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

FORM 8-K/A

CURRENT REPORT PURSUANT
TO SECTION 13 OR 15(D) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported October 4, 2017

HEATWURX, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

333-184948	**45-1539785**
(Commission File Number)	(IRS Employer Identification No.)

7380 Coca Cola Drive, Suite 106,
Hanover, Maryland 21076
(Address of Principal Executive Offices)

(443) 776-3133
(Registrant's Telephone Number, Including Area Code)

530 S Lake Avenue #615, Pasadena, California 91101
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

[ ] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

[ ] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01. Entry into a Material Definitive Agreement.

On October 5, 2017 we filed our report on Form 8-K to disclose that we entered into an Asset Purchase Agreement on October 2, 2017 with Promet Therapeutics LLC and our wholly owned subsidiary, Processa Therapeutics LLC. We closed on this agreement effective October 4, 2017. Under this agreement we acquired all of the assets of Promet, in exchange for approximately 222,217,000 shares of the common stock of the Company, which, at the closing, constituted approximately 90% of the Company's issued and outstanding common stock on a fully diluted basis. Immediately following the closing there were approximately 246,908,000 shares issued and outstanding of which the prior Heatwurx Inc. shareholders own approximately, 24,691,000 shares after giving effect to shares issuances made for Series D Preferred stock and existing debt that converted in common stock. At the closing, the Company assigned to Processa all of the assets and operations of Promet that will constitute the operating business of Promet. Following the closing, Promet will appoint officers and directors of the Company.

Item 2.01. Completion of Acquisition of Disposition of Assets

We completed the acquisition of Promet's assets and business operations pursuant to the Asset Purchase Agreement as noted in Item 1.01 above. The business and operations of Promet is our sole business and focus.

Item 3.02 Unregistered Sales of Equity Securities

In furtherance of the transaction requirements agreed upon by the parties, we eliminated prior to the Asset Purchase approximately $2.5 million of unpaid debt evidenced by promissory notes in exchange for about 12.954 million shares of common stock and converted 178,924 shares of Series D Preferred Stock into 719,500 shares of common stock. In connection with the Asset Purchase Agreement we issued 222,217,000 shares of our common stock to Promet.

The issuance of our shares to these shareholders 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. At the closing Promet also raised $1,250,000 from investors affiliated with Promet and with Heatwurx in the form of Senior Convertible Notes that will convert into securities of the registrant that are placed in the next placement round at a price that will be not greater than 90% of the offering price in that placement.

In instances described above where we issued securities in reliance upon Regulation D, we relied upon Rule 506 of Regulation D. The parties who received the securities in such instances made representations that such party (a) is acquiring the securities for his, her or its own account for investment and not for the account of any other person and not with a view to or for distribution, assignment or resale in connection with any distribution within the meaning of the Securities Act, (b) agrees not to sell or otherwise transfer the purchased securities unless they are registered under the Securities Act and any applicable state securities laws, or an exemption or exemptions from such registration are available, (c) has knowledge and experience in financial and business matters such that the purchaser is capable of evaluating the merits and risks of an investment in us, (d) had access to all of our documents, records, and books pertaining to the investment and was provided the opportunity to ask questions and receive answers regarding the terms and conditions of the offering and to obtain any additional information which we possessed or were able to acquire without unreasonable effort and expense, and (e) has no need for the liquidity in its investment in us and could afford the complete loss of such investment. Management made the determination that the investors in instances where we relied on Regulation D are accredited investors (as defined in Regulation D) based upon management's inquiry into their sophistication and net worth. In addition, there was no general solicitation or advertising for securities issued in reliance upon Regulation D.

In instances described above where we relied upon Section 4.(a)(2) of the Securities Act in issuing securities, our reliance was based upon the following factors: (a) the issuance of the securities was an isolated private transaction by us which did not involve a public offering; (b) there were only a limited number of offerees; (c) there were no subsequent or contemporaneous public offerings of the securities by us; (d) the securities were not broken down into smaller denominations and (e) the securities held or which were originally held and exchanged had been held for over two years. Certain of the shares issued are subject to lock-up/leak-out agreements extending over 12 months subject to partial earlier release by occurrence of certain trading prices or otherwise by the Board of Directors in its discretion. A form of the Lock-up/Leak-out is attached to this report as an exhibit, is incorporated herein by this reference and the summary description given in this paragraph is qualified in its entirety by that reference.

Item 5.01 Changes in Control of Registrant

In connection with the Asset Purchase we issued 222,217,000 shares of the common stock of the Company to Promet constituting about 90% of the issued and outstanding shares of the Company and constitutes a change of control of Heatwurx in favor of Promet.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers

Following close of the Asset Purchase, as of October 4, 2017, John McGrain, our Chief Executive Officer and Director, submitted his resignation as a director and from all other offices of our company, and Christopher Bragg, our director submitted his resignation as a director and from all other offices of our company.

Effective October 4, 2017 David Young and Patrick Lin were appointed to our Board of Directors. Justin Yorke continues to serve as director.

Also, effective as of October 4, 2017 David Young was appointed our Chief Executive Officer. For certain biographical and other information regarding the newly appointed officer and directors, see “Security Ownership of Certain Beneficial Owners and Management”, which disclosures are incorporated herein by reference.

Item 8.01 Other Events

Preliminary Note

Please note that the information provided below relates to the combined enterprises after the Asset Purchase, except that information covering periods prior to the date of the Asset Purchase relate only to the specialty paving and business of Heatwurx Inc., unless otherwise specifically indicated.

Description of Business

Company Overview

We are an emerging pharmaceutical 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 or who have no alternative treatment. Within this group of pharmaceutical products, we currently are developing one product for two indications.

The current status of our principal development programs is as follows:

Product Portfolio

Drug Product	Target Indication	Development Status (1)
499	Necrobiosis Lipoidica	Phase 2 - a potential for orphan designation has not yet been determined

Drug Product	Target Indication	Development Status (1)
499	R/T Effects Head and Neck Cancer	Phase 2 - currently we plan to apply for orphan designation in all countries

(1) Represents the next development or regulatory stage that Processa intends to pursue.

Our first FDA meeting is currently scheduled for the latter half of October 2017. This is intended to be a pre-IND meeting to review the proposed development program of 499 for the treatment of Necrobiosis Lipoidica with special emphasis on the clinical program.

Recent Developments

On October 2, 2017, Heatwurx, Inc., (the "Company" or "Heatwurx") and Processa Therapeutics, LLC ("Processa"), a Delaware limited liability company and a wholly-owned subsidiary of the Company entered into an Asset Purchase Agreement (the "Acquisition Agreement") with Promet Therapeutics, LLC, a limited liability company incorporated pursuant to the laws of the State of Delaware ("Promet"), pursuant to which, at the effective time on October 4, 2017, the Company acquired all of the assets of Promet (the "Acquisition"), in exchange for issuing to Promet approximately 222,217,000 shares of the common stock of the Company, which, at the closing, constituted approximately 90% of the Company's issued and outstanding common stock on a fully diluted basis.

Following the closing, Heatwurx changed its trading symbol from "HUWX" to "PCSA" effective as of October 10, 2017.

All references to the "Combined Company" and Processa Pharmaceuticals, Inc refer to Heatwurx, Inc., its wholly owned subsidiary Processa Therapeutics, LLC and the acquired assets from Promet.

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

- taking an established/successful team having over 25 years of drug development experience and more than 30 drug approvals,
- obtaining drug products in the clinical stage of development,
- collaborating with FDA and other regulatory agencies in defining the development plan for each product, and
- executing on the plan.

Our current intent is to obtain or secure the rights to these drugs only after there is preliminary clinical or pre-clinical evidence that the drug ought to be both efficacious and safe in the condition. Processa expects that it will develop drug products through approval or, if out-licensed to others that it will have minimally negotiated with regulatory agencies the Phase 3 requirements to obtain approval before out licensing.

On October 4, 2017 Promet signed an Option License Agreement with CoNCERT Pharmaceuticals. The Option Agreement is related to CTP-499. Promet is obligated to make a decision to exercise the licensing agreement within nine months from signing the option agreement at which time it shall assign the license agreement to Processa.

On or about October 4, 2017, Promet Therapeutics, LLC received the first tranche of a Senior Convertible Note (convertible to shares of Processa Pharmaceuticals, Inc.). This first tranche was for $1.25M from current Heatwurx and Promet shareholders. We are in the process of raising additional funds by privately placing further tranches of Senior Convertible Notes with accredited investors. No assurance however can be given that Promet and Processa will be successful in doing so.

Our business is subject to a number of risks. You should understand these risks before making an investment decision with respect to the common stock offered hereby. If any of these risks actually occurs, our business, financial condition or results of operations would likely be materially adversely affected. In such case, the value of our common stock would likely decline, and you may lose all or part of your investment. Below is a summary of some of the principal risks we face. The risks are discussed more fully in the section of this Report below titled " Risk Factors. "

- Although we are a clinical stage biopharmaceutical company, we have no corporate history of generating revenue, have a corporate history of operating losses, and we may never achieve or maintain profitability.

- The terms of our exclusive option and license agreement with CoNCERT Pharmaceuticals for the CTP-499 compound include a requirement for us to have not less than $8 million in funding and if we do not meet all the conditions in the agreement we may lose our rights to CTP 499 which will adversely affect our operations and development of our business plan.

- We currently do not have, and, even if we are able to exercise the exclusive option and license agreement for the CTP-499 compound with CoNCERT Pharmaceuticals, we may never develop, any FDA-approved or foreign country-approved or commercialized products.

- Based on regulatory differences in various countries, our development program may become more complex, larger and more complex studies may be required over greater time periods, all of which may result in additional cost and time as well increased probability of non-approval in some of these countries.

- Significant additional research and development and clinical testing will be required before we can potentially seek regulatory approval for or commercialize any of our product candidates.

- We have no history of conducting clinical trials or commercializing biotechnology products, which may make it difficult to evaluate the prospects for the future viability of our business or any of our potential products.

- We have never dosed any of our product candidates in humans. 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.

- We may not be successful in our efforts to identify additional product candidates. Due to our limited resources and access to capital, we must prioritize development of certain product candidates; these decisions may prove to be wrong and may adversely affect our business.

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

- We expect to pursue strategic partnerships and collaborations with third parties that we cannot control, including leading pharmaceutical or biotechnology organizations, to develop, manufacture, commercialize and distribute our potential products. If we are unable to form these relationships, or if these relationships are unsuccessful, our business will be materially harmed.

- Our potential products, development activities, manufacturing and distribution will be subject to extensive and rigorous regulation by numerous agencies, including the FDA and other governmental agencies, both in the United States and overseas. Our potential products will not be viable if we are unable to receive approvals from these agencies or comply with their regulations.

- We will rely on third parties to conduct our clinical trials. 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 of or commercialize our planned product candidates.

- We will need capital beyond the net proceeds we expect to receive from a currently pending offering to certain accredited investors, within the meaning of the federal securities laws, to support our growth and ongoing business operations. Additional capital may be difficult to obtain, restrict our operations, require us to relinquish rights to our technologies or product candidates, or result in substantial dilution to our stockholders.

- Concentration of ownership among our existing executive officers, directors and significant stockholders may prevent other investors from influencing significant corporate decisions

- As an investor, you may lose a portion or all of your investment in the Company.

