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

FORM 10-Q

(Mark One)
[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2018

or

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from ____ to ____

Commission File Number 333-184948

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

Delaware	**45-1539785**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

7380 Coca Cola Drive, Suite 106,
Hanover, Maryland 21076
(443) 776-3133

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES [X] NO [ ]

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES [X] NO [ ]

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [X]

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

The registrant has 38,674,265 shares of common stock outstanding as of November 13, 2018.

PROCESSA PHARMACEUTICALS, INC.
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PART 1: FINANCIAL INFORMATION

ITEM 1: FINANCIAL STATEMENTS

Processa Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets

	September 30, 2018 (Unaudited)	December 31, 2017
ASSETS		
Current Assets		
Cash and cash equivalents	$ 2,424,223	$ 2,847,429
Due from related party	94,766	62,709
Prepaid expenses and other	282,318	41,446
Total Current Assets	2,801,307	2,951,584
Property And Equipment		
Software	19,740	19,740
Office equipment	9,327	9,327
Total Cost	29,067	29,067
Less: accumulated depreciation	9,581	3,246
Property and equipment, net	19,486	25,821
Other Assets		
Security deposit	5,535	5,535
Intangible assets, net of accumulated amortization	10,636,615	-
Total Other Assets	10,642,150	5,535
Total Assets	$ 13,462,943	$ 2,982,940
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Senior convertible notes, net of debt issuance costs	$ 227,772	$ 2,448,570
Accrued interest	15,743	35,693
Accounts payable	80,020	50,686
Due to related parties	100	436
Accrued expenses	367,551	64,428
Total Current Liabilities	691,186	2,599,813
Non-current Liabilities		
Accrued rent liability	-	9,963
Deferred tax liability	2,265,815	-
Total Liabilities	2,957,001	2,609,776
COMMITMENTS AND CONTINGENCIES		
Stockholders' Equity		
Preferred stock, par value $0.0001, 10,000,000 shares authorized; no shares issued and outstanding	-	-
Common stock, par value $0.0001, 350,000,000 shares authorized; 38,674,265 issued and outstanding at September 30, 2018 and 35,272,626 issued and outstanding at December 31, 2017	3,867	3,527
Additional paid-in capital	19,317,036	4,228,723
Subscription receivable	(1,800,000)	-
Accumulated deficit	(7,014,961)	(3,859,086)
Total Stockholders' Equity	10,505,942	373,164
Total Liabilities and Stockholders' Equity	$ 13,462,943	$ 2,982,940

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating Expenses				
Research and development	$ 611,612	$ 457,632	$ 2,477,481	$ 772,533
General and administrative	451,359	255,219	1,305,511	$ 454,592
Total Operating Expenses	1,062,971	712,851	3,782,992	1,227,125
Operating Loss	(1,062,971)	(712,851)	(3,782,992)	(1,227,125)
Other Income (Expense)				
Interest expense	(8,323)	-	(154,377)	-
Interest income	6,457	1,284	10,163	4,672
Total Other Income (Expense)	(1,866)	1,284	(144,214)	4,672
Net Operating Loss Before Income Tax Benefit	(1,064,837)	(711,567)	(3,927,206)	(1,222,453)
Income Tax Benefit	212,015	-	771,332	-
Net Loss	$ (852,822)	$ (711,567)	$ (3,155,874)	$ (1,222,453)
Net Loss per Common Share - Basic and Diluted	$ (0.02)	$ (0.02)	$ (0.09)	$ (0.04)
Weighted Average Common Shares Used to Compute Net Loss Applicable to Common Shares - Basic and Diluted	38,674,265	31,745,242	36,869,323	31,745,242

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

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

	Common Stock		Preferred Stock		Additional Paid-In	Subscription	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Receivable	Deficit	Total
Balance, December 31, 2017	35,272,626	$ 3,527	-	$ -	$ 4,228,723	$ -	$ (3,859,087)	$ 373,163
Recognize the fair value of exclusive license intangible asset acquired from CoNCERT in exchange for 2,090,301 common shares of Processa owned by Promet	-	-	-	-	8,000,000	-	-	8,000,000
Conversion of senior convertible notes for common stock and stock purchase warrants, net of costs of $4,742	1,206,245	121	-	-	2,390,248	-	-	2,390,369
Issuance of common stock units for cash, net of costs of $218,422	1,402,442	140	-		2,964,955	-	-	2,965,095
Issuance of common stock units for a clinical trial funding commitment, net of costs of $117,339	792,952	79	-	-	1,682,582	(1,800,000)	-	(117,339)
Stock-based compensation	-	-	-	-	50,528	-	-	50,528
Net loss for the nine months ended September 30, 2018	-	-	-	-	-	-	(3,155,874)	(3,155,874)
Balance, September 30, 2018	38,674,265	$ 3,867	-	$ -	$ 19,317,036	$ (1,800,000)	$ (7,014,961)	$ 10,505,942

