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, 2019

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 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 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 38,404,530 shares of common stock outstanding as of November 5, 2019.

Securities registered pursuant to Section 12(b) of the Exchange Act: None.

PROCESSA PHARMACEUTICALS, INC.
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PART 1: FINANCIAL INFORMATION

ITEM 1: FINANCIAL STATEMENTS

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

	September 30, 2019	December 31, 2018
ASSETS		
Current Assets		
Cash and cash equivalents	$ 504,302	$ 1,740,961
Due from related party	663	21,583
Prepaid expenses and other	220,280	257,832
Total Current Assets	725,245	2,020,376
Property And Equipment		
Software	19,740	19,740
Office equipment	9,327	9,327
Total Cost	29,067	29,067
Less: accumulated depreciation	18,026	11,692
Property and equipment, net	11,041	17,375
Other Assets		
Operating lease right of use assets, net of accumulated amortization	238,186	-
Intangible assets, net of accumulated amortization	9,841,286	10,437,782
Security deposit	5,535	5,535
Total Other Assets	10,085,007	10,443,317
Total Assets	$ 10,821,293	$ 12,481,068
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Senior convertible notes	$ -	$ 230,000
Current maturities of operating lease liability	77,423	-
Accrued interest	-	20,343
Accounts payable	64,861	292,102
Due to related parties	25,727	-
Accrued expenses	123,670	103,259
Total Current Liabilities	291,681	645,704
Non-current Liabilities		
Noncurrent operating lease liability	166,739	-
Net deferred tax liability	1,692,194	2,134,346
Total Liabilities	2,150,614	2,780,050
COMMITMENTS AND CONTINGENCIES		
Stockholders' Equity		
Preferred stock, par value $0.0001, 1,000,000 and 10,000,000 shares authorized at September 30, 2019 and December 31, 2018, respectively; no shares issued and outstanding	-	-
Common stock, par value $0.0001, 100,000,000 and 350,000,000 shares authorized, respectively; 38,404,530 and 38,674,265 issued and outstanding at September 30, 2019 and December 31, 2018, respectively	3,840	3,867
Additional paid-in capital	18,874,406	19,121,285
Subscription receivable	-	(1,800,000)
Accumulated deficit	(10,207,567)	(7,624,134)
Total Stockholders' Equity	8,670,679	9,701,018
Total Liabilities and Stockholders' Equity	$ 10,821,293	$ 12,481,068

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

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

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

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

Processa Pharmaceuticals, Inc.
Condensed Consolidated Statement of Changes in Stockholders' Equity
Nine Months Ended September 30, 2019 and 2018
(Unaudited)

Nine Months Ended September 30, 2019

	Common Stock		Additional Paid-In	Subscription	Accumulated	
	Shares	Amount	Capital	Receivable	Deficit	Total
Balance, January 1, 2019	38,674,265	$ 3,867	$ 19,121,285	$ (1,800,000)	$ (7,624,134)	$ 9,701,018
Stock-based compensation	-	-	58,559	-	-	58,559
Payments made directly by investor for clinical trial costs	-	-	-	115,000	-	115,000
Net loss	-	-	-	-	(750,832)	(750,832)
Balance, March 31, 2019	38,674,265	3,867	19,179,844	(1,685,000)	(8,374,966)	9,123,745
Stock-based compensation	-	-	66,476	-	-	66,476
Payments made directly by investor for clinical trial costs	-	-	-	280,927	-	280,927
Net loss	-	-	-	-	(969,077)	(969,077)
Balance, June 30, 2019	38,674,265	3,867	19,246,320	(1,404,073)	(9,344,043)	8,502,071
Conversion of Senior convertible debt for common stock and stock purchase warrants	126,741	13	258,917	-	-	258,930
Payments made by investor for clinical trial costs	-	-	-	504,073	-	504,073
Pledged shares of common stock forfeited upon revised research funding commitment	(396,476)	(40)	(899,960)	900,000	-	-
Stock-based compensation	-	-	269,129	-	-	269,129
Net loss	-	-	-	-	(863,524)	(863,524)
Balance, September 30, 2019	38,404,530	$ 3,840	$ 18,874,406	$ -	$ (10,207,567)	$ 8,607,679

Nine Months Ended September 30, 2018

	Common Stock		Additional Paid-In	Subscription	Accumulated	
	Shares	Amount	Capital	Receivable	Deficit	Total
Balance, January 1, 2018	35,272,626	$ 3,527	$ 4,228,723	$ -	$ (3,859,086)	$ 373,164
Recognize the fair value of exclusive license intangible asset acquired from CoNCERT in exchange for 2,090,301 common shares of Processa held by Promet	-	-	8,000,000	-	-	8,000,000
Net loss	-	-	-	-	(1,096,798)	(1,096,798)
Balance, March 31, 2018	35,272,626	3,527	12,228,723	-	(4,955,884)	7,276,366
Conversion of Senior convertible notes for common stock and stock purchase warrants, net of costs of $4,742	1,206,245	121	2,390,248	-	-	2,390,369
Issuance of common stock units for cash, net of costs of $218,422	1,402,442	140	2,964,955	-	-	2,965,095
Issuance of common stock units for a future research funding commitment, net of costs of $117,339	792,952	79	1,682,582	(1,800,000)	-	(117,339)
Net loss	-	-	-	-	(1,206,255)	(1,206,255)
Balance, June 30, 2018	38,674,265	3,867	19,266,508	(1,800,000)	(6,162,139)	11,308,236
Stock-based compensation	-	-	50,528	-	-	50,528
Net loss	-	-	-	-	(852,822)	(852,822)
Balance, September 30, 2018	38,674,265	$ 3,867	$ 19,317,036	$ (1,800,000)	$ (7,014,961)	$ 10,505,942