Status as an Emerging Growth Company

We are an "emerging growth company" as that term is defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (i.e., those that have not had a registration statement declared effective under the Securities Act of 1933, as amended (the "Securities Act"), or do not have a class of securities registered under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) are required to comply with such new or revised financial accounting standards. The JOBS Act also provides that an emerging growth company can elect to opt out of the extended transition period provided by Section 102(b)(1) of the JOBS Act and comply with the requirements that apply to non-emerging growth companies, but any such election to opt out is irrevocable. We may still take advantage of all of the other provisions of the JOBS Act, which include, but are not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, the reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and the exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Corporate Background

Our principal executive offices are located at 7380 Coca Cola Drive, Suite 106, Hanover, MD 21076, and our telephone number is (443) 776-3133. Our website address is www.Processapharmaceuticals.com although as of the date of this submission it is still being built. The information on our website is not part of this report on Form 8-K. We have included our website address as a factual reference and do not intend it to be an active current link to our website.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND OTHER INFORMATION CONTAINED IN THIS REPORT ON FORM 8-K

This Report on Form 8-K contains forward-looking statements. Forward-looking statements give our current expectations or forecasts of future events. You can identify these statements by the fact that they do not relate strictly to historical or current facts. You can find many (but not all) of these statements by looking for words such as "approximates," "believes," "hopes," "expects," "anticipates," "estimates," "projects," "intends," "plans," "would," "should," "could," "may" or other similar expressions in this report on Form 8-K. These statements may be found under the sections of this report on Form 8-K captioned "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business" included in this report on Form 8-K, as well as in this report on Form 8-K generally. In particular, these include statements relating to future actions, prospective products, applications, customers, technologies, future performance or results of anticipated products, expenses, and financial results. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from our historical experience and our present expectations or projections. Factors that could cause actual results to differ from those discussed in the forward-looking statements include, but are not limited to:

- our limited operating history, limited cash and a history of losses;
- our ability to achieve profitability;
- our ability to secure required FDA or other governmental approvals for our product candidates and the breadth of the indication sought;
- the impact of competitive or alternative products, technologies and pricing;
- whether we are successful in developing and commercializing our technology, including through licensing;
- the adequacy of protections afforded to us and/or our licensor by the anticipated patents that we own or license and the cost to us of maintaining, enforcing and defending those patents;
- our and our licensor ' s ability to protect non-patented intellectual property rights;
- our exposure to and ability to defend third-party claims and challenges to our and our licensor ' s anticipated patents and other intellectual property rights;
- our ability to obtain adequate financing to fund our business operations in the future;
- our ability to continue as a going concern; and
- other factors discussed in the "Risk Factors" section of this report on Form 8-K.

The forward-looking statements are based upon management's beliefs and assumptions and are made as of the date of this report on Form 8-K. We undertake no obligation to publicly update or revise any forward-looking statements included in this report on Form 8-K or to update the reasons why actual results could differ from those contained in such statements, whether as a result of new information, future events or otherwise, except to the extent required by federal securities laws. Actual future results may vary materially as a result of various factors, including, without limitation, the risks outlined under the section of this report on Form 8-K captioned "Risk Factors" and matters described in this report on Form 8-K generally. In light of these risks and uncertainties, we cannot assure you that the forward-looking statements contained in this report on Form 8-K will in fact occur. You should not place undue reliance on these forward-looking statements.

RISK FACTORS

We are subject to various risks that may materially harm our business, prospects, financial condition and results of operations. An investment in our common stock is speculative and involves a high degree of risk. In evaluating an investment in of our shares of our common stock, you should carefully consider the risks described below, together with the other information included in this Form 8-K.

If any of the events described in the following risk factors actually occurs, or if additional risks and uncertainties that are not presently known to us or that we currently deem immaterial later materialize, then our business, prospects, results of operations and financial condition could be materially adversely affected. In that event, the trading price of our common stock could decline, and you may lose part or all of your investment in our shares. The risks discussed below include forward-looking statements, and our actual results may differ substantially from those discussed in these forward-looking statements. See "Special Note Regarding Forward-Looking Statements and Other Information Contained in this Form 8-K"

Risks Related to Our New Business, Industry and Financial Condition

Although we are a clinical stage biopharmaceutical company, we have no history of generating revenue, have a corporate history of operating losses, and we may never achieve or maintain profitability.

We are a clinical stage biopharmaceutical company. We have a limited operating history and only a preliminary business plan upon which investors may evaluate our prospects. We have never generated revenues and have a history of losses from operations. As of June 30, 2017, Promet had an accumulated deficit of approximately $2.5 million incurred over about 21 months of existence. Even assuming that we complete the currently pending private offering of our securities, as to which we can give no assurance, our current and additional capital will be insufficient to fully fund our total business plan and the development of our planned product candidates. Our ability to achieve revenue-generating operations and, ultimately, achieve profitability will depend on whether we can obtain additional capital when we need it, complete the development of our technology, receive regulatory approval of our planned product candidates and find strategic collaborators that can incorporate our planned products candidates into new or existing drugs which can be successfully commercialized. There can be no assurance that we will ever generate revenues or achieve profitability.

The terms of our exclusive option and license agreement with CoNCERT Pharmaceuticals for the CTP-499 compound include a requirement for us to have not less than $8 million in funding and if we do not meet all the conditions in the agreement we may lose our rights to CTP 499 which will adversely affect our operations and development of our business plan.

Our business plan and our agreement with CoNCERT Pharmaceuticals have led us to option and then seek to acquire, develop and proceed to commercialize CTP-499 as our initial drug product lead candidate. If we are unable to raise at least $8,000,000 as required or are unable to comply with other provisions of the agreement, these rights made available by CoNCERT may be terminated in which event all rights to CTP-499 will remain with or revert to CoNCERT. Although we have other drugs being positioned into our pipeline, should we lose our rights to CTP 499 our planned growth and business plan would be materially and adversely affected.

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

We currently do not have any products approved by the FDA or any other regulatory agency or any commercialized products and thus have never generated revenue from product sales. We have not yet sought to obtain any regulatory approvals for any planned product candidates in the United States or in any foreign market. Therefore, any estimated timing for our planned product candidates to be commercialized would be highly speculative.

For us to develop any products that might ultimately be 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 commercialized. All of our development efforts will require substantial additional funding, none of which may result in any revenue. Our efforts may not lead to commercially successful products for a number of reasons, including:

- we and our licensor, prospective business partners and other collaborators may not be able to complete research regarding, and nonclinical and clinical development of, our planned product candidates;
- regulatory approvals and marketing authorizations may not be achieved for our planned product candidates, or the scope of the approved indication may be narrower than sought;
- we and our licensor, prospective business partners and other collaborators may experience delays in our development program, clinical trials and the regulatory approval process;
- our technology may not prove to be safe and effective in clinical or preclinical trials and our planned product candidates may have adverse side effects which outweigh any potential benefit to patients;
- we may not be able to identify suitable collaborators to complete development or commercialization of our potential products;
- we may not be able to maintain, protect or expand our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- any future products that are ultimately approved by the FDA or other regulatory bodies may not be commercially accepted in the marketplace by physicians or patients;
- our future products may not be able to be manufactured in commercial quantities or at an acceptable cost;

- physicians may not receive any reimbursement from third-party payors, or the level of reimbursement may be insufficient to support widespread adoption of any of our future products; and

- rapid technological change may make our technology and future products obsolete or otherwise undesirable.

We currently do not have, and may never develop, any other foreign country-approved or commercialized products.

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

In the European Union regulatory systems, marketing authorizations may be submitted either under a centralized or mutual recognition procedure. The timing and process for these different types of submission varies. The regulatory process for the conduct of clinical studies or marketing approval in other foreign countries outside of the European Union also varies greatly both in requirements, process and timing.

Based on regulatory differences in various countries, our development program may become more complex, larger and more complex studies may be required over greater time periods, all of which may result in additional cost and time as well increased probability of non-approval in some of these countries.

In certain countries where we may seek to commercialize our products, pricing, coverage and level of reimbursement or funding of prescription drugs are also subject to governmental control. We may be unable timely or successfully to negotiate coverage, pricing, and reimbursement on terms that are favorable to us, or such coverage, pricing, and reimbursement may differ in separate regions in the same country. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. Therefore, we may not successfully conclude the necessary processes and commercialize our products in every, or even most countries in which we seek to sell our products.

Significant additional research and development and clinical testing will be required before we can potentially seek regulatory approval for or commercialize any of our product candidates.

We have product candidates in our clinical development pipeline, but significant additional research and development activity and clinical testing are required before we and our collaborators will have a chance to achieve a commercially viable product from such candidates. Our research and development efforts remain subject to all of the risks associated with the development of new biopharmaceutical products and treatments based on our preclinical development pipeline. 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.

Processa has no corporate history of conducting clinical trials or commercializing biotechnology products, which may make it difficult to evaluate prospects for our future viability.

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

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

- negative or inconclusive results from our IND-enabling studies, clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- delays in submitting INDs or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or a foreign regulatory authority regarding the number, scope or design of our clinical trials;
- delays in enrolling patients in clinical trials;
- high drop-out rates of patients;
- inadequate supply or quality of clinical trial materials or other supplies necessary to conduct our clinical trials;
- greater than anticipated clinical trial costs;
- poor effectiveness or unacceptable side effects of our product candidates during clinical trials;
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- serious and unexpected drug-related side effects or other safety issues experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;

- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology in particular; or

- varying interpretations of data by the FDA and foreign regulatory authorities.

We have never dosed any of our product candidates in humans. 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.

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

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

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

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

We plan to seek collaborations or strategic alliances. However, we may not be able to establish such relationships, and any relationships we establish may not provide the expected benefits.

We plan to seek strategic alliances or collaborations with third parties that we believe will complement or augment our development and commercialization efforts with respect to our planned product candidates and any future product candidates that we may develop. In addition, we currently do not have sales, marketing, manufacturing or distribution capabilities or arrangements. In order to commercialize our potential products, we plan to seek development and marketing partners or sublicensees to obtain necessary marketing, manufacturing and distribution capabilities.

Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, issue debt which may require liens on our assets and which will increase our monthly expense obligations, or disrupt our management and business. Moreover, we may not be successful in our efforts to establish strategic partnerships or other alternative arrangements for our planned product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our planned product candidates as having the requisite potential to demonstrate safety and efficacy. If we are unable to establish strategic partnerships or other alternative arrangements to develop our drug candidates, the costs for us to independently develop our drug candidates may be higher than we currently anticipate, which could materially harm our business prospects, financial condition and results of operation.

Further, collaborations involving our planned product candidates are subject to numerous risks, which may include the following:

- our collaborators may have significant discretion in determining the efforts and resources that they will apply to our collaboration as compared to their other then-existing collaborations;
- our collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- our collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- our collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of each of our potential products;

- our collaborators may not properly maintain or defend our intellectual property rights in accordance with the terms of our contractual arrangements with them or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to other potential liability;

- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts our managements ' attention and our other resources;

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and

- our collaborators may own or co-own intellectual property covering our potential products that results from our collaboration with them, and in such case, we would not have the exclusive right to commercialize such intellectual property without our collaborators' involvement and consent.

As a result, if we enter into collaboration agreements and strategic partnerships or license our technology or potential products, we may not be able to realize the benefit of such transactions, which could delay our product development timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve sufficient revenue or net income to justify such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our planned product candidates could delay the development and commercialization of our planned product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition, and results of operations.

We may not be successful in our efforts to identify additional product candidates. Due to our limited resources and access to capital, we must prioritize development of certain product candidates; these decisions may prove to be wrong and may adversely affect our business.

Although we intend to explore other therapeutic opportunities, in addition to the product candidates that we are currently developing, we may fail to identify successful product candidates for clinical development for a number of reasons. If we fail to identify additional potential product candidates, our business could be materially harmed.

Research programs to pursue the development of our planned product candidates for additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources whether or not they are ultimately successful. Our research programs may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential indications and/or product candidates;

- potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or

- it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our drug portfolio.

Because we have limited financial and human resources, we intend initially direct our attention on research programs and product candidates for a limited set of indications focused on unmet human needs. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

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

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, a competitor could obtain orphan product exclusivity from the FDA with respect to such competitor's product. If such competitor 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 may never commercialize any of our products or earn a profit.

We, as Processa following our new business direction, currently have no revenues from product sales, have not generated any revenue from operations, and expect to incur substantial net losses for the foreseeable future to further develop and commercialize our product candidates and technologies.

When the assets were owned by Promet, Promet also had no revenues from product sales, had not generated any revenue from operations for the last two fiscal years, and expect to incur substantial net losses for the foreseeable future to further develop and commercialize our product candidates and technologies. We may never be able to commercialize any of our product candidates or be able to generate revenues from products sales. Because of the risks and uncertainties associated with developing and commercializing our specialty pharmaceuticals, we are unable to predict when we may commercially introduce products, the extent of any future losses or when we will become profitable, if ever. We may never successfully commercialize our product candidates, and our business may fail.

Our auditors are likely to express substantial doubt about our ability to continue as a going concern.