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

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

	Nine Months Ended September 30,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (3,155,874)	$ (1,222,455)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	6,334	(2,678)
Amortization of intangible asset	422,814	-
Deferred income tax (benefit) expense	(771,332)	-
Amortization of debt issuance costs	64,841	-
Stock-based compensation	50,528	-
Net changes in operating assets and liabilities:		
Prepaid expenses and other	(240,872)	2,062
Vendor deposit	-	227,657
Accrued interest	89,522	-
Accounts payable	29,334	29,895
Due from related parties	(32,393)	(35,324)
Accrued liabilities	293,160	22,020
Net Cash Used In Operating Activities	(3,243,938)	(978,823)
CASH FLOWS FROM INVESTING ACTIVITIES		
Proceeds from certificates of deposit	-	1,019,294
Purchase of software license	(20,500)	-
Acquisition of intangible asset	(1,782)	-
Net Cash Used In Investing Activities	(22,282)	1,019,294
CASH FLOWS FROM FINANCING ACTIVITIES		
Net proceeds from issuance of common stock	2,965,095	-
Payment of debt issuance costs	-	(75,000)
Transaction costs incurred in connection with the conversion of senior convertible notes	(4,742)	-
Payment of placement agent and legal fees associated with clinical funding commitment	(117,339)	-
Net Cash Provided By Financing Activities	2,843,014	(75,000)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(423,206)	(34,529)
CASH AND CASH EQUIVALENTS		
BEGINNING OF PERIOD	2,847,429	1,071,894
END OF PERIOD	$ 2,424,223	$ 1,037,365
NON-CASH FINANCING AND INVESTING ACTIVITIES		
Recognize exclusive license intangible asset acquired from CoNCERT	$ (11,037,147)	$ -
Recognize deferred tax liability for basis difference for intangible asset	3,037,147	
Recognize additional paid-in capital for consideration paid from the transfer of 2,090,301 common shares of Processa owned by Promet to CoNCERT	8,000,000	-
Cash paid for intangible asset acquired from CoNCERT	$ -	$ -
Conversion of $2,350,000 of Senior Convertible Debt and related accrued interest into 1,206,245 shares of common stock and warrants	$ 2,395,111	$ -
Common stock and stock purchase warrants issued in connection with a clinical trial funding commitment	$ 1,800,000	$ -

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

Note 1 - Organization and Summary of Significant Accounting Policies

Business Activities and Organization

Company Overview

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

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

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

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

Description of Business

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

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

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

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

Basis of Presentation

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

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

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

Going Concern and Management's Plan

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

The Company has relied exclusively on private placements with a small group of accredited investors to finance its business and operations. We do not have any prospective arrangements or credit facilities as a source of future funds. The Company has not had any revenue since its inception on August 31, 2015. We are looking at ways to add a revenue stream to offset some of our expenses. The Company does not currently have any revenue under contract or any immediate sales prospects. As of September 30, 2018, the Company had an accumulated deficit of approximately $7.0 million, incurred a net loss of approximately $3.2 million and used approximately $3.2 million in net cash from operating activities from continuing operations for the nine months ended September 30, 2018. The Company had total cash and cash equivalents of approximately $2.4 million as of September 30, 2018 and a Clinical Trial Funding commitment from an investor (PoC Capital) of $1.8 million.

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

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

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

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

Use of Estimates

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

Cash and Cash Equivalents

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

Intangible Assets

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

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

Intangibles with a finite useful life are amortized and those with an indefinite useful life are not amortized. The useful life is the best estimate of the period over which the asset is expected to contribute directly or indirectly to the future cash flows of the Company. The useful life is based on the duration of the expected use of the asset by the Company and the legal, regulatory or contractual provisions that constrain the useful life and future cash flows of the asset, including regulatory acceptance and approval, obsolescence, demand, competition and other economic factors. If an income approach is used to measure the fair value of an intangible asset, the Company considers the period of expected cash flows used to measure the fair value of the intangible asset, adjusted as appropriate for Company-specific factors discussed above, to determine the useful life for amortization purposes. If no regulatory, contractual, competitive, economic or other factors limit the useful life of the intangible to the Company, the useful life is considered indefinite.

Intangibles with a finite useful life are amortized on the straight-line method unless the pattern in which the economic benefits of the intangible asset are consumed or used up are reliably determinable. The Company evaluates the remaining useful life of intangible assets each reporting period to determine whether any revision to the remaining useful life is required. If the remaining useful life is changed, the remaining carrying amount of the intangible asset will be amortized prospectively over the revised remaining useful life.

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

Impairment of Long-Lived Assets and Intangibles Other Than Goodwill

The Company accounts for the impairment of long-lived assets in accordance with ASC 360 *Property, Plant and Equipment* and ASC 350, *Intangibles – Goodwill and Other* which requires that long-lived assets and certain identifiable intangibles be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to its expected future undiscounted net cash flows generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amounts of the assets exceed the fair value of the assets based on the present value of the expected future cash flows associated with the use of the asset. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. Based on management's evaluation, there was no impairment loss recorded for the three or nine-month periods ended September 30, 2018.

Fair Value Measurements and Disclosure

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

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

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

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

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

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

Stock-based Compensation

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

Net Income (Loss) per Share

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

Recent Accounting Pronouncements

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

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

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

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

In June 2018, the FASB issued ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, which simplifies the accounting for share-based payments granted to nonemployees for goods and services. Under the ASU, most of the guidance on such payment to nonemployees would be aligned with the requirements for share-based payment granted to employees. The changes take effect for fiscal years starting after December 15, 2018, including interim periods within that fiscal year. We expect that the adoption of this ASU would not have a material impact on our condensed consolidated financial statements.

Note 2 – Intangible Asset

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

The negotiation of the modification to the Agreement was in process as of October 4, 2017 and was finalized in mid-February 2018 and the legal documents were thereafter executed and the option exercised on March 19, 2018 in exchange for CoNCERT receiving (i) $8 million of Company common stock that was held by Promet for the benefit of CoNCERT (2,090,301 shares representing 5.93% of total Company common stock issued and outstanding), and (ii) 15% of any sublicense revenue earned by Processa for a period equivalent to the royalty term (as defined in the Agreement) until the earliest to occur of (a) the Company raising $8 million of gross proceeds; and (b) CoNCERT being able to sell its shares of Company common stock without restrictions pursuant to the terms of the amended Agreement. All other terms of the Agreement remained unchanged. The license agreement was assigned to and exercised by the Company. As a result of the transaction, the Company recognized an intangible asset for the fair value of the common stock consideration paid of $8 million with an offsetting amount in additional paid-in capital resulting from Promet releasing the shares to CoNCERT in satisfaction of the Company's obligation to CoNCERT under the Agreement.

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

Intangible assets consist of the following:

	License Rights to PCS-499	Software License	September 30, 2018
Gross intangible assets	$ 11,038,929	$ 20,500	$ 11,059,429
Less: Accumulated amortization	(419,682)	(3,132)	(422,814)
Total intangible assets, net	$ 10,619,247	$ 17,368	$ 10,636,615)

Amortization expense was $200,256 and $422,814 for the three and nine months ended September 30, 2018, respectively. Amortization expense is included within research and development expense in the accompanying consolidated statements of operations. As of September 30, 2018, the estimated amortization expense for the next two years amounts to approximately $795,000 per year. The estimated amortization expense for the annual periods thereafter amounts to approximately $788,000 per year for the license rights to PCS-499.