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

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

	Nine Months Ended September 30,	
	2019	2018
Cash Flows From Operating Activities		
Net loss	$ (2,583,433)	$ (3,155,874)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	6,334	6,334
Amortization of right-of-use assets	55,012	-
Amortization of debt issuance costs	-	64,841
Amortization of intangible asset	596,496	422,814
Deferred income tax benefit	(442,152)	(771,332)
Stock-based compensation	394,164	50,528
Payments made by an investor in satisfaction of their stock subscription receivable	900,000	-
Net changes in operating assets and liabilities:		
Prepaid expenses	37,552	(240,872)
Operating lease liability	(58,999)	-
Accrued interest	8,587	89,522
Accounts payable	(227,241)	29,334
Due (from)/to related parties	46,647	(32,393)
Accrued expenses	30,374	293,160
Net cash used in operating activities	(1,236,659)	(3,243,938)
Cash Flows From Investing Activities		
Purchase of intangible asset	-	(1,782)
Purchase of software license	-	(20,500)
Net cash used in investing activities	-	(22,282)
Cash Flows From Financing Activities		
Net proceeds from issuance of common stock	-	2,965,095
Transaction costs incurred on Senior Convertible Notes	-	(4,742)
Payment of placement agent and legal fees associated with clinical funding commitment	-	(117,339)
Net cash provided by financing activities	-	2,843,014
Net (Decrease)/Increase in Cash and Cash Equivalents	(1,236,659)	(423,206)
Cash and Cash Equivalents – Beginning of Period	1,740,961	2,847,429
Cash and Cash Equivalents – End of Period	$ 504,302	$ 2,424,223

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

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

	Nine Months Ended September 30, 2019	
	2019	2018
Non-Cash Investing and Financing Activities:		
Right-of-use asset obtained in exchange for operating lease liability	$ (293,198)	$ -
Reduction in deferred lease liability	(9,963)	-
Operating lease liability	303,161	-
Recognize the exclusive license intangible asset acquired from CoNCERT	-	(11,037,147)
Recognize deferred tax liability for basis difference for Intangible asset	-	3,037,147
Recognize additional paid-in capital for consideration paid from the transfer of 2,090,301 common shares of Processa released by Promet to CoNCERT for Processa	-	8,000,000
Net	$ -	$ -
Conversion of $230,000 and $2,350,000 (respectively) of Senior Convertible Debt and related accrued interest into 126,741 and 1,206,245 shares (respectively) of common stock and warrants	$ 258,930	$ 2,395,111
Common stock and stock purchase warrants (forfeited) issued in connection with a clinical trial funding commitment	$ (900,000)	$ 1,800,000

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

Note 1 – Organization and Summary of Significant Accounting Policies

Business Activities and Organization

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

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

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

The degeneration of tissue occurring at the NL lesion site is caused by a number of pathophysiological changes, which has made it extremely difficult to develop effective treatments for this condition. PCS-499 may provide a solution since PCS-499 and its metabolites affect a number of biological pathways, several of which contribute to the pathophysiology associated with NL. We will be issuing a press release in the coming weeks with the interim data from the Phase 2 clinical trial.

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

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

Basis of Presentation

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

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

Going Concern and Management's Plans

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

We have relied exclusively on private placements with a small group of accredited investors to finance our business and operations. As described in more detail below, we recently entered into two line of credit agreements providing a revolving commitment of an aggregate up to $1.4 million but have not drawn any amounts as of the date of this report. We have not had any revenue since our inception. We are looking at ways to add a revenue stream to offset some of our expenses but do not currently have any revenue under contract or any immediate sales prospects. During the nine months ended September 30, 2019, we had an accumulated deficit of $10.2 million, incurred a net loss of $2.6 million and used $1.2 million in net cash from operating activities from continuing operations. At September 30, 2019, we had cash and cash equivalents totaling $504,302. During the nine months ended September 30, 2019, PoC Capital (our clinical trial funding commitment investor) made payments directly to our CRO totaling $689,168 for amounts invoiced. PoC Capital also repaid us $210,832 for clinical trial expenses we previously paid to our CRO, $180,119 of which is included in Prepaid and Other on our condensed consolidated balance sheet at September 30, 2019.

On September 20, 2019, we entered into two separate Line of Credit Agreements ("LOC Agreements") with DKBK Enterprises, LLC ("DKBK") and current shareholder CorLyst, LLC ("CorLyst"), both related parties ("Lenders"), which provide a revolving commitment of up to $700,000 each ($1.4 million total). Under the LOC Agreements, all funds borrowed will bear an 8% annual interest rate. The lenders have the right to convert all or any portion of the debt and interest into shares of our common stock at a conversion price equal to the lower of (i) $2.04 per share (ii) a price per share equal to a 10% discount to the pre-money valuation of a Qualified Financing or an Equity State Transaction or (iii) at an adjusted price; all as defined in the 8% Senior Note agreement. The lenders will also receive stock purchase warrants on a 1:1 basis to the number of shares of common stock received that have an exercise price equal to the greater of (i) the closing price of our common stock on the date of conversion or (ii) $2.72 per share. Our Chief Executive Officer (CEO) is also the Chief Executive Officer and Managing Member of both Lenders. CorLyst beneficially owns 6,859,527 shares of Processa common stock, representing approximately 17.7% of the Company's outstanding shares of voting capital stock. We have not drawn any amounts under these LOC agreements.