Although the audited financial statements of Promet for the year ended December 31, 2016, were not prepared with a "going concern" explanatory paragraph in the auditor's report on Promet's financial statements for the years ended December 31, 2016 and 2015, if we (i) are unable to generate substantial revenue, (ii) incur recurring losses and negative cash flow from operations, (iii) are unable quickly and efficiently to navigate a costly and complex regulatory and clinical environment, domestically and in major foreign markets and (iv) continue to maintain limited working capital to pursue our business alternatives, we expect that these factors, and the other risk factors discussed in this report, may in the future raise substantial doubt about our ability to continue as a going concern. Although as of the date of this report we have approximately $2.25 million of cash and are engaged in seeking additional funds from accredited investors no assurance can be given that we will raise adequate funds needed to avoid the "going concern" explanatory paragraph in our next auditor's report on our operations in the current fiscal year. Uncertainty concerning our ability to continue as a going concern may hinder our ability to obtain future financing, as well as adversely affect our collaborative drug development relationships. Continued operations and our ability to continue as a going concern are dependent on our ability to obtain additional funding in the near future and thereafter, and no assurances can be given that such funding will be available at all or will be available in sufficient amounts or on reasonable terms. Our financial statements currently do not include any adjustments that may result from the outcome of these uncertainties. Without additional funds from debt or equity financing, sales of assets, sales or out-licenses of intellectual property or technologies, or other transactions yielding funds, we will rapidly exhaust our resources and will be unable to continue operations. If we cannot continue as a viable entity, our stockholders would likely lose most or all of their investment in us.

We require additional financing to continue as a going concern.

Absent additional funding, we believe that our cash and cash equivalents will be sufficient to fund our operations only for a relatively short period of time of perhaps 12 months. The development of our new business model will require substantial additional capital in the future to further our development and license in additional products. We have historically relied upon private investments to fund our operations. Delays in obtaining additional funding could adversely affect our ability to move forward with additional studies or in licensing activities.

Our ability to obtain additional financing will be subject to a number of factors, including market conditions, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates, restrict our operations or obtain funds by entering into agreements on unattractive terms, which would likely have a material adverse effect on our business, stock price and our relationships with third parties with whom we have business relationships, at least until additional funding is obtained. If we do not have sufficient funds to continue operations, we could be required to seek bankruptcy protection or other alternatives that would likely result in our stockholders losing some or all of their investment in us.

Promet and Heatwurx have incurred losses since their inception, and we anticipate that following the Acquisition we will continue to incur losses. We may never achieve or sustain profitability.

From inception through June 30, 2017 we have incurred aggregate net losses in the amount of $17,288,637 (Promet $2,503,695; Heatwurx $14,784,942). These losses will increase as we:

- continue our research and development activities,
- seek regulatory approvals for our product candidates,
- engage in clinical trials and
- seek to commercialize approved products, if any.

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. 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. 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.

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.

Delays in the commencement or completion of clinical testing of our product candidates could result in increased costs and delay our ability to generate significant revenues.

The actual timing of commencement and completion of clinical trials can vary dramatically from our anticipated timing due to factors such as funding limitations, scheduling conflicts with participating clinicians and clinical institutions, and the rate of patient enrollment. Clinical trials involving our product candidates may not commence or be completed as forecast. Delays in the commencement or completion of clinical testing could significantly impact our product development costs. We do not know whether current or planned clinical trials will begin on time or be completed on schedule, if at all. The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- obtaining required funding;
- obtaining regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;
- obtaining sufficient quantities of clinical trial materials for product candidates;
- obtaining institutional review board approval to conduct a clinical trial at a prospective site; and
- recruiting participants for a clinical trial.

In addition, once a clinical trial has begun, it may be suspended or terminated by us or the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements;
- inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- failure to achieve certain efficacy and/or safety standards; or
- lack of adequate funding to continue the clinical trial.

Clinical trials require sufficient participant enrollment, which is a function of many factors, including the size of the target patient population, the nature of the trial protocol, the proximity of participants to clinical trial sites, the availability of effective treatments for the relevant disease, the eligibility criteria for our clinical trials and competing trials. Delays in enrollment can result in increased costs and longer development times. Our failure to enroll participants in our clinical trials could delay the completion of the clinical trials beyond current expectations. In addition, the FDA could require us to conduct clinical trials with a larger number of participants than we may project for any of our product candidates. As a result of these factors, we may not be able to enroll a sufficient number of participants in a timely or cost-effective manner.

Furthermore, enrolled participants may drop out of clinical trials, which could impair the validity or statistical significance of the clinical trials. A number of factors can influence the discontinuation rate, including, but not limited to: the inclusion of a placebo in a trial; possible lack of effect of the product candidate being tested at one or more of the dose levels being tested; adverse side effects experienced, whether or not related to the product candidate; and the availability of numerous alternative treatment options that may induce participants to discontinue from the trial.

Delays or difficulties in the enrollment of research subjects in clinical trials could result in those clinical trials taking longer than expected to complete and our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of research subjects to participate in these trials. In particular, for some diseases and conditions we are or will be focused on, our pool of suitable patients may be small and more selective and our ability to enroll a sufficient number of suitable patients may be limited or take longer than anticipated. In addition, some competitors may have ongoing clinical trials for drug products that treat the same indications as our drug products, and volunteers or patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' drug products. Patient enrollment for any of our clinical trials may also be affected by other factors, including without limitation:

- the prevalence of the patients with the indication being investigated
- the eligibility criteria for the clinical trial in question;
- the perceived risks and benefits of the drug product under the clinical trial;
- the extent of the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians; and
- the proximity and availability of clinical trial sites.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our drug candidates, and we may not have or be able to obtain sufficient cash to fund such increased costs when needed, which could result in the further delay or termination of the trial.

We may be required to suspend, repeat or terminate our clinical trials if the trials are not well designed, do not meet regulatory requirements or the results are negative or inconclusive, which may result in significant negative repercussions on our business and financial condition.

Before regulatory approval for a potential product can be obtained, we must undertake clinical testing on humans to demonstrate the tolerability and efficacy of the product. We cannot assure you that we will obtain authorization to permit product candidates that are in the preclinical development phase to enter the human clinical testing phase. In addition, we cannot assure you that any authorized preclinical or clinical testing will be completed successfully within any specified time period by us, or without significant additional resources or expertise to those originally expected to be necessary. We cannot assure you that such testing will show potential products to be safe and efficacious or that any such product will be approved for a specific indication. Further, the results from preclinical studies and early clinical trials may not be indicative of the results that will be obtained in later-stage clinical trials. In addition, we or regulatory authorities may suspend clinical trials at any time on the basis that the participants are being exposed to unacceptable health risks.

We are subject to the risk of clinical trial and product liability lawsuits.

The testing of human health care product candidates entails an inherent risk of allegations of clinical trial liability, while the marketing and sale of approved products entails an inherent risk of allegations of product liability and associated adverse publicity. We currently maintain liability insurance coverage of $1,000,000 for US Studies and $5,000,000 GBP for a study, which we expect to commence in the UK during Q1 2018, that will be a Phase 1, Single Center, Open-Label, Randomized Study to Evaluate the Pharmacokinetics of Modified Release Formulations of CTP-499 Administered to 12 healthy volunteers. Such insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms, or at all. As we conduct additional clinical trials and introduce products into the United States market, the risk of adverse events increases and our requirements for liability insurance coverage are likely to increase. We are subject to the risk that substantial liability claims from the testing or marketing of pharmaceutical products could be asserted against us in the future. There can be no assurance that we will be able to obtain or maintain insurance on acceptable terms, particularly in overseas locations, for clinical and commercial activities or that any insurance obtained will provide adequate protection against potential liabilities. An inability to obtain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims could inhibit our business.

Moreover, our current and future coverages may not be adequate to protect us from all of the liabilities that we may incur. If losses from liability claims exceed our insurance coverage, we may incur substantial liabilities that are greater than our financial resources. In addition, a product or clinical trial liability action against us would be expensive and time-consuming to defend, even if we ultimately prevailed. If we are required to pay a claim, we may not have sufficient financial resources and our business and results of operations may be harmed. A product liability claim brought against us in excess of our insurance coverage, if any, could have a material adverse effect upon our business, financial condition and results of operations.

We do not have commercial-scale manufacturing capability, and we lack commercial manufacturing experience. We will likely rely on third parties to manufacture and supply our product candidates.

We do not own or operate manufacturing facilities for clinical or commercial production of product candidates. Accordingly, we expect to depend on third-party contract manufacturers for the foreseeable future. Any performance failure on the part of our contract manufacturers could delay clinical development, regulatory approval or commercialization of our current or future product candidates, depriving us of potential product revenue and resulting in additional losses.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up initial production.

These problems can include difficulties with production costs and yields, quality control (including stability of the product candidate and quality assurance testing), shortages of qualified personnel, and compliance with strictly enforced federal, state and foreign regulations. If our third-party contract manufacturers were to encounter any of these difficulties or otherwise fail to comply with their obligations or under applicable regulations, our ability to provide product candidates to patients in our clinical trials or commercially would be jeopardized. If we file an application for marketing approval of the product and the FDA grants marketing approval, any delay or interruption in the supply of product could delay the commercial launch of the product or impair our ability to meet demand for the product. Difficulties in supplying products for clinical trials could increase the costs associated with our clinical trial programs and, depending upon the period of delay, require us to commence new trials or qualify new manufacturers at significant additional expense, possibly causing commercial delays or termination of the trials.

Our products can only be manufactured in a facility that has undergone a satisfactory inspection by the FDA and other relevant regulatory authorities. For these reasons, we may not be able to replace manufacturing capacity for our products quickly if we or our contract manufacturer(s) were unable to use manufacturing facilities as a result of a fire, natural disaster (including an earthquake), equipment failure, or other difficulty, or if such facilities were deemed not in compliance with the regulatory requirements and such non-compliance could not be rapidly rectified. An inability or reduced capacity to manufacture our products would have a material adverse effect on our business, financial condition, and results of operations.

We are subject to substantial government regulation, which could materially adversely affect our business. If we do not receive regulatory approvals, we may not be able to develop and commercialize our technologies.

We need FDA approval to conduct any studies in the United States, and similar approvals from foreign regulatory authorities to conduct studies outside the United States. We have not yet filed an application with the FDA or agencies outside the US to obtain approval to market any of our proposed products. The production and marketing of our products and potential products and our ongoing research and development, pre-clinical testing and clinical trial activities are currently subject to extensive regulation and review by numerous governmental authorities in the United States and will face similar regulation and review for overseas approval and sales from governmental authorities outside of the United States. The regulatory review and approval process, which may include evaluation of preclinical studies and clinical trials of our products, as well as the evaluation of manufacturing processes and contract manufacturers' facilities, is lengthy, expensive and uncertain. Many of the product candidates that we are currently developing must undergo additional clinical testing and an extensive regulatory approval process before they can be marketed. This process may be lengthy, unexpected difficulties may arise which may require additional clinical or pre-clinical studies and will incur additional costs as we bring our potential products to market, and we cannot guarantee that any of our potential products will be approved. Many products for which FDA or other regulatory approval has been sought by other companies have never been approved for marketing. In addition to testing and approval procedures, extensive regulations also govern marketing, manufacturing, distribution, labeling, and record-keeping procedures. If we or our collaboration partners do not comply with applicable regulatory requirements, such violations could result in non-approval, suspensions of regulatory approvals, civil penalties and criminal fines, product seizures and recalls, operating restrictions, injunctions, and criminal prosecution.

Regulatory authorities generally have substantial discretion in the approval process and may either refuse to accept an application, or may decide after review of an application that the data submitted is insufficient to allow approval of the proposed product. If regulatory authorities do not accept or approve our applications, they may require that we conduct additional clinical, preclinical or manufacturing studies and submit that data before regulatory authorities will reconsider such application. We may need to expend substantial resources to conduct further studies to obtain data that regulatory authorities believe is sufficient. Depending on the extent of these studies, approval of applications may be delayed by several years, or may require us to expend more resources than we may have available. It is also possible that additional studies may not suffice to make applications approvable. If any of these outcomes occur, we may be forced to abandon our applications for approval.

Failure to obtain FDA or other required regulatory approvals, or withdrawal of previous approvals, would adversely affect our business. Even if regulatory approval of a product is granted, this approval may entail limitations on uses for which the product may be labeled and promoted, or may prevent us from broadening the uses of products for different applications.

If we fail to obtain acceptable prices or appropriate reimbursement for our products, our ability to successfully commercialize our products will be impaired.

