in accordance with the following formula until the Company has issued equity securities or securities convertible into equity securities for a total of $14.0 million in cash or assets, including the proceeds from the exercise of the Warrants issued in this Offering. For purposes of calculating the anti-dilution rights using the following formula, no value shall be attributed to the warrants and 100% of the purchase price of the units shall be attributed to the shares of Common Stock

$CP_2 = CP_1 * (A+B) / (A+C)$

$CP_2$ = Purchase Price in effect immediately after new issue

$CP_1$ = Purchase Price in effect immediately prior to new issue

A = Number of shares of Common Stock deemed to be outstanding immediately prior to new issue (includes all shares of outstanding Common Stock, all shares of Common Stock on an as-converted basis, and all outstanding Warrants on an as-exercised basis; all shares of Common Stock reserved for issuance under any Company incentive plan; and does not include any convertible securities converting in the subject transaction such as the outstanding notes).

B = Aggregate consideration received by the Company with respect to the new issue divided by $CP_1$

C = Number of Shares of stock issued in the subject transaction

The following issuances shall not trigger anti-dilution adjustment: (i) shares of Common Stock issued in this Offering and securities issuable upon exercise of the Warrants; (ii) securities issued upon the conversion of any outstanding debenture, warrant, option or other convertible security; (iii) Common Stock issuable upon a stock split, stock dividend, or any subdivision of shares of Common Stock, provided that such securities have not been amended since the date of this Agreement to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities (other than in connection with stock splits or combinations) or to extend the term of such securities; (iv) shares of Common Stock (or options to purchase such shares of Common Stock) issued or issuable to employees or directors of, or consultants to, the Company pursuant to any plan approved by the Company's Board of Directors and (v) securities issued pursuant to acquisitions or strategic transactions approved by a majority of the disinterested directors of the Company, provided that any such issuance shall only be to a person (or to the equity holders of a person) which is, itself or through its subsidiaries, believed by the Company to be an operating company or an owner of an asset in a business synergistic with the business of the Company.

Section 4. Negative Covenants. As long as any portion of this Note remains outstanding, unless the Holder shall have otherwise given prior written consent, the Company shall not, and shall not permit any of its subsidiaries (whether or not a Subsidiary on any Closing Date), to, directly or indirectly:

a) other than Permitted Indebtedness, enter into, create, incur, assume, guarantee or suffer to exist any indebtedness for borrowed money of any kind, including but not limited to, a guarantee, on or with respect to any of its property or assets now owned or hereafter acquired or any interest therein or any income or profits therefrom;

b) other than Permitted Liens, enter into, create, incur, assume or suffer to exist any Liens of any kind, on or with respect to any of its property or assets now owned or hereafter acquired or any interest therein or any income or profits therefrom;

c) repay, repurchase or offer to repay, repurchase or otherwise acquire more than a de minimis number of shares of its Common Stock or Common Stock Equivalents other than repurchases of Common Stock or Common Stock Equivalents of departing employees of the Company, provided that such repurchases shall not exceed an aggregate of $150,000 for all employees during the term of this Note, or withholding shares for the payment of taxes or exercise price under a Company employee benefit plan;

d) pay cash dividends or distributions on Common Stock of the Company;

e) enter into any transaction with any Affiliate of the Company which would be required to be disclosed in any public filing with the Commission, unless such transaction is expressly approved by a majority of the disinterested directors of the Company (even if less than a quorum otherwise required for board approval); or

f) enter into any agreement with respect to any of the foregoing.

Section 5. Events of Default.

a) "Event of Default" means, wherever used herein, any of the following events (whatever the reason for such event and whether such event shall be voluntary or involuntary or effected by operation of law or pursuant to any judgment, decree or order of any court, or any order, rule or regulation of any administrative or governmental body), provided that an event specified in item i, ii, iii, or vii below will not become an Event of Default unless and until it is not cured, if possible to cure, within the earlier to occur of (i) five (5) Business Days after notice of such failure sent by the Holder or by any other Holder and (ii) ten (10) Business Days after the Company has become or should have become aware of such failure:

i. any default in the payment of (A) the principal amount of this Note or (B) interest, and other amounts owing to the Holder of this Note, as and when the same shall become due and payable;

ii. the Company shall fail to observe or perform any other covenant or agreement contained in this Note.'