In connection with the LOC Agreements, we amended the existing pledge agreement with PoC Capital on September 30, 2019 to reduce the committed funds from $1.8 million to $900,000, which has now been paid in full. As part of the original pledge agreement, we issued 792,952 shares of common stock and 792,952 warrants to purchase shares of common stock to PoC Capital but held 396,476 shares and 396,476 warrants as collateral until certain payment milestones were met. PoC Capital forfeited the pledged collateral in the amended agreement and the shares have been reissued to Processa and will be retired.

We are currently in the process of raising additional funds through the private sale of 8% Senior Convertible Notes ("8% Senior Notes") to accredited investors. As of November 5, 2019, $745,000 from the sale of 8% Senior Notes to both new and existing investors has been received in escrow. We have not recorded these amounts in the accompanying condensed consolidated financial statements at September 30, 2019 since these investors, in connection with the revision of our agreement with PoC Capital and our entering into the LOC agreements, had the opportunity through October 18, 2019 to rescind their investment. No investors indicated their plan to rescind any investment and we plan to close the escrow account in the fourth quarter of 2019, at which time we will record the proceeds. We have also delayed some of our cash outflows, primarily through the deferred payment of salaries ($48,840 has been accrued and included in accrued expenses during the three and nine months ended September 30, 2019) until such time as we have raised sufficient funding.

Based on our current plan, we likely need to raise additional capital to fund our future operations. While we believe our current resources are adequate to complete our current Phase 2a trial for NL, we do not currently have resources to conduct other future trials or develop HT-100 without raising additional capital. As noted above, the timing and extent of our spending will depend on the costs associated with, and the results of our Phase 2a trial for NL. Our anticipated spending and our cash flow needs could change significantly as the trial progresses. There may be costs we incur during our trial that we do not currently anticipate in order to complete the trial, requiring us to need additional capital sooner than currently expected.

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

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

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

Use of Estimates

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

Intangible Assets

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

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

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

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

Impairment of Long-Lived Assets and Intangibles Other Than Goodwill

We account for the impairment of long-lived assets in accordance with ASC 360, *Property, Plant and Equipment* and ASC 350, *Intangibles – Goodwill and Other,* which require that long-lived assets and certain identifiable intangibles be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to its expected future undiscounted net cash flows generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amounts of the assets exceed the fair value of the assets based on the present value of the expected future cash flows associated with the use of the asset. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. Based on management's evaluation, there was no impairment loss recorded during the nine months ended September 30, 2019.

Stock-based Compensation

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

Net Loss Per Share

Basic loss per share is computed by dividing our net loss available to common shareholders by the weighted average number of shares of common stock outstanding during the period. Diluted loss per share is computed by dividing our net loss available to common shareholders by the diluted weighted average number of shares of common stock during the period. Since we experienced a net loss for all periods presented, basic and diluted net loss per share are the same. As such, diluted loss per share for the three and nine months ended September 30, 2019 and 2018 excludes the impact of potentially dilutive common shares related to outstanding stock options and warrants and the conversion of our Senior Convertible Notes since those shares would have an anti-dilutive effect on loss per share.

Research and Development

Research and development costs are expensed as incurred and consisted of direct and overhead-related expenses.

Recently Adopted Accounting Pronouncements

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

The adoption of the new guidance did not have a material impact on the condensed consolidated statement of operations. For further details regarding the adoption of this standard, see Note 9, "Operating Leases."

Note 2 – Intangible Assets

Intangible assets at September 30, 2019 and December 31, 2018 consisted of the following:

	September 30, 2019	December 31, 2018
Gross intangible assets	$ 11,059,429	$ 11,059,429
Less: Accumulated amortization	(1,218,143)	(621,647)
Total intangible assets, net	$ 9,841,286	$ 10,437,782

Amortization expense was $198,832 and $200,256 for the three months ended September 30, 2019 and 2018, respectively, and $596,496 and $422,814 for the nine months ended September 30, 2019 and 2018, respectively. This expense is included within research and development expense in the accompanying condensed consolidated statements of operations. Our estimated amortization expense for the next year will be approximately $795,000 and approximately $788,000 per year for annual periods thereafter.

The capitalized costs for the license rights to PCS-499 included the $8 million purchase price, $1,782 in transaction costs and $3,037,147 associated with the initial recognition of an offsetting deferred tax liability related to the acquired temporary difference for an asset purchased that is not a business combination and has a tax basis of $1,782 in accordance with ASC 740-10-25-51 *Income Taxes.* In accordance with ASC Topic 730, *Research and Development*, we capitalized the costs of acquiring the exclusive license rights to PCS-499, as the exclusive license rights represent intangible assets to be used in research and development activities that management believes has future alternative uses.

Note 3 – Income Taxes

We account for income taxes in accordance with ASC Topic 740, *Income Taxes.* Deferred income taxes are recorded for the expected tax consequences of temporary differences between the tax basis of assets and liabilities for financial reporting purposes and amounts recognized for income tax purposes. As of September 30, 2019, and December 31, 2018, we recorded a valuation allowance equal to the full recorded amount of our net deferred tax assets related to deferred start-up costs and other minor temporary differences since it is more-likely-than-not that such benefits will not be realized. The valuation allowance is reviewed quarterly and is maintained until sufficient positive evidence exists to support its reversal.