Government and insurance reimbursements for healthcare expenditures play an important role for all healthcare providers, including physicians and pharmaceutical companies such as Processa, that plan to offer various products in the United States and other countries in the future. Physicians and patients may decide not to order our products unless third-party payors, such as managed care organizations as well as government payors such as Medicare and Medicaid, pay a substantial portion of the price of the products. Market acceptance and sales of our products and potential products will depend in part on the extent to which reimbursement for the costs of such products will be available from government health administration authorities, private health coverage insurers, managed care organizations, and other organizations. In the United States, our ability to have our products eligible for Medicare, Medicaid or private insurance reimbursement will be an important factor in determining the ultimate success of our products. If, for any reason, Medicare, Medicaid or the insurance companies decline to provide reimbursement for our products, our ability to commercialize our products would be adversely affected.

Third-party payors may challenge the price of medical and pharmaceutical products. Reimbursement by a third-party payor may depend on a number of factors, including a payor's determination that our product candidates are:

- not experimental or investigational;
- effective;
- medically necessary;
- appropriate for the specific patient;
- cost-effective;
- supported by peer-reviewed publications; and
- included in clinical practice guidelines.

If purchasers or users of our products and related treatments are not able to obtain appropriate reimbursement for the cost of using such products, they may forego or reduce such use. Significant uncertainty exists as to the reimbursement status of newly approved pharmaceutical products, and there can be no assurance that adequate third-party coverage will be available for any of our products. Even if our products are approved for reimbursement by Medicare, Medicaid and private insurers, of which there can be no assurance, the amount of reimbursement may be reduced at times or even eliminated. This would have a material adverse effect on our business, financial condition and results of operations.

Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably.

In both the United States and certain foreign jurisdictions, there have been and are expected to be a number of legislative and regulatory changes to the healthcare system in ways that could impact our ability to sell our products profitably, including the Patient Protection and Affordable Care Act signed into law in the United States in March 2010. Given the enactment of these laws and other federal and state legislation and regulations relating to the healthcare system, it is still too early to determine their impact on the biotechnology and pharmaceutical industries and our business.

The U.S. Congress continues to consider issues relating to the healthcare system, and future legislation or regulations may affect our ability to market and sell products on favorable terms, which would affect our results of operations, as well as our ability to raise capital, obtain additional collaborators or profitably market our products. Such legislation or regulation may reduce our revenues, increase our expenses or limit the markets for our products. In particular, we expect to experience pricing pressures in connection with the sale of our products due to the influence of health maintenance and managed health care organizations and additional legislative proposals.

In certain countries where we may seek to commercialize our products, pricing, coverage and level of reimbursement or funding of prescription drugs are subject to governmental control. We may be unable to timely or successfully negotiate coverage, pricing, and reimbursement on terms that are favorable to us, or such coverage, pricing, and reimbursement may differ in separate regions in the same country. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. Therefore, we may not successfully conclude the necessary processes and commercialize our products in every, or even most countries in which we seek to sell our products.

We have limited sales, marketing and distribution experience.

We have limited experience in the sales, marketing, and distribution of pharmaceutical products in US and outside the US. There can be no assurance that we will be able to establish sales, marketing, and distribution capabilities or make arrangements with our current collaborators or others to perform such activities or that such efforts will be successful. If we decide to market any products directly, we must either acquire or internally develop a marketing and sales force with technical expertise and with supporting distribution capabilities. The acquisition or development of a sales, marketing and distribution infrastructure would require substantial resources, which may not be available to us or, even if available, could divert the attention of our management and key personnel and have a negative impact on further product development efforts.

We may seek to enter into arrangements to develop and commercialize our products. These collaborations, if secured, may not be successful.

We may decide to enter into arrangements with third parties regarding development of some of our products and may in the future seek to enter into collaborative arrangements to commercialize some of our potential products both in North America and international markets. There can be no assurance that we will be able to negotiate collaborative arrangements on favorable terms or at all or that our current or future collaborative arrangements will be successful. The amount and timing of resources such third parties will devote to these activities may not be within our control. There can be no assurance that such parties will perform their obligations as expected. There can be no assurance that our collaborators will devote adequate resources to our products.

If our potential products are unable to compete effectively with current and future products targeting similar markets as our potential products, our commercial opportunities will be reduced or eliminated.

We face competition from numerous sources, including major biotechnology and pharmaceutical companies worldwide. Many of our competitors have substantially greater financial and technical resources, and development, production and marketing capabilities, than we do. Certain companies have established technologies that may be competitive with our product candidates and any future products that we may develop or acquire. Some of these products may use different approaches or means to obtain results, which could be more effective or less expensive than our products for similar indications. In addition, many of these companies have more experience than we do in pre-clinical testing, clinical trials and manufacturing of compounds, obtaining FDA and foreign regulatory approvals, and brand name exposure and expertise in sales and marketing. We also compete with academic institutions, governmental agencies and private organizations that are conducting research in the same fields.

Competition among these entities to recruit and retain highly qualified scientific, technical and professional personnel and consultants is also intense. As a result, there is a risk that one or more of our competitors will develop a more effective product for the same indications for which we are developing a product or, alternatively, bring a similar product to market before we can do so. Failure to successfully compete will adversely impact our ability to raise additional capital and ultimately achieve positive cash flow, resulting in material harm to our operations.

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.

Our failure to adequately protect or to enforce our intellectual property rights or secure rights to third party patents could materially harm our proprietary position in the marketplace or prevent the commercialization of our products.

Our success depends in part on our ability to obtain and maintain protection in the United States and other countries for the intellectual property covering or incorporated into our technologies and products. The patents and patent applications in our existing patent portfolio are either owned by us or licensed to us. Our ability to protect our product candidates from unauthorized use or infringement by third parties depends substantially on our ability to obtain and maintain, or license, valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to obtain and enforce patents is uncertain and involves complex legal and factual questions for which important legal principles are unresolved.

There is a substantial backlog of patent applications at the United States Patent and Trademark Office, or USPTO. There can be no assurance that any patent applications relating to our products or methods will be issued as patents, or, if issued, that the patents will not be challenged, invalidated or circumvented or that the rights granted thereunder will provide a competitive advantage. We may not be able to obtain patent rights on products, treatment methods or manufacturing processes that we may develop or to which we may obtain license or other rights. Even if we do obtain patents, rights under any issued patents may not provide us with sufficient protection for our product candidates or provide sufficient protection to afford us a commercial advantage against our competitors or their competitive products or processes. It is possible that no patents will be issued from any pending or future patent applications owned by us or licensed to us. Others may challenge, seek to invalidate, infringe or circumvent any patents we own or license. Alternatively, we may in the future be required to initiate litigation against third parties to enforce our intellectual property rights. The defense and prosecution of patent and intellectual property claims are both costly and time consuming, even if the outcome is favorable to us. Any adverse outcome could subject us to significant liabilities, require us to license disputed rights from others, or require us to cease selling our future products.

In addition, many other organizations are engaged in research and product development efforts that may overlap with our products. Such organizations may currently have, or may obtain in the future, legally blocking proprietary rights, including patent rights, in one or more products or methods under development or consideration by us. These rights may prevent us from commercializing technology, or may require us to obtain a license from the organizations to use the technology.

We may not be able to obtain any such licenses that may be required on reasonable financial terms, if at all, and we cannot be sure that the patents underlying any such licenses will be valid or enforceable. As with other companies in the pharmaceutical industry, we are subject to the risk that persons located in other countries will engage in development, marketing or sales activities of products that would infringe our patent rights if such activities were conducted in the United States.

Our patents also may not afford protection against competitors with similar technology. We may not have identified all patents, published applications or published literature that affect our business either by blocking our ability to commercialize our product candidates, by preventing the patentability of our products or by covering the same or similar technologies that may affect our ability to market or license our product candidates. Many companies have encountered difficulties in protecting and defending their intellectual property rights in foreign jurisdictions. If we encounter such difficulties or are otherwise precluded from effectively protecting our intellectual property rights in either the United States or foreign jurisdictions, our business prospects could be substantially harmed. In addition, because of funding limitations and our limited cash resources, we may not be able to devote the resources that we might otherwise desire to prepare or pursue patent applications, either at all or in all jurisdictions in which we might desire to obtain patents, or to maintain already-issued patents.

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 Drs Young or 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 have provided and expect that we will continue to provide stock options, restricted stock units or other equity securities that vest over time. 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.

Risks Related to Government Regulation

We will be subject to stringent domestic and foreign therapeutic and drug regulation in respect of any potential products. The regulatory approval processes of the FDA and other comparable regulatory authorities outside the United States are lengthy, time-consuming and inherently unpredictable. Any unfavorable regulatory action may materially and adversely affect our future financial condition and business operations.

Our potential products, further development activities and manufacturing and distribution, once developed and determined, will be subject to extensive and rigorous regulation by numerous government agencies, including the FDA and comparable foreign agencies. To varying degrees, each of these agencies monitors and enforces our compliance with laws and regulations governing the development, testing, manufacturing, labeling, marketing, distribution, and the safety and effectiveness of our drugs. The process of obtaining marketing approval or clearance from the FDA and comparable foreign bodies for new products, or for enhancements, expansion of the indications or modifications to existing products, could:

- take a significant, indeterminate amount of time;
- require the expenditure of substantial resources;
- involve rigorous preclinical and clinical testing, and possibly post-market surveillance;
- involve modifications, repairs or replacements of our potential products;
- require design changes of our potential products;
- result in limitations on the indicated uses of our potential products; or
- result in our never being granted the regulatory approval we seek.

Any of these occurrences may cause our operations or potential for success to suffer, harm our competitive standing and result in further losses that adversely affect our financial condition. We will have ongoing responsibilities under FDA and international regulations, both before and after a product is approved and commercially released. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA. If the FDA were to conclude that there is non-compliance with applicable laws or regulations, or that any of our potential therapeutics are ineffective or pose an unreasonable health risk, the FDA could ban such drugs, detain or seize such drugs, order a recall, repair, replacement, or refund of purchases of such drugs, or require us to notify health professionals and others that the drugs present unreasonable risks of substantial harm to the public health. Additionally, the FDA may impose other operating restrictions, enjoin and restrain certain violations of applicable law pertaining to therapeutics and assess civil or criminal penalties against us, our officers, our employees, or our collaborative partners. The FDA has increased its scrutiny of the therapeutic industry and U.S. and foreign governments are expected to continue to scrutinize the industry closely with inspections and possibly enforcement actions by the FDA or other agencies. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively commercializing our potential products. In addition, negative publicity and product liability claims resulting from any adverse regulatory action could have a material adverse effect on our financial condition and results of operations.

We may seek orphan designation for our drug product candidates. Even if received, this designation may not actually lead to a more streamlined development program and/or a faster review process.

We aim to benefit from the orphan designation allowed by the FDA and the drug regulatory agencies of other countries. However, our drug product candidates may not receive the designation. Without the designation, developing the drug, submitting a new drug application, or NDA, and getting through the regulatory process to gain marketing approval is a lengthy process.

We may seek fast-track designation for our drug product candidates. Even if received, fast-track designation may not actually lead to a faster review process.

We aim to benefit from the FDA's fast track and expedited review and approval programs. However, our drug product candidates may not receive an FDA fast-track designation or be eligible for inclusion in these expedited review programs such as priority review. Without fast-track designation, submitting a new drug application, or NDA, and getting through the regulatory process to gain marketing approval is a lengthy process. Under fast-track designation, the FDA may initiate review of sections of a fast-track drug's NDA before the application is complete. However, the FDA's time period goal for reviewing an application does not begin until the last section of the NDA is submitted. Additionally, the fast-track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process. Under the FDA policies, a drug candidate is eligible for priority review, or review within a six-month time frame from the time a complete NDA is accepted for filing, if the drug candidate provides a significant improvement compared to marketed drugs in the treatment, diagnosis or prevention of a disease. A fast-track designated drug candidate would ordinarily meet the FDA's criteria for priority review.

The fast-track designation for our drug product candidates, if obtained, may not actually lead to a faster review process and a delay in the review process or in the approval of our potential products will delay revenue from their potential sales and will increase the capital necessary to fund these product development programs.

Similar expedited programs may not be available in other foreign countries and the requirements for the design and conduct of those clinical studies may become more complex or additional studies may be required to meet the requirements for regulatory approval in the countries where we are seeking approval for the drug product candidates .

To obtain the necessary approval of our potential products, as a precondition, clinical trials will be required to demonstrate the efficacy and safety of the product and possibly preclinical trials will also be required, all of which will be costly and time consuming, and may not provide results that will allow us to seek regulatory approval.