Note 3 – Senior Convertible Notes

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

	Senior Convertible Notes	Unamortized Debt Issuance Costs	Senior Convertible Notes, Net	Accrued Interest
Balance, December 31, 2017	$ 2,580,000	$ (131,430)	$ 2,448,570	$ 35,693
Conversion of debt	$ (2,350,000)	$ 64,361	$ (2,285,639)	$ (109,472)
Accrued interest	-	-	-	89,522
Amortize debt issuance costs	-	64,841	64,841	-
Balance, September 30, 2018	230,000	(2,228)	227,772	15,743
Current portion	(230,000)	2,228	(227,772)	(15,743)
Long-term portion	$ -	$ -	$ -	$ -

Interest expense totaled $8,323 for the three months ended September 30, 2018, consisting of interest on the Senior Notes at 8% of $4,600 and the amortization of debt issuance costs of $3,723. Interest expense totaled $154,377 for the nine months ended September 30, 2018 consisting of interest on the Senior Notes at 8% of $89,536 and the amortization of debt issuance costs of $64,841. The Senior Notes and related accrued interest are classified as current liabilities in our consolidated balance sheets.

Issuance of Senior Convertible Notes

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

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

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

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

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

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

Conversion of Our Senior Convertible Notes

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

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

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

Note 4 – Stockholders' Equity

2018 Private Placement Transactions

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

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

The Company also entered into a pledge agreement with PoC, under which the Company received a security interest for 396,476 shares, or half the shares we issued to them and we are holding these shares as collateral. These shares will be released in two tranches of 198,238 shares each, with each tranche released upon PoC making payments totaling $720,000. During the nine months ended September 30, 2018, we have made payments to our CRO of $239,129, including the prepayment of certain amounts, all of which will be repaid to us by PoC.

The common stock, but not the warrants, issued for the 2018 Private Placement Transactions and the conversion of the Senior Convertible Notes have, subject to certain customary exceptions, full ratchet anti-dilution protection. Until the Company has issued equity securities or securities convertible into equity securities for a total of an additional $20.0 million in cash or assets, including the proceeds from the exercise of the warrants issued above, in the event we issue additional equity securities or securities convertible into equity securities at a purchase price less than $2.27 per share of common stock, the above purchase prices shall be adjusted and new shares of common stock issued as if the purchase price was such lower amount (or, if such additional securities are issued without consideration, to a price equal to $0.01 per share).

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

Purchase of the CoNCERT License

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

Note 5 – Income Taxes

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

As of September 30, 2018, and December 31, 2017, the Company recorded a valuation allowance equal to the full recorded amount of the Company's net deferred tax assets related to intangible start-up costs since it is more-likely-than-not that such benefits will not be realized. The valuation allowance is reviewed quarterly and is maintained until sufficient positive evidence exists to support its reversal.

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

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

As required under ASC 740-270, *Interim Financial Reporting*, the Company has estimated its annual effective tax rate for the full fiscal year and applied that rate to its year-to-date consolidated pre-tax ordinary loss before income taxes in determining its benefit for income taxes. The Company recorded a benefit for income taxes of approximately $212,000 and $0 for the three months ended September 30, 2018 and 2017, respectively, and $771,000 and $0 for the nine months ended September 30, 2018 and 2017, respectively.

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

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

Note 6 - Stock-based Compensation

The amended and restated Heatwurx, Inc. 2011 Equity Incentive Plan (the "Plan") was adopted on April 15, 2011 by the board of directors and approved by the shareholders on October 15, 2012. Under this Plan, employees, non-employee directors, advisors, and consultants of the Company and its affiliates are eligible to receive grants under the Plan. The Plan authorizes the issuance of up to 257,143 shares of common stock. If unexercised options expire or are terminated, the underlying shares will again become available for future grants under the Plan. At September 30, 2018, there were no outstanding awards that had been granted under this Plan.

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

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

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

During the nine months ended September 30, 2018, the Company granted non-qualified stock options outside of the Plan for a total of 334,400 shares of common stock. An option for the purchase of 316,400 shares of common stock vests over a four-year term and an option for the purchase of 18,000 shares of common stock vests over one-year term. Both stock option grants have a maximum contractual term of ten years. Vesting is subject to the holder's continuous service with the Company.

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

The fair value of the Company's option awards granted during the nine-month period ended September 30, 2018 was estimated using the following assumptions:

Exercise price	$ 2.84
Risk-free rate of interest	3.09%
Expected term (years)	5.0 to 6.25
Expected stock price volatility	85.31%
Dividend yield	0%

The following table summarizes the Company's stock option activity for the nine months ended September 30, 2018:

	Total options Outstanding	Weighted average exercise price	Weighted average remaining contractual life (in years)
Outstanding as of January 1, 2018	-	$ -	-
Options granted	334,400	2.84	9.9
Exercised	-	-	-
Forfeited	-	-	-
Outstanding as of September 30, 2018	334,400	$ 2.84	9.9

No options were vested or exercisable as of September 30, 2018. The weighted average grant date fair value per share of options granted during the nine months ended September 30, 2018 was between $2.00 and $2.10. No forfeiture rate was applied to these stock options.

The Company recorded $50,528 of stock-based compensation expense for the three and nine months ended September 30, 2018 for awards issued under the above-mentioned plan as general and administrative expense.

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

As of September 30, 2018, there was approximately $649,913 of total unrecognized compensation expense, related to the unvested stock options which are expected to be recognized over a weighted average period of 3.9 years.