A deferred tax liability was recorded on March 19, 2018 when Processa received CoNCERT's license and "Know-How" in exchange for Processa stock that had been issued in an Internal Revenue Code Section 351 Transaction. The Section 351 Transaction treats the acquisition of the license and Know-How for stock as a tax-free exchange. As a result, under ASC 740-10-25-51 *Income Taxes*, Processa recorded a deferred tax liability of $3,037,147 for the acquired temporary difference between intangible assets (see Note 2) for the financial reporting basis of $11,038,929 and the tax basis of $1,782. The deferred tax liability will be reduced for the effect of non-deductibility of the amortization of the intangible asset and may be offset by the deferred tax assets resulting from net operating tax losses.

Under ACS 740-270 *Income Taxes – Interim Reporting*, we are required to project our annual federal and state effective income tax rate and apply it to the year to date ordinary operating tax basis loss before income taxes. Based on the projection, we expect to recognize the tax benefit from our projected ordinary tax loss, which can be used to offset the deferred tax liabilities related to the intangible assets and resulted in the recognition of a deferred tax benefit shown in the condensed consolidated statements of operations for three and nine months ended September 30, 2019 and 2018. No current income tax expense is expected for the foreseeable future as we expect to generate net operating tax losses.

Note 4 - Stock-based Compensation

On June 20, 2019, our Board of Directors granted stock options for the purchase of 909,230 shares of our common stock to employees. The stock options awarded contained either service or performance vesting conditions, as described below, have a contractual term of five years and an exercise price equal to the closing price of our common stock on the OTCQB on the date of grant of $2.40. We granted 334,400 stock options to employees and non-employees during the nine months ended September 30, 2018.

Stock options representing the purchase of 456,000 shares of common stock (of the 909,230 stock options granted on June 20, 2019) contained service vesting conditions. The service condition related solely to employees rendering service over a three-year period. These awards vest one-third on the first anniversary of the grant date, and then vest ratably over the remaining twenty-four months, $1/36^{th}$ of the original award each month.

Stock options representing the purchase of 453,230 shares of common stock (of the 909,230 stock options granted on June 20, 2019) vest upon meeting the following performance criteria: (i) 90,646 shares vest when we in-license one new or additional drug; (ii) 90,646 shares vest when our current Phase 2a clinical trial for PCS-499 is complete; and (iii) 271,938 shares vest when we up-list from the OTCQB to either the Nasdaq or NYSE markets. As of September 30, 2019, we are recognizing compensation cost for the awards related to completion of our current clinical trial and for in-licensing a new drug. The clinical trial is progressing as planned with no significant adverse events, is fully enrolled, and fully funded. Management does not foresee any reasons why this study will not be completed as planned and believes it is probable that this performance condition will be met in mid-2020. On August 29, 2019, we reached a license agreement with Akashi Therapeutics for HT-100 and as such, the performance condition related to the award for in-licensing one new or additional drug has been met. As for the last award with performance conditions related to up-listing on Nasdaq or NYSE markets, management has determined that until we complete the performance related condition, it is not probable to conclude the performance condition will be achieved. As such, no stock-based compensation expense is being recorded for those awards.

We had outstanding options to purchase 334,400 and 1,293,630 shares of our common stock at September 30, 2018 and 2019, respectively, of which options for the purchase of 187,746 shares of our common stock have been vested. We recorded $50,528 and $269,129 for the three months ended September 30, 2018 and 2019, respectively, and $50,528 and $394,164 of stock-based compensation expense for the nine months ended September 30, 2018 and 2019, respectively. The allocation of stock-based compensation expense between research and development and general and administrative expense was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and Development	$ 88,707	$ -	$ 92,111	$ -
General and Administrative	180,422	50,528	302,053	50,528
	$ 269,129	$ 50,528	$ 394,164	$ 50,528

Note 5 – Debt

Line of Credit Agreements

On September 20, 2019, we entered into two separate Line of Credit Agreements ("LOC Agreements") with DKBK Enterprises, LLC ("DKBK") and current shareholder CorLyst, LLC ("CorLyst"), both related parties ("Lenders"), which provide a revolving commitment of up to $700,000 each ($1.4 million total). Under the LOC Agreements, all funds borrowed will bear an 8% annual interest rate. The lenders have the right to convert all or any portion of the debt and interest into shares of our common stock at a conversion price equal to the lower of (i) $2.04 per share, (ii) a price per share equal to a 10% discount to the pre-money valuation of a Qualified Financing or an Equity State Transaction, or (iii) at an adjusted price; all as defined in the 8% Senior Note agreement. The lenders will also receive stock purchase warrants on a 1:1 basis to the number of shares of common stock received that have an exercise price equal to the greater of (i) the closing price of our common stock on the date of conversion or (ii) $2.72 per share. Our Chief Executive Officer (CEO) is also the Chief Executive Officer and Managing Member of both Lenders. CorLyst beneficially owns 6,859,527 shares of Processa common stock, representing approximately 17.7% of the Company's outstanding shares of voting capital stock.

We have not drawn any amounts under these LOC agreements.