The number of preclinical and clinical tests that will be required for regulatory approval varies depending on the disease or condition to be treated, the method of treatment, the nature of the drug, the jurisdiction in which approval is sought and the applicable regulations. Regulatory agencies can delay, limit or deny approval of a product for many reasons. For example, regulatory agencies may:

- not deem a therapeutic to be safe or effective;
- interpret data from preclinical and clinical testing differently than we do;
- not approve the manufacturing processes;

- conclude that our drug candidate does not meet quality standards for durability, long-term reliability, biocompatibility, compatibility, or safety; and

- change their approval policies or adopt new regulations.

The FDA may make requests or suggestions regarding conduct of any preclinical and clinical trials, resulting in an increased risk of difficulties or delays in obtaining regulatory approval in the United States. Foreign regulatory agencies may similarly have the ability to influence any clinical trials occurring outside the United States. Any of these occurrences could prove materially harmful to our operations and business.

Even if a potential therapeutic is ultimately approved by the various regulatory authorities, it may be approved only for narrow indications which may render it commercially less viable.

Even if a potential therapeutic of ours is approved, it may not be approved for the indications that are necessary or desirable for successful commercialization. Our preference will be to obtain as broad an indication as possible for use in connection with the particular disease and treatment for which it is designed. However, the final classification may be more limited than originally sought. The limitation on use may make the product commercially less viable and more difficult, if not impractical, to market. Therefore, we may not obtain the revenues that we seek in respect of the proposed product, and we may not be able to become profitable and provide an investment return to our investors.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA or foreign regulatory agencies may also require a risk evaluation and mitigation strategy in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing processes ("cGMPs") and current good clinical practices ("cGCPs") for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;

- fines, warning letters or holds on clinical trials;

- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;

- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any approval that we may have obtained and we may not achieve or sustain profitability.

Unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives could harm our business in the future.

There is increasing pressure on biotechnology companies to reduce healthcare costs. In the United States, these pressures come from a variety of sources, such as managed care groups and institutional and government purchasers. Increased purchasing power of entities that negotiate on behalf of federal healthcare programs and private sector beneficiaries could increase pricing pressures in the future. Such pressures may also increase the risk of litigation or investigation by the government regarding pricing calculations. The biotechnology industry will likely face greater regulation and political and legal actions in the future.

Adverse pricing limitations may hinder our ability to recoup our investment in one or more future product candidates, even if our future product candidates obtain regulatory approval. Adverse pricing limitations prior to approval will also adversely affect us by reducing our commercial potential. Our ability to commercialize any potential products successfully also will depend in part on the extent to which reimbursement for these products and related treatments becomes available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize in the future and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval in the future. If reimbursement is not available or is available only to limited levels, we may not be able to obtain the support and acceptance of physicians, pharmacists and their patients which would result in our inability successfully to commercialize any drug candidate that we develop.

There may be significant delays in obtaining reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent.

Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government funded and private payors for future products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize potential products and our overall financial condition.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

Our business operations will subject us to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also may produce hazardous waste products. We expect to generally contract with third parties for the disposal of these materials and wastes. However, we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations.

These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions and we may not have sufficient (or any) insurance to cover any such costs.

We may experience difficulties in managing growth.

We are a small, pre-revenue stage company. Future growth will impose significant added responsibilities on members of management, including the need to identify, attract, retain, motivate and integrate highly skilled personnel. We may increase the number of employees in the future depending on the progress of our development of our products. 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.

Risks Related to Our Common Stock

Our common stock price is expected to be volatile.

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

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

- our filing for protection under federal bankruptcy laws;
- a negative outcome in any litigation or potential legal proceeding; or
- other potentially negative financial announcements, such as a review of any of our filings by the Securities and Exchange Commission, referred to as the Commission or the SEC, changes in accounting treatment or restatement of previously reported financial results or delays in our filings with the SEC.

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

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

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

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

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

- Before the sale of penny stock by a broker-dealer to a new purchaser, the broker-dealer must determine whether the purchaser is suitable to invest in penny stocks. To make that determination, a broker-dealer must obtain, from a prospective investor, information regarding the purchaser's financial condition and investment experience and objectives. Subsequently, the broker-dealer must deliver to the purchaser a written statement setting forth the basis of the suitability finding and obtain the purchaser's signature on such statement.
- A broker-dealer must obtain from the purchaser an agreement to purchase the securities. This agreement must be obtained for every purchase until the purchaser becomes an " established customer. "
- The Securities Exchange Act of 1934, or the Exchange Act, requires that before effecting any transaction in any penny stock, a broker-dealer must provide the purchaser with a "risk disclosure document" that contains, among other things, a description of the penny stock market and how it functions and the risks associated with such investment. These disclosure rules are applicable to both purchases and sales by investors.

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

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

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

Based on the number of outstanding shares of our common stock held by our stockholders as of October 10, 2017, our directors, executive officers and their respective affiliates beneficially owned or controlled over 90% of our outstanding shares of common stock and Promet, our largest stockholder, directly owned approximately 90% of the outstanding shares of our common stock. Dr. Young by virtue of his position as a Managing Member of Promet, may be deemed under federal securities laws to be the beneficial owner of those shares. As a result, those stockholders have the ability to exert a significant degree of influence with respect to the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. The interests of these persons may not always coincide with our interests or the interests of our other stockholders. This concentration of ownership could harm the market price of our common stock by (i) delaying, deferring or preventing a change in corporate control, (ii) impeding a merger, consolidation, takeover or other business combination involving us, or (iii) discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

We have not paid dividends on our common stock in the past and do not expect to pay dividends on our common stock for the foreseeable future. Any return on investment may be limited to the value of our common stock.

No cash dividends have been paid on our common stock, and we do not expect to pay cash dividends on our common stock in the foreseeable future. Payment of dividends would depend upon our profitability at the time, cash available for those dividends, and other factors as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on a stockholder's investment will only occur if our stock price appreciates.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline and may impair our ability to raise capital in the future.

Our common stock is currently traded on the OTCQB, and there have been and may continue to be periods when it could be considered "thinly-traded," meaning that the number of persons interested in purchasing our common stock at or near bid prices at any given time may be relatively small or non-existent. We have executed lock-up/leak out agreements with certain of our shareholders. These agreements are for a term of one year and allow for leak outs of shares on occurrence of certain events such being tied to the trading price of our shares or otherwise in the discretion of our board of directors should the board believe that market conditions so warrant.

Moreover, finance transactions resulting in a large amount of newly issued shares that become readily tradable, conversion of outstanding convertible notes or debentures and sale of the shares issuable upon conversion of such notes or debentures, or other events that cause stockholders to sell shares, could place downward pressure on the trading price of our stock. In addition, the lack of a robust resale market may require a stockholder who desires to sell a large number of shares of common stock to sell the shares in increments over time in an attempt to mitigate any adverse impact of the sales on the market price of our stock. If our stockholders sell, or the market perceives that our stockholders intend to sell for various reasons, substantial amounts of our common stock in the public market, the market price of our common stock could decline. Sales of a substantial number of shares of our common stock may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

MARKET FOR COMMON STOCK AND RELATED STOCKHOLDER MATTERS

Market and Other Information

Our common stock is quoted on the OTCQB under the symbol "PCSA (formerly HUWX)." Immediately following the offering, we expect to have one class of common stock and no classes of preferred stock outstanding. As of October 4, 2017, there were approximately 161 registered holders of record of our common stock, and the last reported sale price of our common stock on the OTCQB on that date was $0.60 per share.

The following table sets forth the high and low sales price of our common stock on the OTCQB in US Dollars during the prior 12 months:

Date	High	Low
9/1/17	0.60	0.60
8/1/17	0.60	0.60
7/1/17	0.67	0.14
6/1/17	0.14	0.14
5/1/17	0.14	0.14
4/1/17	0.14	0.14
3/1/17	0.15	0.14
2/1/17	0.15	0.15
1/1/17	0.25	0.15
12/1/16	0.25	0.16
11/1/16	0.16	0.16
10/1/16	0.33	0.16

DIVIDEND POLICY

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

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

The following discussion and analysis should be read together with our financial statements and the related notes appearing elsewhere in this report on Form 8-K. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements" for a discussion of the uncertainties, risks and assumptions associated with these statements. Actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth under "Risk Factors" and elsewhere in this report on Form 8-K.

Going Concern and Management's Plan

Although the audited financial statements of Promet for the year ended December 31, 2016, were not prepared with a "going concern" explanatory paragraph in the auditor's report on Promet's financial statements for the years ended December 31, 2016 and 2015, if we (i) are unable to generate substantial revenue, (ii) incur recurring losses and negative cash flow from operations, (iii) are unable quickly and efficiently to navigate a costly and complex regulatory and clinical environment, domestically and in major foreign markets and (iv) continue to maintain limited working capital to pursue our business alternatives, we expect that these factors, and the other risk factors discussed in this report, may in the future raise substantial doubt about our ability to continue as a going concern. Although as of the date of this report we have approximately $2.25 million of cash and are engaged in seeking additional funds from accredited investors no assurance can be given that we will raise adequate funds needed to avoid the "going concern" explanatory paragraph in our next auditor's report on our operations in the current fiscal year. Uncertainty concerning our ability to continue as a going concern may hinder our ability to obtain future financing, as well as adversely affect our collaborative drug development relationships. Continued operations and our ability to continue as a going concern are dependent on our ability to obtain additional funding in the near future and thereafter, and there are no assurances that such funding will be available at all or will be available in sufficient amounts or on reasonable terms. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. Without additional funds from debt or equity financing, sales of assets, sales or out-licenses of intellectual property or technologies, or other transaction, we will rapidly exhaust our resources and will be unable to continue operations. If we cannot continue as a viable entity, our stockholders would likely lose most or all of their investment in us.

Our management intends to attempt to secure additional required funding primarily through additional equity or debt financings. We may also seek to secure required funding through sales or out-licensing of intellectual property assets, seeking partnerships with other pharmaceutical companies or third parties to co-develop and fund research and development efforts, or similar transactions. However, there can be no assurance that we will be able to obtain required funding. If we are unsuccessful in securing funding from any of these sources, we will defer, reduce or eliminate certain planned expenditures and delay development or commercialization of some or all of our products. If we do not have sufficient funds to continue operations, we could be required to seek bankruptcy protection or other alternatives that could result in our stockholders losing some or all of their investment in us.

Results of Operations

Promet's consolidated results of operations are presented for the fiscal years ending December 31, 2015 (from inception on August 31, 2015) and December 31, 2016, and for the six months ending June 30, 2017.

Year Ended December 31, 2016 and Year Ended December 31, 2015

Revenues . Promet had no revenues during the year ending December 31, 2016 and 2015, respectively.

Selling, General and Administrative Expenses . Selling, general and administrative expenses for fiscal 2016 and 2015 were approximately $1,347,078 and $84,705, respectively. Selling, general and administrative expenses consist primarily of legal fees, accounting and audit fees, consulting expenses, and employee salaries.

Research and Development Expenses . Our research and development costs are expensed as incurred. Non-refundable advance payments for goods and services to be used in future research and development activities are recorded as an asset and are expensed when the research and development activities are performed. Research and development expenses were approximately $606,769 and $1,000 for the fiscal years ended December 31, 2016 and 2015, respectively, which were expensed.

Six Months Ended June 30, 2017 (Unaudited)

Revenues . Processa had no revenues during the six-month periods ending June 30, 2017.

Selling, General and Administrative Expenses . Selling, general and administrative expenses for the six months ending June 30, 2017 were approximately $541,883. Selling, general and administrative expenses consist primarily of legal fees, accounting and audit fees, professional/consulting fees and employee salaries.

Research and Development Expenses . Our research and development costs are expensed as incurred. Non-refundable advance payments for goods and services to be used in future research and development activities are recorded as an asset and are expensed when the research and development activities are performed. Research and development costs were approximately $19,240.

Cash and Cash Equivalents

We consider all highly liquid investments with a maturity of three months or less to be cash equivalents. We do have certificates of deposit that we purchase through an investment company and are held at multiple banks. The maturities of said certificates of deposit are typically six months or less.

Critical Accounting Policies and Estimates

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

We believe the following accounting policies and estimates are most critical to aid in understanding and evaluating our reported financial results. For further discussion of our accounting policies, see Note 3 in the accompanying notes to our audited consolidated financial statements appearing elsewhere in this report on Form 8-K.