Note 7 – Net Loss per Share of Common Stock

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Basic and diluted net loss per share:				
Net loss	$ (852,822)	$ (711,567)	$ (3,155,874)	$ (1,222,453)
Weighted-average number of common shares-basic and diluted	38,674,265	31,745,242	36,869,323	31,745,242
Basic and diluted net loss per share	$ (0.02)	$ (0.02)	$ (0.09)	$ (0.04)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Stock options and purchase warrants	3,947,186	-	3,947,186	-
Senior convertible notes	119,195	-	119,195	-

Note 8 – Related Party Transactions

A shareholder, CorLyst, LLC, reimburses the Company for shared costs related to payroll, health care insurance and rent based on actual costs incurred and recognized as a reduction of the general and administrative operating expenses being reimbursed in the Company's condensed consolidated statement of operations. The reimbursed amounts totaled $1,025 and $0 for the three months ended September 30, 2018 and 2017, respectively, and $28,505 and $49,089 for the nine months ended September 30, 2018 and 2017, respectively. Amounts due from CorLyst at September 30, 2018 and December 31, 2017 were $79,422 and $62,709, respectively. CorLyst also purchased 132,159 shares of our common stock for $300,001 in a private placement transaction.

A Director of the Company is the manager of the JMW Fund, LLC, San Gabriel Fund, LLC, and Richland Fund, LLC, collectively known as the "Funds". The Funds received 515,583 shares of our common stock and warrants to purchase 515,583 shares of our common stock upon the conversion of $1 million of Senior Convertible Notes held by the Funds purchased on October 4, 2017. At September 30, 2018, the Funds owned a total of 2,566,639 shares of common stock and warrants to purchase 515,583 shares of common stock.

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

Note 9 – Commitments and Contingencies

Purchase Obligations

The Company enters into contracts in the normal course of business with contract research organizations and subcontractors to further develop its products. The contracts are cancellable, with varying provisions regarding termination. If a contract with a specific vendor were to be terminated, the Company would only be obligated for products or services that it received as of the effective date of the termination and any applicable cancellation fees. The Company had purchase obligations of approximately $41,000 and $896,000 at September 30, 2018 and December 31, 2017, respectively.

Due to the contingent nature of the amounts and timing of the payments, we have excluded our agreement with the CRO with whom we have contracted to conduct our Phase 2a NL clinical trial. We were contractually obligated for up to approximately $1.8 million of future services under the agreement, but our actual contractual obligations will vary depending on the progress and results of the clinical trial.

Cybersecurity Fraud

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

Note 10 - Subsequent Events

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

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. Forward-looking statements give our current expectations or forecasts of future events. You can identify these statements by the fact that they do not relate strictly to historical or current facts. You can find many (but not all) of these statements by looking for words such as "approximates," "believes," "hopes," "expects," "anticipates," "estimates," "projects," "intends," "plans," "would," "should," "could," "may" or other similar expressions in this report on Form 10-Q. These statements may be found under the section of this report on Form 10-Q captioned "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as in this report on Form 10-Q generally. In particular, these include statements relating to future actions, prospective products, applications, customers, technologies, future performance or results of anticipated products, expenses, and financial results. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from our historical experience and our present expectations or projections. Factors that could cause actual results to differ from those discussed in the forward-looking statements include, but are not limited to:

- our limited operating history, limited cash and history of losses;
- our ability to achieve profitability;
- our ability to secure required FDA or other governmental approvals for our product candidates and the breadth of the indication sought;
- the impact of competitive or alternative products, technologies and pricing;
- whether we are successful in developing and commercializing our technology, including through licensing;
- the adequacy of protections afforded to us and/or our licensor by the anticipated patents that we own or license and the cost to us of maintaining, enforcing and defending those patents;
- our and our licensor's ability to protect non-patented intellectual property rights;
- our exposure to and ability to defend third-party claims and challenges to our and our licensor's anticipated patents and other intellectual property rights;
- our ability to obtain adequate financing to fund our business operations in the future;
- our ability to continue as a going concern; and
- other factors discussed in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the SEC (as amended) on April 17, 2018.

The forward-looking statements are based upon management's beliefs and assumptions and are made as of the date of this report on Form 10-Q. We undertake no obligation to publicly update or revise any forward-looking statements included in this report on Form 10-Q or to update the reasons why actual results could differ from those contained in such statements, whether as a result of new information, future events or otherwise, except to the extent required by federal securities laws. Actual future results may vary materially as a result of various factors, including, without limitation, the risks disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the SEC (as amended) on April 17, 2018. In light of these risks and uncertainties, we cannot assure you that the forward-looking statements contained in this report on Form 10-Q will in fact occur. You should not place undue reliance on these forward-looking statements.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources.

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

Overview

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

Part of our business strategy is:

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

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

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

Our lead product, PCS-499, is an oral tablet that is an analog (i.e.,a compound having a structure similar to that of the approved drug but differing from it in respect to a certain component of the molecule) of an active metabolite of an already approved drug called pentoxifylline (PTX). PTX (Trental®) was approved by the FDA on August 30,1984 for the treatment of patients with intermittent claudication on the basis of chronic occlusive arterial disease of the limbs. In the body PCS-499 is broken down to multiple metabolites with PCS-499 and many of these metabolites being pharmacologically active. In animal and healthy human volunteer studies, higher exposure of certain active metabolites are seen after PCS-499 administration compared to PTX. Despite the greater exposure to these pharmacologically active molecules, PCS-499 appears to be well tolerated, even at higher doses than the standard dosing of PTX. Based on our findings in the literature that PTX has some activity in a number of conditions, PCS-499 may potentially provide clinical benefit over other on-label or off-label products used for the various conditions. These conditions include NL and RIF in head and neck cancer patients. NL is a chronic, disfiguring condition for which most patients do not have any treatment options. It develops more commonly in women than in men on the lower extremities, and ulceration can occur in approximately 30% of NL patients, which may lead to more severe complications, such as deep tissue infections and osteonecrosis that can threaten life of the limb. RIF or radiation-induced fibrosis can occur after radiation treatment in head and neck cancer. Some patients develop late radiation-induced fibrotic effects 90 days after initiation of radiation therapy and sometimes months or years later. RIF can significantly affect the quality of life of these patients causing symptoms such as dry mouth, oral mucositis, muscular atrophy, swallowing dysfunction, vascular damage, and neural damage.