Senior Convertible Notes

At September 30, 2019 and December 31, 2018, we had $0 and $230,000 of Senior Convertible Notes outstanding. The $230,000 outstanding at December 31, 2018 were held by Canadian investors that, although qualifying for automatic and mandatory conversion, could not be converted until the Alberta Securities Commission released us from a cease trade order, which predated our merger with HeatWurx, and permitted us to issue common stock units (consisting of shares of our common stock and stock purchase warrants) to these Canadian investors. In June 2019, the Alberta Securities Commission released the cease trade order and assessed us a $10,000 fine, which was expensed. On July 2, 2019, we converted the principal and related accrued interest of $258,930 into 126,741 shares of common stock and 126,741 stock purchase warrants.

We are currently in the process of raising additional funds through the private sale of 8% Senior Convertible Notes ("8% Senior Notes") to accredited investors. As of November 5, 2019, we have received into escrow $745,000 from the sale of 8% Senior Notes. We have not recorded these amounts in the accompanying condensed consolidated financial statements at September 30, 2019 since these investors, in connection with the revision of our agreement with PoC Capital and our entering into the LOC agreements, had the opportunity through October 18, 2019 to rescind their investment. No investors indicated their plan to rescind any investment and we plan to close the escrow account in the fourth quarter of 2019, at which time we will record the proceeds.

Note 6 – License Agreement for HT-100

As described in Note 1 – Business Activities and Organization, on August 29, 2019, we entered into an exclusive license agreement with Akashi to develop and commercialize an anti-fibrotic, anti-inflammatory drug, HT-100. As partial consideration for the licenses, we paid $10,000 to Akashi upon full execution of the license agreement. This upfront payment was expensed as a research and development cost. As additional consideration, we will pay Akashi up to $12 million over the period of achieving certain future development and regulatory milestones related to the drug. The expense related to these milestone payments will be recorded as research and development expense over the period from when achieving the milestone is probable to when the milestone is actually achieved. The agreement also contains provisions for sales milestone payments and royalty payments.

Note 7 – Stockholders' Equity

During the nine months ended September 30, 2019 and 2018, there were no sales of our preferred stock. At September 30, 2019 and December 31, 2018, there were no issued or outstanding shares of preferred stock. During the nine months ended September 30, 2019, PoC Capital (our clinical trial funding commitment investor), made payments directly to our CRO totaling $689,168 for amounts invoiced. PoC Capital also repaid us $210,832 for clinical trial expenses we previously paid to our CRO, $180,119 of which is included in Prepaid and Other on our condensed consolidated balance sheet at September 30, 2019. As explained in Note 1 – Going Concern, we amended the existing pledge agreement with PoC Capital on September 30, 2019 to reduce the committed funds from $1.8 million to $900,000, which has now been paid in full. As part of the original pledge agreement, we issued 792,952 shares of common stock and 792,952 warrants to purchase shares of common stock to PoC Capital but held 396,476 shares and 396,476 warrants as collateral until certain payment milestones were met. PoC Capital forfeited the pledged collateral in the amended agreement and the shares have been reissued to Processa and will be retired.

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

Note 8 – Net Loss per Share of Common Stock

Basic net loss per share is computed by dividing net loss by the weighted average common shares outstanding. Diluted net loss per share is computed by dividing net loss by the weighted average common shares outstanding, which includes potentially dilutive effect of stock options, warrants and senior convertible notes. Since we experienced a loss for all periods presented, including any dilutive common shares outstanding would have an anti-dilutive impact on diluted net loss per share, and as shown below, were excluded from the computation. The treasury-stock method is used to determine the dilutive effect of our stock options and warrants grants, and the if-converted method is used to determine the dilutive effect of the Senior Notes.

The computation of net loss per share for the three and nine months ended September 30, 2019 and 2018 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Basic and diluted net loss per share:				
Net loss from continuing operations	$ (863,524)	(852,822)	$ (2,583,433)	$ (3,155,874)
Weighted average number of common shares-basic and diluted	38,798,251	38,674,265	38,716,048	36,869,323
Basic and diluted net loss per share	$ (0.02)	$ (0.02)	$ (0.07)	$ (0.09)

The following potentially dilutive securities were excluded from the computation of diluted net income per share as their effect would have been anti-dilutive for the periods presented.

	September 30, 2019	December 31, 2018
Stock options and purchase warrants	4,636,682	3,997,187
Senior convertible notes and related accrued interest	-	122,717

Note 9 - Operating Leases

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

Lease costs included in our condensed consolidated statement of operations totaled $73,621 and $66,712 for the nine months ended September 30, 2019 and 2018, respectively. The weighted average remaining lease terms and discount rate for our operating leases were as follows at September 30, 2019:

Weighted average remaining lease term (years) for our facility and equipment leases	2.6
Weighted average discount rate for our facility and equipment leases	8%

Maturities of our lease liabilities for all operating leases were as follows as of September 30, 2019:

2019	$	23,396
2020		92,603
2021		90,495
2022		69,741
Total lease payments		276,235
Less: Interest		(32,073)
Present value of lease liabilities		244,162
Less: current maturities		(77,423)
Non-current lease liability	$	166,739

Note 10 – Related Party Transactions

A shareholder, CorLyst, LLC, reimburses us for shared costs related to payroll, health care insurance and rent based on actual costs incurred, which are recognized as a reduction of our general and administrative operating expenses being reimbursed in our condensed consolidated statements of operations. Reimbursable expenses from CorLyst totaled $79,058 and $80,447 for rent and other costs during the nine months ended September 30, 2019 and 2018, respectively. In August 2019, CorLyst prepaid us for Q3 and Q4 shared expenses. At September 30, 2019, we recognize $25,727 in prepaid reimbursements as due to related parties in the accompanying condensed consolidated balance sheet. Amounts due from CorLyst at September 30, 2019 and December 31, 2018 were $0 and $21,583, respectively.