Stock-Based Compensation . We account for stock-based compensation transactions in which we receive employee services in exchange for options to purchase common stock. Stock-based compensation cost for restricted stock units, or RSUs, is measured based on the closing fair market value of our common stock on the date of grant. Stock-based compensation cost for stock options is estimated at the grant date based on each option's fair-value as calculated by the Black-Scholes option-pricing model. We recognize stock-based compensation cost as expense ratably on a straight-line basis over the requisite service period.

Derivative Financial Instruments . Derivatives are recognized as either assets or liabilities in the consolidated balance sheets and are measured at fair value. The treatment of gains and losses resulting from changes in the fair values of derivative instruments is dependent on the use of the respective derivative instrument and whether they qualify for hedge accounting. As of the date of this report, no derivative instruments qualified for hedge accounting.

Accounting Standards Codification (ASC) 815 - Derivatives and Hedging provides guidance to determine what types of instruments, or embedded features in an instrument, are considered derivatives. This guidance can affect the accounting for convertible instruments that contain provisions to protect holders from a decline in the stock price, or down-round provisions. Down-round provisions reduce the exercise price of a convertible instrument if a company either issues equity share for a price that is lower than the exercise price of those instruments, or issues new convertible instruments that have a lower exercise price.

Off Balance Sheet Arrangements

At December 31, 2016 and December 30, 2015, we did not have any off balance sheet arrangements.

Recent Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board (FASB) issued accounting guidance on the presentation of an unrecognized tax benefit when a net operating loss carryforward exists. Under this guidance, an unrecognized tax benefit, or a portion of an unrecognized tax benefit, should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward. This guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. Other than a potential change in presentation within a potential consolidated balance sheet, this accounting guidance will not have an impact on our consolidated financial position, results of operations or cash flows.

BUSINESS

Promet was founded in late August 2015 and assigned its assets and operations to Processa Pharmaceuticals in October 2017 with a mission to develop products that can improve the survival and/or quality of life for patients who have a high unmet medical need. The company is headquartered in Hanover, Maryland.

To advance its mission, Processa has assembled an experienced, talented management and product development teams. 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 U.S. Food and Drug Administration (FDA) and more than 50 drug development programs, including drug products targeted to orphan disease conditions.

Part of the business strategy for Processa is (i) to identify new products that can be quickly developed to treat patients with unmet medical needs based on clinical evidence and/or strong pre-clinical evidence and (ii) to identify products that have been developed or approved for other indications but can be repurposed to treat these rare diseases on which Processa decides to focus. Processa's lead product, Drug 499, has previously been investigated for other indications in Phase 2 studies before we obtained an option to license Drug 499 from CoNCERT Pharmaceuticals. Based on the diverse pharmacological activity of Drug 499, the Processa team has defined a strategy to develop the product in two new indications where physicians and patients seek significant medical help. Drug 499 will be investigated for the treatment of a mixed pathophysiology condition, Necrobiosis Lipoidica, as well as for the treatment of radiation therapy related adverse effects in head and neck cancer. These two indications do not have any FDA approved treatments and seriously affect the day-to-day quality of life of the patients. Our team is scheduled to meet with the FDA for a pre-IND meeting in the latter part of October 2017 for Necrobiosis Lipoidica as the first part of the implementation of that strategy.

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

Clinical Supplies and Manufacturing

We have no in-house manufacturing capabilities. We rely on third-party contract manufacturers to make the material used to support the development of our product candidates. We purchase the material used in our clinical trial activities from various companies and suppliers.

Sales and Marketing

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

Customers and Distribution

We do not currently sell or distribute pharmaceutical products.

Competition

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

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;
- preserve our trade secrets; and
- operate without infringing the patents and proprietary rights of other parties.

We intend to continue to seek appropriate patent protection for product candidates in our research and development programs where applicable and their uses by filing patent applications in the United States and other selected countries. We intend for these patent applications to cover, where possible, claims for composition of matter, medical uses, processes for preparation and formulations.

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

Government Regulation

Pharmaceutical Regulation

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

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

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

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

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

Regulation in the United States

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

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

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

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

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

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

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

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

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

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

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

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

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

Foreign Regulation

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

Additional Regulation

Third-Party Reimbursement

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

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

Fraud and Abuse Laws

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

HIPAA

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

Other Laws

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

License Agreements

Option Agreement Relating to CTP-499 (CoNCERT Pharmaceuticals)

Promet Therapeutics, LLC and CoNCERT Pharmaceuticals Inc have entered into an exclusive option and license agreement for the CTP-499 compound. However, under the terms of this agreement, if Promet fails to meet the conditions set forth in the agreement which include having adequate funding for the support of the drug as defined within the agreement, or if Promet elects not to exercise the option, then the product reverts back to ownership by CoNCERT. Since CPT-499 is currently our drug product lead candidate this would negatively impact the Company. See "Risk Factors" above.

Employees

As of October 5, 2017, we have 12 employees. None of our employees is subject to a collective bargaining agreement or represented by a labor or trade union, and we believe that our relations with our employees is good. We believe that we have been successful in attracting skilled and experienced personnel, but competition for personnel is intense and there can be no assurance that we will be able to attract and retain the individuals needed.

Properties

In October 2016, we leased approximately 6500 square feet of office space in Hanover, Maryland. The term of the lease is three years. The rent for the remaining months of the lease term is approximately $7,195 per month. There are no options to extend the lease term. Total rent expense was $50,997 and $0 for the years ended December 31, 2016 and 2015, respectively.

Legal Proceedings

We are not currently, nor have we been in the past, party to any material legal proceedings.

MANAGEMENT

Executive Officers, Directors and Key Employees

The following table sets forth the names and ages of the members of our executive officers and the positions held by each as of October 4, 2017.

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

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

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

Dr. Young has over 30 years of pharmaceutical research, drug development, and corporate experience. He was a Founder and CEO of Promet Therapeutics, LLC since its formation in August 2015. Dr. Young was Chief Scientific Officer of Questcor Pharmaceuticals from 2009-2014 and was responsible for working with the FDA on modernizing the Acthar Gel label and in obtaining FDA approval in Infantile Spasms. From 2006-2009 prior to joining the executive management team, Dr. Young served as an independent Director on the Questcor Board of Directors. During the eight years that Dr. Young was involved with Questcor, Questcor transitioned to an orphan drug specialty pharmaceutical company, moving from near bankruptcy in 2007 to a valuation of approximately $5.6 billion in 2014. While serving on Questcor's Board of Directors, Dr. Young was Executive Director & President, U.S. Operations of AGI Therapeutics plc. Dr. Young has also served as the Executive Vice President of the Strategic Drug Development Division of ICON plc, an international CRO, and was the Founder and CEO of GloboMax LLC, a CRO specializing in FDA drug development, purchased by ICON plc in 2003. Prior to forming GloboMax, Dr. Young was a Tenured Associate Professor at the School of Pharmacy, University of Maryland., where he led a group of 30 faculty, scientists, postdocs, graduate students and technicians in evaluating the biological properties of drugs and drug delivery systems in animals and humans.

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

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

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

Patrick Lin
Chief Business and Strategy Officer and Founder

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

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

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

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

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

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

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

Wendy Guy
Chief Administrative Officer and Founder

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

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

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

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

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

Executive Biographies

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

Justin W. Yorke

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

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

Virgil Thompson

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

From July 2009 to July 2015, he served as Chief Executive Officer and Director of Spinnaker Biosciences, Inc., and now serves as Chairman of the Board of that company. Mr. Thompson is also the Chairman of the Board of Aradigm Corporation and a Director of Genz Corporation.

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

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

Key Employees

Maya Das, M.D., J.D.
VP, Clinical Research

Dr. Das brings more than 10 years of experience in the healthcare and life science sectors. Prior to joining Processa, Dr. Das led clinical development teams in neurology, rheumatology, and nephrology therapeutic areas at Mallinckrodt and Questcor Pharmaceuticals. In these roles, her experience includes both strategic and hands-on involvement in the design and implementation of clinical studies. Earlier, Dr. Das worked in clinical informatics managing system implementation and content development at Epic Systems and program evaluation projects at NORC at the University of Chicago, an independent research organization.

Dr. Das received a B.S. in Biochemistry (summa cum laude) from Beloit College and both Medical Doctorate and Juris Doctorate degrees from the University of Wisconsin-Madison. She completed a residency in Preventive Medicine, where she served as Chief Resident and rotated through the National Cancer Institute (NCI) and the Food and Drug Administration (FDA), and received a M.S. in Epidemiology from the University of Maryland. She is also registered to practice as an attorney before the U.S. Patent and Trademark Office (USPTO).

Yvonne Madden
Vice President, Project Management

Ms. Madden has approximately 20 years' experience in project management primarily in pharmaceutical research and development. Prior to her current role she was responsible for the development and leadership of the Project Management function at Mallinckrodt Pharmaceuticals (formerly Questcor). This involved project management of all internal clinical and nonclinical programs for its autoimmune and rare disease programs and external collaborations. Prior to this role she worked on international cross functional teams and spent over eight years with Elan Pharmaceuticals, Ireland working on both internal programs and collaborations with major pharma; she was responsible for the project management of development programs for both ANDA and NDA submissions that utilized Elan's proprietary controlled release delivery technology.

Ms. Madden received a B.S. from Kansas State University.

Helen Pentikis, Ph.D.,
Vice President, Pharmacology

Dr. Pentikis has over 25 years' experience in strategic drug development, regulatory science and clinical research. Dr. Pentikis is a Founder and on the Management Team for Symbiomix Therapeutics, a venture backed, late-stage pharmaceutical company. She co-founded in 2008 SAJE Consulting, a clinical, pharmacokinetic, and strategic regulatory consulting company. Prior to SAJE Consulting, she served as Head, Clinical Pharmacology at AkaRx Inc. Her work on the senior management team was instrumental in the $300-million acquisition of AkaRx. Previously, Dr. Pentikis was Global Vice President, Pharmacokinetics and Pharmacodynamics at ICON plc, responsible for the scientific management of the PK and biostatistics teams. She was a research fellow in the pharmacometrics section at Sanofi-Aventis, where she successfully applied PK and PD principles to the design of Phase 1-3 studies. Dr. Pentikis was also involved in several worldwide regulatory submissions in the areas of women's health, allergy, and oncology supportive care.

Dr. Pentikis received a Bachelor of Science in biology from Wake Forest University, a Ph.D. in Pharmacology and Toxicology from the University of Maryland, and completed a Fellowship in Pharmacokinetics and Infectious Diseases at the FDA.

Family Relationships

There is no family relationship between any of our officers.

No Involvement in Certain Legal Proceedings

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

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

Board Leadership Structure and Role in Risk Oversight

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

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

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

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

Corporate Governance

Board Committees

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

Director Independence

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

Summary Compensation Table

The following sets forth all compensation awarded, earned or paid for services rendered in all capacities to Processa during fiscal year: No named officer of Heatwurx, Inc. received compensation in excess of $100,000 in 2016 and no named officer of Heatwurx received any salary during the nine months ended September 2017. No named officer or director of Heatwurx received or had vested options to acquire securities of Heatwurx in in 2016 or 2017. No named officer of Promet received compensation exceeding $100,000 during either of the years ended December 31, 2015 or December 31, 2016. No named director of Promet received compensation for services during the nine months ended September 30, 2017.

Outstanding Equity Awards at Year-End

The Company recognizes the value of providing equity based incentives to its employees and intends to adopt an equity incentive plan prior to December 31, 2017. There are no currently outstanding equity awards to any of our named executive officers.

No director was compensated for his services as a director during the fiscal year ended December 31, 2016

Description of Securities

Our authorized capital stock consists of 350,000,000 shares of $0.0001 par value common stock and 10,000,000 shares of $0.0001 par value preferred stock. We are incorporated in the state of Delaware.

Common Stock

We are authorized to issue up to 350,000,000 shares of common stock, $0.0001 par value. Each share of common stock entitles a stockholder to one vote on all matters upon which stockholders are permitted to vote. Common stock does not confer on the holder any preemptive right or other similar right to purchase or subscribe for any additional securities issued by us and is not convertible into other securities. No shares of common stock are subject to redemption or any sinking fund provisions. All the outstanding shares of our common stock are fully paid and non-assessable. Subject to the rights of the holders of the preferred stock, the holders of shares of our common stock are entitled to dividends out of funds legally available when and as declared by our Board of Directors. In the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to receive, ratably, the net assets available to stockholders after payment of all creditors and any liquidation preference on outstanding preferred stock.