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

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

Going Concern and Management's Plan

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

We have relied exclusively on private placements with a small group of accredited investors to finance our business and operations. We do not have any credit facilities as a source of future funds. We have not had any revenue since our inception on August 31, 2015 and we do not currently have any revenue under contract or any immediate sales prospects. As of September 30, 2018, we had an accumulated deficit of approximately $7.0 million incurred since inception. For the nine months ended September 30, 2018, we incurred a net loss from continuing operations of approximately $3.2 million and used approximately $3.2 million in net cash from operating activities. We expect our operating costs to be substantial as we incur costs related to the various clinical trials for our product candidates and that we will operate at a loss for the foreseeable future.

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

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

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

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

Recent Developments

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

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

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

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

Our placement agent received $167,526 and Placement Agent Warrant to purchase up to 84,146 shares of common stock at an exercise price equal to $2.724.

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

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

Note Conversion. On May 25, 2018, we converted approximately $2.35 million of our mandatory convertible 8.0% Senior Notes and accrued interest of $109,472 into 1,206,245 shares of common stock, at a price of $2.043 per share. The noteholders also received warrants to purchase one share of common stock for each share of common stock purchased at an exercise price equal to $2.452. Our placement agent received a warrant to purchase 72,375 shares of common stock at an exercise price of $2.452.

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

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

Critical Accounting Policies and Use of Estimates

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

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

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

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

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

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

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

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

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

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

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

We expense research and development costs as they are incurred.

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

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

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

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

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

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

Results of Operations

Comparison of the three and nine months ended September 30, 2018 and 2017

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	Change	2018	2017	Change
Operating Expenses						
Research and development costs	$ 611,612	$ 457,632	$ 153,980	$ 2,477,481	$ 772,533	$ 1,704,948
General and administrative expenses	451,359	255,219	196,140	1,305,511	454,592	850,919
Total operating expenses	1,062,971	712,851	350,120	3,782,992	1,227,125	2,555,867
Other Income (Expense)						
Interest Expense	(8,323)	-	(8,323)	(154,377)	-	(154,377)
Interest Income	6,457	1,284	5,173	10,163	4,672	5,491
Total other income (expense)	(1,866)	1,284	(3,150)	(144,214)	4,672	(148,886)
Net Operating Loss Before Income Tax Benefit	1,064,837	711,567	353,270	3,927,206	1,222,453	2,704,753
Income Tax Benefit	(212,015)	-	(212,015)	(771,332)	-	(771,332)
Net Loss	$ 852,822	$ 711,567	$ 141,255	$ 3,155,874	$ 1,222,453	$ 1,933,421

Revenues.

We have not had any revenue since our inception in August 2015. The Company does not currently have any revenue under contract, nor does it have any immediate sales prospects.

Research and Development Expenses.

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

During the three and nine months of 2018, we incurred expenses totaling $611,612 and $2,477,481 for the continued development and testing of our lead product, PCS-499. These amounts represent an increase over amounts we incurred during comparable periods in 2017. During 2017, we incurred research and development costs of $457,632 and $772,533 for the three and nine month ended September 30, 2017. A majority of the costs incurred in 2017 and all the costs incurred in 2018 relate to the development of PCS-499.

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

Costs for the three-month periods ended September 30, 2018 and 2017 were as follows.

	Three months ended September 30, 2018	Three months ended September 30, 2017
Amortization of intangible assets	$ 200,256	$ -
Research and development salaries and benefits	156,098	137,976
Preclinical, clinical trial and other costs	255,258	319,656
Total	$ 611,612	$ 457,632

As shown above, during the three months ended September 30, 2018 we increased our overall research and development expenses by $153,980. As a result of exercising the CoNCERT license and option agreement for PCS-499 in March 2018, and purchase of a software license we recognized $200,256 of amortization expense during the three months ended September 30, 2018. We had no similar expense in 2017. As we continue development of PCS-499, our research and development salaries and benefits increased by $18,122 for the three months ended September 30, 2018 when compared to the same period in 2017 due to an increase in full-time equivalent staff and related costs. We recognized lower research and development expenses for preclinical, clinical trial and other costs of $64,398 during the three months ended September 30, 2018 when compared to the same period in 2017. During the three months ended September 30, 2017, we entered into an agreement with a contract research organization (CRO) for formulation development to determine the optimal composition and dosage of PCS-499 for manufacturing and delivery. During the three months ended September 30, 2018, we concluded a Phase 1 study to test the formulation, described below in detail. We anticipate our research and development costs to increase in the future as we begin our Phase 2a clinical trial activities for NL in the fourth quarter of 2018.

Costs for the nine-month periods ended September 30, 2018 and 2017 were as follows.

	Nine months ended September 30, 2018	Nine months ended September 30, 2017
Amortization of intangible assets	$ 422,814	$ -
Research and development salaries and benefits	494.274	390,375
Preclinical, clinical trial and other costs	1,560,393	382,158
Total	$ 2,477,481	$ 772,533

During the nine months ended September 30, 2018 our research and development costs increased by $1,704,948 to $2,477,481 from $772,533 for nine months ended September 30, 2017. As noted above, following the exercise of the option and license agreement with CoNCERT, we started recognizing amortization expense; $422,814 was recognized during the nine months ended September 30, 2018. We had no similar expense in 2017. During the nine months ended September 30, 2018, we completed a Phase 1 study to evaluate the safety and pharmacokinetics of single and optional multiple dosing regimens of modified release formulations of PCS-499 compared to Trental® (pentoxifylline) administered to healthy subjects. We also incurred costs to establish a new site to manufacture the tablets of PCS-499 needed for our clinical trial since the original CoNCERT tablet manufacturing site could no longer be used. Our research and development salaries and benefits increased $103,899 for the nine months ended September 30, 2018 when compared to the same period in 2017 related to an increase in full-time equivalent staff and related staff costs. We recognized higher research and development expenses for preclinical, clinical trial and other costs of $1,178,235 during the nine months ended September 30, 2018 when compared to the same period in 2017 due to the completion of our Phase 1 pharmacokinetics study described above, the scaling up of clinical trial material we will need for our Phase 2a clinical trial for NL and other research and development costs that we incurred. The majority of costs going forward into the remainder of 2018 and 2019 will be costs related to our Phase 2a clinical trial for NL. We will also incur additional costs when we need to scale up as we currently do not have enough clinical trial material to complete our Phase 2a clinical trial.