As described further in Note 1 – Going Concern, we also entered into two separate Line of Credit Agreements with CorLyst, LLC and DKBK Enterprises, LLC, both related parties, on September 20, 2019.

Note 11 – Commitments and Contingencies

Purchase Obligations

We enter into contracts in the normal course of business with contract research organizations and subcontractors to further develop our products. The contracts are cancellable, with varying provisions regarding termination. If a contract with a specific vendor were to be terminated, we would only be obligated for products or services that we received as of the effective date of the termination and any applicable cancellation fees. We had a purchase obligation of approximately $16,000 and $35,000 at September 30, 2019 and December 31, 2018, respectively.

Note 12 – Subsequent Events

Senior Convertible Notes

As of November 5, 2019, we have received into escrow $745,000 from the sale of 8% Senior Convertible Notes (8% Senior Notes). We have not recorded these amounts in the accompanying condensed consolidated financial statements at September 30, 2019 since these investors, in connection with the revision of our agreement with PoC Capital and our entering into the LOC agreements, had the opportunity through October 18, 2019 to rescind their investment. No investors indicated their plan to rescind any investment and we plan to close the escrow account in the fourth quarter of 2019, at which time we will record the proceeds.

Upon completion of listing our common stock on either the Nasdaq Capital Market or the New York Stock Exchange, our 8% Senior Notes are mandatorily convertible into shares of our common stock at a conversion price equal to the lower of (i) $2.04 per share or (ii) a price per share equal to a 10% discount to the pre-money valuation of a Qualified Financing or an Equity State Transaction, both as defined in the 8% Senior Note agreement, occurring after the closing of the 8% Senior Note financing. Upon maturity (December 15, 2020), the 8% Senior Note holders have the option to convert the 8% Senior Note into shares of our common stock at the lower of $2.04 per share or an adjusted price as set forth in the 8% Senior Note agreement. Upon either mandatory conversion or conversion at the holder's option, the holder will also receive stock purchase warrants on a 1:1 basis to the number of shares of common stock received that have an exercise price equal to the greater of (i) the closing price of our common stock on the date of conversion or (ii) $2.72 per share.

Reverse Stock Split

On October 31, 2019, our Board of Directors authorized management to effect a reverse stock split of our common stock in a ratio between four for one share to ten to one share, subject to regulatory approval and at the discretion of the Board of Directors. The accompanying condensed consolidated financial statements have not been adjusted to reflect the effect of any future reverse stock split.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operation

Forward Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" that reflect, when made, the Company's expectations or beliefs concerning future events that involve risks and uncertainties. Forward-looking statements frequently are identified by the words "believe," "anticipate," "expect," "estimate," "intend," "project," "will be," "will continue," "will likely result," or other similar words and phrases. Similarly, statements herein that describe the Company's objectives, plans or goals also are forward-looking statements. Actual results could differ materially from those projected, implied or anticipated by the Company's forward-looking statements. Some of the factors that could cause actual results to differ include: our limited operating history, limited cash and history of losses; our ability to achieve profitability; our ability to obtain adequate financing to fund our business operations in the future; our ability to secure required FDA or other governmental approvals for our product candidates and the breadth of the indication sought; the impact of competitive or alternative products, technologies and pricing; whether we are successful in developing and commercializing our technology, including through licensing; the adequacy of protections afforded to us and/or our licensor by the anticipated patents that we own or license and the cost to us of maintaining, enforcing and defending those patents; our and our licensor's ability to protect non-patented intellectual property rights; our exposure to and ability to defend third-party claims and challenges to our and our licensor's anticipated patents and other intellectual property rights; and our ability to continue as a going concern. For a discussion of these and all other known risks and uncertainties that could cause actual results to differ from those contained in the forward-looking statements, see "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2018, as amended, which is available on the SEC's website at www.sec.gov. All forward-looking statements are qualified in their entirety by this cautionary statement, and the Company undertakes no obligation to revise or update this Quarterly Report on Form 10-Q to reflect events or circumstances after the date hereof.

For purposes of this Management's Discussion and Analysis of Financial Condition and Results of Operations, references to the "Company," "we," "us" or "our" refer to the operations of Processa Pharmaceuticals, Inc. and its direct and indirect subsidiaries for the periods described herein.

Overview

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

On October 4, 2017, we acquired all the net assets of Promet Therapeutics, LLC ("Promet"), a private Delaware limited liability company, including the rights to the CoNCERT Agreement in exchange for 31,745,242 shares of our common stock. Immediately following the transaction, the former equity holders of Promet owned approximately 84% and held approximately 6% of the shares for the benefit of CoNCERT in relation to the CoNCERT contribution of the license to Processa as part of the Section 351 transaction, and our stockholders immediately prior to the transaction owned approximately 10% of our common stock. We traded on the OTC Pink Marketplace until December 8, 2018 when we listed our common stock on the OTCQB.