In connection with the Asset Purchase we issued 222,217,000 shares of the common stock of the Company to Promet and currently have approximately 246,908,000 issued and outstanding shares of common stock. See Items 1.01, 2.01 and 3.02 above.

Preferred Stock

We may issue up to 10,000,000 shares of "blank check" preferred stock, $0.0001 par value, in one or more classes or series within a class as may be determined by our Board of Directors, who may establish, from time to time, the number of shares to be included in each class or series, may fix the designation, powers, preferences and rights of the shares of each such class or series and any qualifications, limitations or restrictions thereof. Any preferred stock so issued by the Board of Directors may rank senior to the common stock with respect to the payment of dividends or amounts upon liquidation, dissolution or winding up of us, or both.

No other series or shares of preferred stock are currently outstanding. The issuance of preferred stock, while providing desirable flexibility in connection with possible acquisitions and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from acquiring, a majority of our outstanding voting stock.

Transfer Agent and Registrar

Our common shares are issued in registered form. The registrar and transfer agent for our common shares is Corporate Stock Transfer, Inc., 3200 Cherry Creek Drive South, #430, Denver, Colorado 80209.

Indemnification of Directors and Officers

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

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

Changes in and Disagreements with Accountants

None.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The Audited Financial Statements of Promet Therapeutics LLC as of December 31, 2015 and 2016 and for the period From August 31, 2015 (inception) through December 31, 2015 and the year ended December 31, 2016 and the Unaudited Interim Financial Statements of Promet Therapeutics LLC as of and for the six months ended June 30, 2017 are filed as exhibits 99.1 and 99.2 respectively, to the Current Report and are incorporated herein by reference.

Exhibit No.	Description
2.1	Asset Purchase Agreement. Dated October 2, 2017, among the Company, Promet Therapeutics LLC and Processa Therapeutics LLC.*
3.1	Fourth Amended and Restated Certificate of Incorporation of Heatwurx, Inc.
10.1	Form of Lock Up Agreement - Heatwurx**
10.2	Form of Lock Up/Leak Out Agreement - Promet**
23.1	Consent of Independent Registered Public Accounting Firm
99.1	Financial statements of Promet Therapeutics LLC as of December 31, 2015 and 2016 and for the period from August 31, 2015 (inception) through December 31, 2015 and the year ended December 31, 2016
99.2	Unaudited interim financial statements of Promet Therapeutics LLC for the six months ended June 30, 2017**

*Incorporated by reference to exhibits accompanying Form 8-K filed on October 5, 2017
** Incorporated by reference to exhibits accompanying Form 8-K filed on October 12, 2017

SIGNATURES

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

Date: October 17, 2017

HEATWURX, INC.

/s/ David Young
By: David Young
Chief Executive Officer

FOURTH AMENDED AND REST A TED CERTIFICATE OF INCORPORATION

OF

HEATWURX, INC.

Heatwurx, Inc, (hereinafter called the "Corporation"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware, does hereby certify as follows:

1. The name of the corporation is Heatwurx, Inc. The date of the filing of its original Certificate of Incorporation with the Secretary of State of the State of Delaware was March 29, 2011. The Certificate of Incorporation was restated on April 15, 2011, October 25, 2011, and July 24, 2012, was amended on June 28, 2011, and June 21, 2013.

2. This Fourth Amended and Restated Certificate of Incorporation was duly adopted by the board of directors and the stockholders of the Corporation in accordance with the applicable provisions of Sections 141,228,242 and 245 of the General Corporation Law of the State of Delaware.

3. This Fourth Amended and Restated Certificate of Incorporation amends and restates the current Restated Certificate of Incorporation, and the text of the Restated Certificate of Incorporation is hereby amended and restated to read as herein set forth in full:

FIRST: The name of the Corporation is: Heatwurx, Inc.

SECOND: The address of the Corporation's registered office in the State of Delaware is 160 Greentree Drive, Suite 101, City of Dover, County of Kent, Delaware 19904. The name of its registered agent at such address is National Registered Agents, Inc.

THIRD: The nature of the business or purposes to be conducted or promoted by the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of Delaware.

FOURTH: The total number of shares of all classes of stock which the Corporation shall have authority to issue is (i) 350,000,000 shares of Common Stock, $0.0001 par value per share ("Common Stock") and (ii) 10,000,000 shares of Preferred Stock, $0.000 I par value per share ("Preferred Stock").

The following is a statement of the designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation.

A. COMMON STOCK.

1. General . The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights ofthe holders of the Preferred Stock of any series as may be designated by the Board of Directors upon any issuance of the Preferred Stock of any series.

2. Voting . The holders of the Common Stock shall have voting rights at all meetings of stockholders, each such holder being entitled to one vote for each share thereof held by such holder; provided, however, that, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Certificate of Incorporation (which, as used herein, shall mean the certificate of incorporation of the Corporation, as amended from time to time, including the terms of any certificate of designations of any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon pursuant to this Certificate of Incorporation. There shall be no cumulative voting.

State of Delaware
Secretary of State
Division of Corporations
Delivered 10:51 AM 09/27/2017
FILED 10:51 AM 09/27/2017
SR 20176357090 - File Number 4961094

The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(bX2) of the General Corporation Law of the State of Delaware.

3. Dividends . Dividends may be declared and paid on the Common Stock from funds lawfully available therefor as and when determined by the Board of Directors and subject to any preferential dividend or other rights of any then outstanding Preferred Stock.

4. Liquidation . Upon the dissolution or liquidation of the Corporation, whether voluntary or involuntary, holders of Common Stock will be entitled to receive all assets of the Corporation available for distribution to its stockholders, subject to any preferential or other rights of any then outstanding Preferred Stock.

B. PREFERRED STOCK.

Preferred Stock may be issued from time to time in one or more series, each of such series to have such terms as stated or expressed herein and in the resolution or resolutions providing for the issue of such series adopted by the Board of Directors of the Corporation as hereinafter provided. Any shares of Preferred Stock which may be redeemed, purchased or acquired by the Corporation may be reissued except as otherwise provided by law.

Authority is hereby expressly granted to the Board of Directors from time to time to issue the Preferred Stock in one or more series, and in connection with the creation of any such series, by adopting, a resolution or resolutions providing for the issuance of the shares thereof and by filing a certificate of designations relating thereto in accordance with the General Corporation Law of the State of Delaware, to determine and fix the number of shares of such series and such voting powers, full or limited, or no voting powers, and such designations, preferences and relative participating, optional or other special rights, and qualifications, limitations or restrictions thereof, including without limitation thereof, dividend rights, conversion rights, redemption privileges and liquidation preferences, as shall be stated and expressed in such resolutions, as to the full extent now or hereafter permitted by the General Corporation Law of the State of Delaware. Without limiting the generality of the foregoing, the resolutions providing for issuance of any series of Preferred Stock may provide that such series shall be superior or rank equally or be junior to any other series of Preferred Stock to the extent permitted by law.

The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares then outstanding) by the affirmative vote of the holders of a majority of the voting power of the capital stock of the Corporation entitled to vote thereon, voting as a single class, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law of the State of Delaware.

FIFTH: In furtherance of and not in limitation of powers conferred by statute, it is further provided:

1. The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors.
2. Election of directors need not be by written ballot.
3. The Board of Directors is expressly authorized to adopt., amend, alter or repeal the By-Laws of the Corporation.

SIXTH: Except to the extent that the General Corporation Law of Delaware prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty, no director of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability. No amendment to or repeal of this provision shall apply to or have any effect on the liability or alleged liability of any director or the Corporation for or with respect to any acts or omissions of such director occurring prior to such amendment.

SEVENTH: The Corporation shall, to the fullest extent permitted by Section 145 of the General Corporation Law of Delaware, as amended from time to time, indemnify each 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, by reason of the fuct that he or she is or was, or has agreed to become, a director or officer of the Corporation, or is or was serving, or has agreed to serve, at the request of the Corporation, as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan) (all such persons being referred to hereafter as an " Indemnitee "), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees),judgments, fines and amounts paid in settlement actually and reasonably incurred by or on behalf of an Indemnitee in connection with such action, suit or proceeding and any appeal therefrom.

As a condition precedent to an Indemnitee's right to be indemnified, the Indemnitee must notify the Corporation in writing as soon as practicable of any action, suit, proceeding or investigation involving such Indemnitee for which indemnity will or could be sought. With respect to any action, suit, proceeding or investigation of which the Corporation is so notified, the Corporation will be entitled to participate therein at its own expense and/or to assume the defense thereof at its own expense, with legal counsel reasonably acceptable to the Indemnitee.

In the event that the Corporation does not assume the defense of any action, suit, proceeding or investigation of which the Corporation receives notice under this Article, the Corporation shall pay in advance of the final disposition of such matter any expenses (including attorneys' fees) incurred by an Indemnitee in defending a civil or criminal action, suit, proceeding or investigation or any appeal therefrom; provided , however , that the payment of such expenses incurred by an Indemnitee in advance of the final disposition of such matter shall be made only upon receipt of an undertaking by or on behalf of the Indemnitee to repay all amounts so advanced in the event that it shall ultimately be determined that the Indemnitee is not entitled to be indemnified by the Corporation as authorized in this Article, which undertaking shall be accepted without reference to the financial ability of the Indemnitee to make such repayment; and further provided that no such advancement of expenses shall be made under this Article ifit is determined that (i) the Indemnitee did not act in good fuith and in a manner he reasonably believed to be in, or not opposed to, the best interests of the Corporation, or (ii) with respect to any criminal action or proceeding, the Indemnitee had reasonable cause to believe his conduct was unlawful.

The Corporation shall not indemnity an Indemnitee pursuant to this Article in connection with a proceeding (or part thereof) initiated by such Indemnitee unless the initiation thereof was approved by the Board of Directors of the Corporation. In addition, the Corporation shall not indemnity an Indemnitee to the extent such Indemnitee is reimbursed from the proceeds of insurance, and in the event the Corporation makes any indemnification payments to an Indemnitee and such Indemnitee is subsequently reimbursed from the proceeds of insurance, such Indemnitee shall promptly refund such indemnilication payments to the Corporation to the extent of such insurance reimbursement.

All determinations hereunder as to the entitlement of an Indemnitee to indemnification or advancement of expenses shall be made in each instance (a) by a majority vote of the directors of the Corporation consisting of persons who are not at that time parties to the action, suit or proceeding in question " disinterested directors "), whether or not a quorum, (b) by a committee of disinterested directors designated by majority vote of disinterested directors, whether or not a quorum, (e) if there are no disinterested directors, or if the disinterested directors so direct, by independent legal counsel (who may, to the extent permitted by law, be regular legal counsel to the Corporation) in a written opinion, or (d) by the stockholders of the Corporation.

The rights provided in this Article (i) shall not be deemed exclusive of any other rights to which an Indemnitee may be entitled under any law, agreement or vote of stockholders or disinterested directors or otherwise, and (ii) shall inure to the benefit of the heirs, executors and administrators of the Indemnitees. The Corporation may, to the extent authorized from time to time by its Board of Directors, grant indemnification rights to other employees or agents of the Corporation or other persons serving the Corporation and such rights may be equivalent to, or greater or less than, those set forth in th.is Article.

EIGHTH: The Corporation reserves the right to amend, aiter, change or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by statute and this Certificate of Incorporation, and all rights conferred upon stockholders herein are granted subject to this reservation.

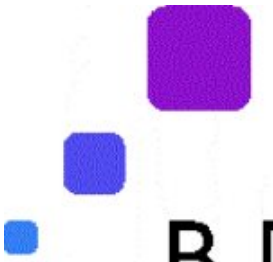
EXECUTED on September 26, 2017

/s/ John P. McGrain
By: John P. McGrain
Title: President

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in this filing on Form 8-K of our report dated September 15, 2017, of our audit of the financial statements of Promet Therapeutics, LLC as of December 31, 2016 and 2015, and for the year ended December 31, 2016 and the period from August 31, 2015 through December 31, 2015.

/s/ BD & Company, Inc.
Owings Mills, MD
October 17, 2017



BD&CO.