During the early part of 2017, we were finalizing a contract we had with Drexel University that officially terminated in June 2017. We incurred nominal costs in 2017 in connection with the contract we had with Drexel University.

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

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

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

General and Administrative Expenses.

General and administrative expenses for the three months ended September 30, 2018 increased $196,140 to $451,359 from $255,219 for the three months ended September 30, 2017. The increase related to payroll and related costs of approximately $103,000 were incurred in connection with building our finance team, including hiring a chief financial officer and a Director of Finance and Accounting. Included in this amount is stock-based compensation expense of $50,528. We also experienced an increase of approximately $96,000 in professional fees related to public company compliance costs and the filing of a Selling Shareholder Form S-1 and related amendments. There was an overall decrease of $2,900 in other general and administrative expenses due to recategorization of expenses. Reimbursements from CorLyst of $26,947 for rent and other costs during the three months ended September 30, 2018 were similar to reimbursements for the same period in 2017.

General and administrative expenses for the nine months ended September 30, 2018 increased $850,919 to $1,305,511 from $454,592 for the nine months ended September 30, 2017. The increase related primarily to professional fees for legal, accounting, advisory and consulting costs of approximately $508,000 related to Company operations and compliance and other costs of operating as a public company. During the second and third quarters of 2018 we experienced increased payroll, and related costs of approximately $158,000 as we build our finance team, including hiring a Chief Financial Officer and a Director of Finance and Accounting to support our growth and public company reporting and compliance requirements. Included in this amount is stock-based compensation of $50,528. We also incurred a cybersecurity fraud loss of approximately $144,000 for which we do not have insurance coverage. The remaining increase in our general and administrative expense was due to additional administrative costs such as insurance, office expenses, continuing education, and travel. Reimbursements from CorLyst of $80,447 for rent and other costs during the nine months ended September 30, 2018 were approximately $4,000 less than reimbursements for the same period in 2017.

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

Interest Expense.

Interest expense was $8,323 and $154,377 for the three and nine months ended September 30, 2018, respectively. We had no interest expense during the corresponding periods in 2017. For the three months ended September 30, 2018, interest expense consisted of interest of $4,600 and the amortization of debt issuance costs of $3,723. For the nine months ended September 30, 2018, interest expense consisted of interest of $89,536 and the amortization of debt issuance costs of approximately $64,841. We incurred interest expense related to our issuance of $2.58 million of 8% Senior Notes issued on October 4, 2017 ($1,250,000) and November 21, 2017 ($1,330,000). See Recent Developments above regarding the conversion of $2,350,000 of these Senior Convertible Notes into shares of our common stock and warrants.

Interest Income.

Interest income was $6,457 and $1,284 for the three months ended September 30, 2018 and 2017, respectively. Interest income was $10,163 and $4,672 for the nine months ended September 30, 2018 and 2017, respectively. Interest income represents interest earned on money market funds and certificates of deposit.

Income Tax Benefit.

An income tax benefit of approximately $212,000 and $0 was recognized for the three months ended September 2018 and 2017, respectively. An income tax benefit of approximately $771,000 and $0 was recognized for the nine months ended September 30, 2018 and 2017, respectively. A deferred tax liability was recorded when Processa received CoNCERT's license and "Know-How" in exchange for Processa stock that had been issued in the Internal Revenue Code Section 351 transaction on March 19, 2018. A Section 351 transaction treats the acquisition of the Know-How for stock as a tax-free exchange. As a result, under ASC 740-10-25-51 *Income Taxes*, Processa recorded a deferred tax liability of approximately $3,037,000 for the acquired temporary difference between the financial reporting basis of approximately $11,039,000 and the tax basis of approximately $2,000. The deferred tax liability may be offset by the deferred tax assets resulting from 2017 and 2018 net operating losses. Under ACS 740-270 *Income Taxes – Interim Reporting*, the Company is required to project its 2018 federal and state effective income tax rate and apply it to the September 30, 2018 operating loss before income taxes. Based on the projection, the Company expects to recognize a tax benefit from the 2017 net operating loss carryover and the projected 2018 loss that offset the deferred tax liability from the acquired Know-How. This offset results in the recognition of a deferred tax benefit shown in the consolidated statements of operations for 2018.

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

Financial Condition

Our total assets increased by approximately $10.5 million to $13.5 million at September 30, 2018 compared to $3.0 million at December 31, 2017. Our assets increased by $11 million when we exercised our option to acquire the exclusive license from CoNCERT related to patent rights and know-how to develop and commercialize compounds and products for PCS-499 and each metabolite thereof in exchange for $8 million of our common stock (2,090,301 shares), and the related income tax effects resulting from the temporary difference between the book and tax basis of the intangible asset and transaction costs. The intangible asset is used in research and development activities and management believes it has alternative future uses (in research and development projects or otherwise). As a result, the acquisition cost of approximately $11 million was capitalized and is being amortized over the intangible asset's useful life in accordance with Topic 350, Intangibles – *Goodwill and Other*. In May and June of 2018, we sold 1,402,442 common stock units for approximately $3.2 million and are using these proceeds to fund our operating activities. Lastly, we made prepayments totaling $220,000 to our contract research organization (CRO) related to our Phase 2a clinical trial for NL.