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

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

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

Going Concern and Management's Plan

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

We have relied exclusively on private placements with a small group of accredited investors to finance our business and operations. As described in more detail below, we recently entered into two line of credit agreements providing a revolving commitment of an aggregate of up to $1.4 million but have not drawn any amounts as of the date of this report. We have not had any revenue since our inception and we do not currently have any revenue under contract or any immediate sales prospects. For the nine months ended September 30, 2019, we incurred a net loss from continuing operations of $2.6 million and used $1.2 million in net cash from operating activities. We expect our operating costs to be substantial as we incur costs related to the clinical trials for our product candidates and that we will operate at a loss for the foreseeable future. At September 30, 2019, we had cash and cash equivalents totaling $504,302. During the nine months ended September 30, 2019, PoC Capital made payments directly to our CRO totaling $689,168 for amounts invoiced. PoC Capital also repaid us $210,832 for clinical trial expenses we previously paid to our CRO, $180,119 of which is included in Prepaid and Other on our condensed consolidated balance sheet at September 30, 2019.

On September 20, 2019, we entered into two separate Line of Credit Agreements ("LOC Agreements") with DKBK Enterprises, LLC ("DKBK") and current shareholder CorLyst, LLC ("CorLyst"), both related parties ("Lenders"), which provide a revolving commitment of up to $700,000 each ($1.4 million total). Under the LOC Agreements, all funds borrowed will bear an 8% annual interest rate. The lenders have the right to convert all or any portion of the debt and interest into Processa common shares. Our Chief Executive Officer (CEO) is also the Chief Executive Officer and Managing Member of both Lenders. CorLyst beneficially owns 6,859,257 shares of Processa common stock, representing approximately 17.7% of the Company's outstanding shares of voting capital stock. We have not drawn any amounts under these LOC agreements.

In connection with the LOC Agreements, we amended the existing pledge agreement with PoC Capital on September 30, 2019 to reduce the committed funds from $1.8 million to $900,000, which has now been paid in full. As part of the original pledge agreement, we issued 792,952 shares of common stock and 792,952 warrants to purchase shares of common stock to PoC Capital but held 396,476 shares and 396,476 warrants as collateral until certain payment milestones were met. PoC Capital forfeited the pledged collateral in the amended agreement and the shares have been reissued to Processa and will be retired.

We are currently in the process of raising additional funds through the private sale of 8% Senior Convertible Notes ("8% Senior Notes") to accredited investors. As of November 5, 2019, we have received into escrow $745,000 from the sale of 8% Senior Notes. We have not recorded these amounts in the accompanying condensed consolidated financial statements at September 30, 2019 since these investors, in connection with the revision of our agreement with PoC Capital and our entering into the LOC agreements, had the opportunity through October 18, 2019 to rescind their investment. No investors indicated their plan to rescind any investment and we plan to close the escrow account in the fourth quarter of 2019, at which time we will record the proceeds. We have also delayed some of our cash outflows, primarily through the deferred payment of salaries ($48,840 has been accrued and included in accrued expenses during the three and nine months ended September 30, 2019) until such time as we have raised sufficient funding.

We are looking at ways to add an additional revenue stream to offset some of our expenses. We will likely need to raise additional funds, 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 on acceptable terms, or at all, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates, restrict our operations or obtain funds by entering into agreements on unattractive terms, which would likely have a material adverse effect on our business, stock price, and our relationships with third parties with whom we have business relationships, at least until additional funding is obtained.

As a result, substantial doubt existed about our ability to continue as a going concern as of the date of the filing of this quarterly report on Form 10-Q for the quarter ended September 30, 2019. The accompanying condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of recorded assets, or the amounts and classification of liabilities that might be different should the Company be unable to continue as a going concern based on the outcome of these uncertainties described above.

Status of our Phase 2a Clinical Trial in Necrobiosis Lipoidica

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

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

The degeneration of tissue occurring at the NL lesion site is caused by a number of pathophysiological changes, which has made it extremely difficult to develop effective treatments for this condition. PCS-499 may provide a solution since PCS-499 and its metabolites affect a number of biological pathways, several of which contribute to the pathophysiology associated with NL. We will be issuing a press release in the coming weeks with the interim data from the Phase 2 clinical trial.

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

License Agreement for HT-100

On August 29, 2019, we entered into an exclusive license agreement with Akashi Therapeutics, Inc. (“Akashi”) to develop and commercialize an anti-fibrotic, anti-inflammatory drug, HT-100. As partial consideration for the licenses, we paid $10,000 to Akashi upon full execution of the license agreement. This upfront payment was expensed as a research and development cost. As additional consideration, we will pay Akashi development and regulatory milestone payments when we or our affiliate begin developing HT-100, as described in Note 6 – License Agreement for HT-100.

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

Results of Operations

Comparison of the three and nine months ended September 30, 2019 and 2018

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

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

Revenues.

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

Research and Development Expenses.

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

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

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

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

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

During the year ended December 31, 2018, we made payments to our CRO related to our Phase 2a trial of approximately $239,000. We have accounted for these payments as either a prepaid expense or a research and development expense depending on whether the related service has been provided. During the nine months ended September 30, 2019, PoC Capital made payments directly to our CRO totaling $689,168 for amounts invoiced. PoC Capital also repaid us $210,832 for clinical trial expenses we previously paid to our CRO, $180,119 of which is included in Prepaid and Other on our condensed consolidated balance sheet at September 30, 2019. we amended the existing pledge agreement with PoC Capital on September 30, 2019 to reduce the committed funds from $1.8 million to $900,000, which has now been paid in full. As part of the original pledge agreement, we issued 792,952 shares of common stock and 792,952 warrants to purchase shares of common stock to PoC Capital but held 396,476 shares and 396,476 warrants as collateral until certain payment milestones were met. PoC Capital forfeited the pledged collateral in the amended agreement and the shares have been reissued to Processa and will be retired.

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

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

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

General and Administrative Expenses.