iii. a default or event of default shall occur under any of the Offering Documents (subject to any grace or cure period provided in the applicable Offering Document);

iv. any representation or warranty made in the Offering Documents shall be untrue or incorrect in any material respect as of the date when made or deemed made;

v. the Company or any Significant Subsidiary shall be subject to a Bankruptcy Event;

vi. the Company or any Subsidiary shall default on any of its obligations under any mortgage, credit agreement or other facility, indenture agreement, factoring agreement or other instrument under which there may be issued, or by which there may be secured or evidenced, any indebtedness for borrowed money or money due under any long term leasing or factoring arrangement that (A) involves an obligation greater than $100,000, whether such indebtedness now exists or shall hereafter be created, (B) results in such indebtedness becoming or being declared due and payable prior to the date on which it would otherwise become due and payable, and (C) is not listed on Schedule I to this Note;

vii. if at any time commencing six months from the date hereof the Company is not subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act or has failed to file all reports required to be filed thereunder during the then preceding twelve (12) months;

viii. if Dr. David Young ceases to serve full time as the President and Chief Executive Officer of the Company and perform the duties consistent with such positions for similarly situated companies, provided that if such cessation is due to death, permanent disability, voluntary termination or termination by the Company for cause, then an Event of Default shall not be deemed to have occurred unless and until the Company shall have failed to retain a full-time replacement reasonably acceptable to the Holder within ninety (90) days following such death, permanent disability, voluntary termination or termination by the Company for cause; or

ix. any monetary judgment, writ or similar final process shall be entered or filed against the Company, any subsidiary or any of their respective property or other assets for more than $100,000, and such judgment, writ or similar final process shall remain unvacated, unbonded or unstayed for a period of forty-five (45) calendar days; provided, however, that any judgment which is covered by insurance or an indemnity from a creditworthy party (such creditworthiness as reasonably determined by the Holder) shall not be included in calculating the amount of such judgment, writ or final process so long as the Company provides the Holder a written statement from such insurer or indemnity provider (which written statement shall be reasonably satisfactory to the Holder) to the effect that such judgment is covered by insurance or an indemnity and the Company will receive the proceeds of such insurance or indemnity within forty-five (45) calendar days of the issuance of such judgment.

b) Acceleration upon Event of Default. If any Event of Default occurs, the outstanding principal amount of this Note, plus accrued but unpaid interest and other amounts owing in respect thereof through the date of acceleration, shall become, at the Holder's election (which the Holder shall not make more than the later of thirty (30) calendar days after the date (a) such Event of Default is cured or otherwise resolved and (b) the Holder is aware of such cure or resolution), immediately due and payable in cash. If there is such an acceleration, then upon the payment in full of the amounts due hereunder, the Holder shall promptly surrender this Note to or as directed by the Company. In connection with such acceleration described herein, the Holder need not provide, and the Company hereby waives, any presentment, demand, protest or other notice of any kind, and the Holder may immediately and without expiration of any grace period enforce any and all of its rights and remedies hereunder and all other remedies available to it under applicable law. Such acceleration may be rescinded and annulled by Holder at any time prior to payment hereunder and the Holder shall have all rights as a holder of the Note

until such time, if any, as the Holder receives full payment pursuant to this Section 5(b). No such rescission or annulment shall affect any subsequent Event of Default or impair any right consequent thereon.

Section 6. Miscellaneous.

a) Notices. Any and all notices or other communications or deliveries to be to be provided by the Holder hereunder, including, without limitation, any Notice of Conversion, shall be in writing and delivered personally, by facsimile, or sent by a nationally recognized overnight courier service, addressed to the Company, at the address set forth above, or such other facsimile number or address as the Company may specify for such purpose by notice to the Holder delivered in accordance with this Section 6. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by facsimile, or sent by a nationally recognized overnight courier service addressed to each Holder at the facsimile number or address of the Holder appearing on the books of the Company, or if no such facsimile number or address appears, at the principal place of business of the Holder. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the date of transmission or delivery, if such notice or communication is delivered via facsimile at the facsimile number, or delivered by such courier service to the address, specified in this Section 6 prior to 5:30 p.m. (New York City time), (ii) the date immediately following the date of transmission or delivery, if such notice or communication is delivered via facsimile at the facsimile number, or delivered by such courier to the address, specified in this Section 6 between 5:30 p.m. (New York City time) and 11:59 p.m. (New York City time) on any date, or (iii) upon actual receipt by the party to whom such notice is required to be given. The address for such notices and communications shall be as set forth on the signature pages attached to the Subscription Agreement.