At September 30, 2018, our total liabilities increased $348,000 to $3.0 million when compared our total liabilities of $2.6 million at December 31, 2017. In May 2018, $2,350,000 of senior convertible notes were converted into 1,206,245 shares of our common stock. This left $230,000 of senior convertible notes outstanding at September 30, 2018. These notes are held by Canadian investors and will be converted into 119,195 shares of our common stock once certain Canadian regulatory matter (mainly reporting) have been resolved. We anticipate this will occur in early 2019. In connection with the exercise of the option agreement with CoNCERT we recognized a $3,037,147 deferred income tax liability since the intangible assets purchased had only a nominal tax basis. We also experienced an increase in our accounts payable and accrued expenses related to the continued development of PCS-499, costs related to beginning our Phase 2 clinical trial and other operating costs.

As noted above, many of the transactions had a direct impact on our stockholders' equity, including:

- the 2,090,301 shares of our common stock valued at $8 million paid by Proment to CoNCERT to acquire the exclusive license intangible asset recorded along the related tax effect;
- the conversion of $2.35 million in senior convertible notes into 1,206,245 shares of common stock;
- completing private placement transactions with net proceeds totaling $2.96 million for 1,402,442 shares of our common stock;
- receipt of a future clinical trial funding commitment of $1.8 million in exchange for 792,952 shares of common stock; and
- the results of our operations, including stock-based compensation of $50,528.

Liquidity and Capital Resources

To date, we have funded our business and operations primarily through the private placement of equity securities and senior secured convertible notes. At September 30, 2018, we had $2.4 million in cash and cash equivalents compared to $2.8 million at December 31, 2017. We also have a Clinical Trial Funding commitment of $1.8 million to fund clinical trial expenses. We will use the clinical trial committed funds for our Phase 2a clinical trial of PCS-499 in patients with NL. We do not have any credit facilities as a source of future funds, and there can be no assurance that we will be able to raise sufficient additional capital on acceptable terms, or at all. As a result, substantial doubt exists about the Company's ability to continue as a going concern within one year after the date that this Form 10-Q is available to be issued.

As described under Recent Developments, in May and June of 2018 we received proceeds of approximately $3.2 million dollars from the sale of 1,402,442 shares of our common stock and warrants to purchase a similar number of shares of common stock exercisable at $2.724 per share. On May 25, 2018, we also entered into an agreement with an investor (PoC Capital) for a commitment to fund up to $1.8 million of clinical trial expenses in exchange for 792,952 shares of our common stock and warrants to purchase a similar number of shares of common stock exercisable at $2.27 per share. This investor will typically make payments not to us, but rather directly to the CRO conducting our Phase 2a trial based on the CRO's invoicing. We have made payments of approximately $239,000 to the CRO which we expect this investor to repay us for in the fourth quarter. Finally, on May 25, 2018 we converted approximately $2.35 million of our 8% convertible debt into 1,206,245 shares of our common stock.

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

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

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

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

Cash Flows

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

	For the Nine Months Ended September 30,	
	2018	2017
Net cash provided by (used in):		
Operating activities	$ (3,243,938)	$ (978,823)
Investing activities	(22,282)	1,019,294
Financing activities	2,843,014	(75,000)
Net increase in cash and cash equivalents	$ (423,206)	$ (34,529)

Net cash used in operating activities

We used net cash in our operating activities of $3,243,938 and $978,823 during the nine months ended September 30, 2018 and 2017, respectively. The increase in cash used in operating activities in 2018 compared to 2017 is primarily related to the increased spending on research and development activities for PCS-499 licensing, program and testing costs, including internal staff costs and increased general and administrative costs related to internal staff growth, professional fees primarily for legal and accounting, and other costs of being a public company. In addition, we incurred a cybersecurity fraud loss of approximately $144,000 in January 2018, which was recognized in general and administrative expenses.

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

Net cash used in investing activities

We used net cash in our investing activities of $22,282 during the nine months ended September 30, 2018 for transactions costs related to the exercise of the option agreement with CoNCERT and for the purchase a software license. Investing inflows in 2017 of $1,019,294 were proceeds we received when certificates of deposits matured.

Net cash provided by (used in) financing activities

During the nine months ended September 30, 2018, net cash was provided from financing activities of $2,843,014 from the sale of 1, 402,442 common stock units (each unit consisted of one share of common stock and a warrant to purchase one share of common stock). During the nine months ended September 30, 2017 we paid $75,000 of debt issuance cost related to our Senior Convertible Notes issued in November 2017.

Contractual Obligations and Commitments

At September 30, 2018 our contractual obligations were $41,000 compared to $896,000 at December 31, 2017. See Note 8 included in the consolidated financial statements in this Form 10-Q. There were no other significant changes in the other components of our “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K/A for the year ended December 31, 2017 filed with the SEC on April 17, 2018.

Due to the contingent nature of the amounts and timing of the payments, we have excluded our agreement with the CRO with whom we have contracted to conduct our Phase 2 NL clinical trial. We were contractually obligated for up to approximately $1.8 million of future services under the agreement, but our actual contractual obligations will vary depending on the progress and results of the clinical trial.

Off Balance Sheet Arrangements

At September 30, 2018 and 2017, we did not have any off-balance sheet arrangements.

Recently Issued Accounting Pronouncements

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.

See Note 2 of our Condensed Financial Statements for new accounting pronouncements or changes to the recent accounting pronouncements during the nine months ended September 30, 2018.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes to the information set forth in our Annual Report on Form 10-K for the year ended December 31, 2017.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Principal Executive Officer and Chief Financial Officer has evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's ("SEC's") rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective at the reasonable assurance level as of September 30, 2018, due to the material weaknesses in internal control over financial reporting that is described below. Notwithstanding the material weaknesses, management has concluded that the Company's unaudited consolidated financial statements for the periods covered by and included in this quarterly report on Form 10-Q are fairly stated in all material respects in accordance with U.S. generally accepted accounting principles ("GAAP") for each of the periods presented herein.

Internal Control Over Financial Reporting

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. As previously disclosed in Item 9A of our Form 10-K for the year ended December 31, 2017, (i) due to budget constraints and limited financial resources, the Company's accounting department does not maintain the number of accounting personnel (either in-house or external) necessary to ensure more complete and effective financial reporting and disclosure controls and (ii) we incurred a loss of approximately $144,000 due to fraud from a cybersecurity breach. These control deficiencies did not result in a misstatement to our consolidated financial statements. However, these control deficiencies could have resulted in a material misstatement to our annual or interim consolidated financial statements that would not be prevented or detected. Accordingly, our management has determined that these control deficiencies constitute material weaknesses.