CERTIFIED PUBLIC ACCOUNTANTS
MANAGEMENT CONSULTANTS

PROMET THERAPEUTICS, LLC
FINANCIAL STATEMENTS
FOR THE YEAR ENDED
DECEMBER 31, 2016 AND THE PERIOD
FROM AUGUST 31, 2015 (INCEPTION)
THROUGH DECEMBER 31, 2015

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Independent Auditors' Report

Promet Therapeutics, LLC
Hanover, MD

Report on Financial Statements

We have audited the accompanying balance sheets of Promet Therapeutics, LLC ("the Company") as of December 31, 2016 and 2015, and the related statements of operations, members' equity (deficit) and cash flows for the year ended December 31, 2016 and the period from August 31, 2015 (inception) through December 31, 2015, and the related notes to the financial statements.

Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Promet Therapeutics, LLC as of December 31, 2016 and 2015, and the results of its operations and its cash flows for the year ended December 31, 2016 and the period from August 31, 2015 (inception) through December 31, 2015 in accordance with accounting principles generally accepted in the United States of America.

BD & Company, Inc.
Owings Mills, MD
September 15, 2017

Promet Therapeutics, LLC
Balance Sheets
December 31, 2016 and 2015

	December 31, 2016	December 31, 2015
ASSETS		
Current Assets		
Cash	$ 1,071,894	$ -
Certificates of deposit	1,019,294	-
Vendor deposit	227,657	-
Prepaid expenses	18,147	1,869
Total Current Assets	2,336,992	1,869
Property And Equipment		
Equipment	8,445	-
Software	15,330	-
Total Cost	23,775	-
Less: accumulated depreciation	1,381	-
Property and equipment, net	22,394	-
Other Assets		
Security deposit	5,535	-
Total Other Assets	5,535	-
Total Assets	$ 2,364,921	$ 1,869
LIABILITIES and MEMBERS' EQUITY (DEFICIT)		
Current Liabilities		
Accounts payable	$ 14,593	$ 10,886
Due to related party	95	69,474
Accrued expenses	83,004	7,214
Total Current Liabilities	97,692	87,574
Total Liabilities	97,692	87,574
Members' Equity (Deficit)		
Class A member interests	3,000,000	-
Class B member interests	1,270,000	-
Accumulated deficit	(2,002,771)	(85,705)
Total Members' Equity (Deficit)	2,267,229	(85,705)
Total Liabilities and Members' Equity (Deficit)	$ 2,364,921	$ 1,869

The information in the notes is an integral part of these financial statements.

Promet Therapeutics, LLC
Statements of Operations
Year ended December 31, 2016 and the Period from
August 31, 2015 (Inception) through December 31, 2015

	December 31, 2016	August 31, 2015 through December 31, 2015
Operating Expenses	$ 1,953,847	$ 85,705
Operating Loss	(1,953,847)	(85,705)
Other Income		
Administrative services	32,327	-
Interest income	4,454	-
Other Income	36,781	-
Net Loss	$ (1,917,066)	$ (85,705)

The information in the notes is an integral part of these financial statements.

Promet Therapeutics, LLC
Statement of Members' Equity (Deficit)
Year Ended December 31, 2016 and the Period from
August 31, 2015 (inception) through December 31, 2015

	Members' Equity (Deficit)			
	Class A	Class B	Accumulated Deficit	Total
Balance, August 31, 2015	$ -	$ -	$ -	$ -
Net Loss	-	-	(85,705)	(85,705)
Balance, December 31, 2015	-	-	(85,705)	(85,705)
Members' Contributions - January 1, 2016	3,000,000	-	-	3,000,000
Members' Contributions - July 1, 2016	-	1,270,000	-	1,270,000
Net Loss	-	-	(1,917,066)	(1,917,066)
Balance, December 31, 2016	$ 3,000,000	$ 1,270,000	$ (2,002,771)	$ 2,267,229

The information in the notes is an integral part of these financial statements.

Promet Therapeutics, LLC
Statements of Cash Flows
Year Ended December 31, 2016 and the period from
August 31, 2015 (inception) through December 31, 2015

	December 31, 2016	August 31, 2015 through December 31, 2015
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (1,917,066)	$ (85,705)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,381	-
Net changes in operating assets and liabilities:		
Prepaid expenses	(16,278)	(1,869)
Vendor deposit	(227,657)	-
Security deposit	(5,535)	-
Accounts payable	3,707	10,886
Due to related parties	(69,379)	69,474
Accrued liabilities	75,790	7,214
Net cash used in operating activities	(2,155,037)	-
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(23,775)	-
Certificates of deposit	(1,019,294)	-
Net cash used in investing activities	(1,043,069)	-
CASH FLOWS FROM FINANCING ACTIVITIES		
Contributions from members	4,270,000	-
Net cash provided by financing activities	4,270,000	-
NET INCREASE IN CASH	1,071,894	-
CASH - BEGINNING OF YEAR	-	-
CASH - END OF YEAR	$ 1,071,894	$ -

The information in the notes is an integral part of these financial statements

NOTE 1 - NATURE OF BUSINESS

Promet Therapeutics, LLC. (Promet or "the Company") was formed on August 31, 2015 to develop medical products for patients with unmet medical needs. The Company was organized under the laws of the state of Delaware. The Company's operations are performed in the state of Maryland.

As the Company was formed on August 31, 2015 and Promet is still in the organizational and research and development phase of Company operations, the Company has minimal activity during 2015 and did not have any sources of revenue during 2016.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Accounting

The company prepares its financial statements on the accrual basis of accounting.

Organization and Capitalization

The Company's operating agreement provides for three classes of members: Class A, Class B and Profit Interest Members. As of December 31, 2016, the Company has authorized 6,762,000 total member units to be issued, of which 4,200,000 Class A units and 762,000 Class B units have been issued.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Estimates also affect the reported amounts of expenses during the reporting period. Actual events and results could differ from those assumptions and estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less to be cash equivalents.
Certificates of Deposit

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

Fair Market Value of Financial Instruments

The carrying amounts of cash and cash equivalents, accounts receivable and accounts payable approximate fair value because of the short-term maturity of these instruments.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Related Party Administrative Fees

Administrative fees are collected from a related party, Corlyst, LLC ("Corlyst"), for shared costs and are due on demand at the beginning of each month. Receivables are stated at the invoice amount. The balances at December 31, 2016 and 2015 were $0.

Property and Depreciation

Property is stated at cost, less accumulated depreciation. Depreciation is computed under the straight-line method over the estimated useful lives of the assets. Expenditures for maintenance and routine repairs are charged to expense as incurred; expenditures for improvements and major repairs that materially extend the useful lives of assets are capitalized. Depreciation expense for the year ended December 31, 2016 and the period from August 31, 2015 (inception) through December 31, 2015 was $1,381 and $0, respectively. Following are the estimated useful lives for the various classifications of assets:

Software	3 years
Equipment	5 years

Valuation of Long-Lived Assets

The Company accounts for the valuation of long-lived assets under ASC 360 Property, Plant and Equipment. This guidance requires that long-lived assets and certain identifiable intangible assets be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of the long-lived asset is measured by a comparison of the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the estimated fair value of the assets. Assets to be disposed of are reportable at the lower of the carrying amount or fair value, less costs to sell. As of December 31, 2016, management does not believe any long-lived assets are impaired.

Advertising Costs

Advertising costs are recognized as expenses in the year incurred. Total advertising expense for the year ended December 31, 2016 and the period from August 31, 2015 (inception) through December 31, 2015 was $3,850 and $0, respectively.

Research and Development Expenses

Research and development expenditures, which are expensed as incurred, totaled $606,769 and $1,000 for 2016 and the period from August 31, 2015 (inception) through December 31, 2015, respectively.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Income Taxes

The Company is treated as a partnership for federal income tax purposes and does not incur income taxes. In lieu of company income taxes, the partners are taxed separately on their proportionate share of the Company's income, deductions, losses and credits. Therefore, no provision or liability for income taxes has been included in these financial statements.

The Company determined that it was not required to record a liability related to uncertain tax positions as a result of implementing the requirements of ASC 740 Income Taxes.

Equity

Member units are comprised of three types: Class A Units, Class B Units and Profit Interest Units. Class A and Class B units are designated based on the date of share issuance - Class A units were issued on January 1, 2016, while Class B units were issued on July 1, 2016. All Units are non-transferable. As of December 31, 2016, 4,200,000 Class A Units and 762,000 Class B Units have been authorized and issued, and an additional 1,800,000 Profit Interest Units have been authorized for possible future grants to employees, board members and consultants. Profit Interest Units may be awarded to the aforementioned parties based on the Company's officers' discretion.

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09, "Revenue from Contracts with Customers (Topic 606)". The topic of revenue recognition had become broad with several other regulatory agencies issuing standards, which lacked cohesion. The new guidance established a "comprehensive framework" and "reduces the number of requirements to which an entity must consider in recognizing revenue" and yet provides improved disclosures to assist stakeholders reviewing financial statements. The amendments in this update are effective for annual reporting periods beginning after December 15, 2018 for privately-held companies. The Company is currently in the pre-revenue stages of operations and will adopt the methodologies prescribed by this ASU by the date required. Adoption of the ASU is not expected to have a significant effect on the Company's financial statements.

In February 2016, FASB issued ASU-2016-02, "Leases (Topic 842)." The guidance requires that a lessee recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right of use asset representing its right to use the underlying asset for the lease term. For finance leases: the right-of-use asset and a lease liability will be initially measured at the present value of the lease payments, in the statement of financial position; interest on the lease liability will be recognized separately from amortization of the right-of-use asset in the statement of comprehensive income; and repayments of the principal portion of the lease liability will be classified within financing activities and payments of interest on the lease liability and variable lease payments within operating activities in the statement of cash flows. For operating leases: the right-of-use asset and a lease liability will be initially measured at the present value of the lease payments, in the statement of financial position; a single lease cost will be recognized, calculated so that the cost of the lease is allocated over the lease term on a generally straight-line basis; and all cash payments will be classified within operating activities in the statement of cash flows. Under Topic 842 the accounting applied by a lessor is largely unchanged from that applied under previous GAAP. The amendments in Topic 842 are effective for the Company beginning January 1, 2020. Management is currently evaluating the impact of adopting the new guidance on the Company's financial statements.

NOTE 3 - RELATED PARTY TRANSACTIONS

The Company's largest member, Corlyst, LLC, pays Promet for administrative services performed by the Company. These administrative fees are included in other income on the Company's statement of operations. These fees were charged beginning in October 2016 and totaled $32,327 for the year ended December 31, 2016.

During 2015 and through January 2016, Corlyst paid expenses on behalf of the Company and Promet reimbursed Corlyst at later dates. The outstanding balance the Company owed Corylst as of December 31, 2016 and 2015 was $95 and $69,474, respectively.

NOTE 4 - INCOME TAXES

The Company files income tax returns in the U.S. federal jurisdiction, Delaware and Maryland. The Company is a pass-through entity for income tax purposes whereby any income tax liabilities or benefits are attributable to its members. Any amounts paid by the Company for income taxes are treated as distributions to its members.

The Company's federal and state income tax returns for 2015 and 2016 are subject to examination by the Internal Revenue Service and state taxing authorities, generally for three years after they were filed.

NOTE 5 - OPERATING LEASE OBLIGATIONS

The Company leases office space and equipment under non-cancelable operating leases. Rent expense under the current lease for the year ended December 31, 2016 was $50,997. Future annual minimum rental payments under the lease as of December 31, 2016, are as follows:

2017	$	73,843
2018		90,057
2019		76,773
2020		2,930
Total future minimum lease payments	$	243,603

NOTE 6 - CONCENTRATION OF CREDIT RISK

The Company maintains its operating cash in one commercial bank. Balances on deposit are insured by the Federal Deposit Insurance Corporation (FDIC) up to specified limits. Balances in excess of FDIC limits are insured. Total cash held by the bank was $1,068,221 and $0 at December 31, 2016 and 2015, respectively. The Company also maintains cash in a financial institution, which is not insured by the FDIC. Cash held by the financial institution was $4,860 and $0 at December 31, 2016 and 2015, respectively.

NOTE 7 - SUBSEQUENT EVENTS

In preparing these financial statements, the Company has evaluated events and transactions for potential recognition or disclosure through September 15, 2017, the date the financial statements were available to be issued. During the period from January 1, 2017 through September 15, 2017, the Company did not have any material recognizable subsequent events.