b) Absolute Obligation. Except as expressly provided herein, no provision of this Note shall alter or impair the obligation of the Company, which is absolute and unconditional, to pay the principal of, and accrued interest, as applicable, on this Note at the time, place, and rate, and in the coin or currency, herein prescribed. This Note is a direct debt obligation of the Company Section 6 between 5:30 p.m. (New York City time) and 11:59 p.m. (New York City time) on any date, or (iii) upon actual receipt by the party to whom such notice is required to be given. The address for such notices and communications shall be as set forth on the signature pages attached to the Subscription Agreement.

c) Lost or Mutilated Note. If this Note shall be mutilated, lost, stolen or destroyed, the Company shall execute and deliver, in exchange and substitution for and upon cancellation of a mutilated Note, or in lieu of or in substitution for a lost, stolen or destroyed Note, a new Note for the principal amount of this Note so mutilated, lost, stolen or destroyed, but only upon receipt of evidence of such loss, theft or destruction of such Note, and of the ownership hereof, reasonably satisfactory to the Company

d) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Note shall be governed by and construed and enforced in accordance with the internal laws of the State of Maryland, without regard to the principles of conflict of laws thereof. Each party agrees that all legal proceedings concerning the interpretation, enforcement and defense of the transactions contemplated by any of the Offering Documents (whether brought against a party hereto or its respective Affiliates, directors, officers, shareholders, employees or agents) shall be commenced in the state and federal courts sitting in Hanover, Maryland (the "Maryland Courts"). Each party hereto hereby irrevocably submits to the exclusive jurisdiction of the Maryland Courts for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Offering Documents), and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of such Maryland Courts, or such Maryland Courts are improper or

inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Note and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by applicable law. Each party hereto hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Note or the transactions contemplated hereby. If either party shall commence an action or proceeding to enforce any provisions of this Note, then the prevailing party in such action or proceeding shall be reimbursed by the other party for its attorney's fees and other costs and expenses reasonably incurred in the investigation, preparation, and prosecution of such action or proceeding.

e) Waiver. Any waiver by the Company or the Holder of a breach of any provision of this Note shall not operate as or be construed to be a waiver of any other breach of such provision or of any breach of any other provision of this Note. The failure of the Company or the Holder to insist upon strict adherence to any term of this Note on one or more occasions shall not be considered a waiver or deprive that party of the right thereafter to insist upon strict adherence to that term or any other term of this Note. Any waiver by the Company or the Holder must be in writing

f) Severability. If any provision of this Note is invalid, illegal or unenforceable, the balance of this Note shall remain in effect, and if any provision is inapplicable to any Person or circumstance, it shall nevertheless remain applicable to all other Persons and circumstances. If it shall be found that any interest or other amount deemed interest due hereunder violates the applicable law governing usury, the applicable rate of interest due hereunder shall automatically be lowered to equal the maximum rate of interest permitted under applicable law. The Company covenants (to the extent that it may lawfully do so) that it shall not at any time insist upon, plead, or in any manner whatsoever claim or take the benefit or advantage of, any stay, extension or usury law or other law which would prohibit or forgive the Company from paying all or any portion of the principal of or interest on this Note as contemplated herein, wherever enacted, now or at any time hereafter in force, or which may affect the covenants or the performance of this indenture, and the Company (to the extent it may lawfully do so) hereby expressly waives all benefits or advantage of any such law, and covenants that it will not, by resort to any such law, hinder, delay or impeded the execution of any power herein granted to the Holder, but will suffer and permit the execution of every such as though no such law has been enacted.

g) Next Business Day. Whenever any payment or other obligation hereunder shall be due on a day other than a Business Day, such payment shall be made on the next succeeding Business Day.

h) Headings. The headings contained herein are for convenience only, do not constitute a part of this Note and shall not be deemed to limit or affect any of the provisions hereof.

i) Right to Participate in Future Offerings. The Holder shall be permitted a pro rata right to participate in any future offerings made by the Company which occur prior to December 30, 2021.

IN WITNESS WHEREOF, the Company has caused this Note to be duly executed by a duly authorized officer as of the date first above indicated.

**PROCESSA PHARMACEUTICALS, INC.**

By: _____
Name: Dr. David Young
Title: Chief Executive Officer
Facsimile No. for delivery of Notices

**Exhibit 23.2**


**Consent of Independent Registered Public Accounting Firm**

We hereby consent to the inclusion in this Registration Statement on Form S-1 and the related prospectus of our report dated April 5, 2019, of our audit of the consolidated financial statements of Processa Pharmaceuticals, Inc. as of and for the years ended December 31, 2018 and 2017. We also consent to the reference to our firm under the caption "Experts" in such Registration Statement.

*/s/ BD & Co.*

Owings Mills, MD
December 13, 2019