Remediation Plan and Activities

As we disclosed in our Item 9A of our Form 10-K for the year ended December 31, 2017, we developed remediation plans for the material weaknesses related to the inadequate number of accounting personnel (either in-house or external) necessary to ensure more complete and effective financial reporting and disclosure controls and the fraud from a cybersecurity breach. We hired a Chief Financial Officer and he started on September 1, 2018. We are still evaluating the level of our staffing, and due to the current limited number of employees and limited financial resources to hire required accounting and finance staff to implement more complete and effective financial reporting and disclosure controls, the Company was unable to remediate the related material weakness through the date this report on Form 10-Q was available to be issued. However, management, with participation and input from the board of directors, continue to monitor and provide oversight in the areas where material misstatements may occur to enable management to provide reasonable assurance that the Company's unaudited consolidated financial statements for the periods covered by and included in this quarterly report on Form 10-Q are fairly stated in all material respects in accordance with GAAP for each of the periods presented herein.

As we disclosed in our Item 9A of our Form 10-K for the year ended December 31, 2017, management and external consultants, with participation and input from the board of directors, has implemented security measures to alleviate the risk of a future cybersecurity breach during the nine months ended September 30, 2018. These measures included the implementation of certain review and approval procedures internally and with our banks and, IT system changes to enhance system access controls and limit the ability of hackers to gain access to internal systems to provide preventative and detective measures to safeguard Company assets.

We are committed to maintaining a strong internal control environment with our limited financial resources and we will continue to address internal and disclosure control weaknesses, in a cost-effective manner, as necessary, to improve the effectiveness of our internal and disclosure controls. The remediation plans developed that we have implemented and plan to implement are subject to ongoing senior management review, as well as board of directors' oversight. We will not be able to conclude whether the steps we are taking will fully remediate these material weaknesses in our internal control over financial reporting until we have completed our remediation efforts and subsequent evaluation of their effectiveness. We may also conclude that additional measures may be required to remediate the material weaknesses in our internal control over financial reporting, which may necessitate additional implementation and evaluation time. We will continue to assess the effectiveness of our internal control over financial reporting and take steps to remediate the known material weakness in a cost-effective manner.

Changes in Internal Control Over Financial Reporting

During the nine months ended September 30, 2018, we began to make changes in our internal control over financial reporting as noted above. Other than the remediation steps taken above, there were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Management recognizes that a control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or error, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are currently not a party to any material legal proceedings.

ITEM 1A. RISK FACTORS

Other than the additional risk factors disclosed below, there are no material changes to the Company's risk factors as described in Item 1A of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017.

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

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

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(a) Recent Sale of Unregistered Securities

We did not have any sales of unregistered securities during the three months ended September 30, 2018.

(b) Use of Proceeds from Public Offering of Common Stock

None.

(c) Issuer Purchases of Equity Securities

We did not repurchase any shares of our common stock during the three months ended September 30, 2018.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

SEC Ref. No.	Title of Document
10.1	Agreement dated May 25, 2018 by and between Processa Pharmaceuticals, Inc. and PoC Capital, LLC (incorporated by reference from Form 8-K filed June 1, 2018)
31.1*	Rule 153-14(a) Certification by Principal Executive Officer
31.2*	Rule 153-14(a) Certification by Principal Financial Officer
32.1*++	Section 1350 Certification of Principal Executive Officer and Principal Financial Officer
99.1	XBRL Files

* Filed herewith.

++ This certification is being furnished solely to accompany this Quarterly Report pursuant to 18 U.S.C. Section 1350 and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing herewith.

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 thereunto duly authorized.

PROCESSA PHARMACEUTICALS, INC.

By: */s/ David Young*
David Young
Chief Executive Officer
(Principal Executive Officer)
Dated: November 13, 2018

By: */s/ James Stanker*
James Stanker
Chief Financial Officer
(Principal Financial and Accounting Officer)
Dated: November 13, 2018

Exhibit 31.1

CERTIFICATIONS

I, David Young, Chief Executive Officer of PROCESSA PHARMACEUTICALS, INC. certify that:

1. I have reviewed this quarterly report on Form 10-Q of PROCESSA PHARMACEUTICALS, INC.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules13a-15(f) and 15d-15 (f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2018

By: */s/ David Young*
David Young
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, James Stanker, Chief Financial Officer of PROCESSA PHARMACEUTICALS, INC. certify that:

1. I have reviewed this quarterly report on Form 10-Q of PROCESSA PHARMACEUTICALS, INC.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules13a-15(f) and 15d-15 (f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2018

By: */s/ James Stanker*
James Stanker
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

Written Statement of the Chief Executive and Financial Officer Pursuant to 18 U.S.C. §1350

Solely for the purposes of complying with 18 U.S.C. §1350, I, the undersigned Chief Executive Officer of PROCESSA PHARMACEUTICALS, INC. (the "Company"), hereby certify, to the best of my knowledge, that the quarterly report on Form 10-Q of the Company for the quarter ended September 30, 2018 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This certification is being furnished solely to accompany this Report pursuant to 18 U.S.C. 1350 and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and is not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Date: November 13, 2018

By: */s/ David Young*
David Young
Chief Executive Officer
(Principal Executive Officer)

Solely for the purposes of complying with 18 U.S.C. §1350, I, the undersigned Chief Financial Officer of PROCESSA PHARMACEUTICALS, INC. (the "Company"), hereby certify, to the best of my knowledge, that the quarterly report on Form 10-Q of the Company for the quarter ended September 30, 2018 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This certification is being furnished solely to accompany this Report pursuant to 18 U.S.C. 1350 and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and is not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Date: November 13, 2018

By: */s/ James Stanker*
James Stanker
Chief Financial Officer
(Principal Financial and Accounting Officer)