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

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

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

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

Interest Expense.

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

Interest Income.

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

Income Tax Benefit.

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

Financial Condition

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

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

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

We had $0 and $230,000 of Senior Convertible Notes outstanding at September 30, 2019 and 2018, respectively. The Senior Convertible Notes outstanding at September 30, 2018 were held by Canadian investors that, although qualifying for automatic and mandatory conversion, could not be converted until the Alberta Securities Commission released us from a cease trade order, which predated our merger with HeatWurx, and permitted us to issue common stock units (consisting of shares of our common stock and stock purchase warrants) to these Canadian investors. In June 2019, the Alberta Securities Commission released the cease trade order and assessed us a $10,000 fine. On July 2, 2019, we converted the principal and related accrued interest of approximately $259,000 into 126,741 shares of common stock and 126,741 stock purchase warrants.

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

Liquidity and Capital Resources

To date, we have funded our business and operations primarily through the private placement of equity securities and senior secured convertible notes. We are currently in the process of raising additional funds through the private sale of 8% Senior Convertible Notes (“8% Senior Notes”) to accredited investors. As of November 5, 2019, we have received into escrow $745,000 from the sale of 8% Senior Notes. We have not recorded these amounts in the accompanying condensed consolidated financial statements at September 30, 2019 since these investors, in connection with the revision of our agreement with PoC Capital and our entering into the LOC agreements, had the opportunity through October 18, 2019 to rescind their investment. No investors indicated their plan to rescind any investment and we plan to close the escrow account in the fourth quarter of 2019, at which time we will record the proceeds. We have also delayed some of our cash outflows, primarily through the deferred payment of salaries ($48,840 has been accrued and included in accrued expenses during the three and nine months ended September 30, 2019) until such time as we have raised sufficient funding.

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

On September 20, 2019, we entered into two separate Line of Credit Agreements (“LOC Agreements”) with DKBK Enterprises, LLC (“DKBK”) and current shareholder CorLyst, LLC (“CorLyst”), both related parties (“Lenders”), which provide a revolving commitment of up to $700,000 each ($1.4 million total). Under the LOC Agreements, all funds borrowed will bear an 8% annual interest rate. Our Chief Executive Officer (CEO) is also the Chief Executive Officer and Managing Member of both Lenders. CorLyst beneficially owns 6,859,527 shares of Processa common stock, representing approximately 17.7% of the Company’s outstanding shares of voting capital stock. We have not drawn any amounts under these LOC Agreements.

In connection with the LOC Agreements, we amended the existing pledge agreement with PoC Capital on September 30, 2019 to reduce the amount committed from $1.8 million to $900,000, which has now been paid in full. As part of the original pledge agreement, we issued 792,952 shares of common stock and 792,952 warrants to purchase shares of common stock to PoC Capital but held 396,476 shares and 396,476 warrants as collateral until certain payment milestones were met. PoC Capital forfeited the pledged collateral in the amended agreement. We anticipate the total cost to fund our current Phase 2a clinical trial of PCS-499 for patients with NL to be between $1.5 to $1.6 million. We will cover the remaining $600,000 to $700,000 with funds received from the sale of our 8% Senior Notes and our LOC Agreements, as necessary.

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, HT-100 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, our available resources, the LOC Agreements and the outcome of the additional 8% Senior Notes funding, we will likely need to raise additional capital in order to fund our future operations. While we believe our current resources are adequate to complete our Phase 2a trial, we do not currently have resources to conduct other future trials or to develop HT-100 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 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 in order to complete our current trial, requiring us to need additional capital sooner than currently expected.

Additional funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend our current or future clinical trials or research and development programs. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. To the extent that we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we 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.

As a result, substantial doubt exists about our ability to continue as a going concern within one year after the date that this Form 10-Q is filed with the SEC.

Cash Flows

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

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

Net cash used in operating activities

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

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

Net cash used in investing activities

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

Net cash provided by financing activities

We had no cash sources or uses for financing activities during the nine months ended September 30, 2019. Net cash provided from financing activities was approximately $2.8 million for the nine months ended September 30, 2018. We expect that we will continue to seek additional capital through a combination of private and public equity offerings, debt financings, and strategic collaborations to fund future operations. However, no assurance can be given that we will be successful in raising adequate funds needed. Absent additional financing, substantial doubt exists about our ability to continue as a going concern, as noted under “Going Concern” above.

Contractual Obligations and Commitments

There have been no significant changes to the contractual obligations reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

Off Balance Sheet Arrangements

At September 30, 2019, we did not have any off-balance sheet arrangements.

Critical Accounting Policies and Use of Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our Unaudited Condensed Consolidated Financial Statements, which have been prepared in accordance with U.S. GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities.

We believe that the estimates, assumptions and judgments involved in the accounting policies described in the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of our most recent Annual Report on Form 10-K have the greatest potential impact on our financial statements, so we consider these to be our critical accounting policies. Actual results could differ from the estimates we use in applying our critical accounting policies. We are not currently aware of any reasonably likely events or circumstances that would result in materially different amounts being reported.

There have been no changes in our critical accounting policies from our most recent Annual Report on Form 10-K.

Recently Issued Accounting Pronouncements

See Note 1 in the accompanying Notes to the Unaudited Condensed Consolidated Financial Statements for recently adopted accounting standards.

Emerging Growth Company

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Item 3 is not applicable to us as a smaller reporting company and has been omitted.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Report. Based upon that evaluation, the CEO and CFO concluded that our disclosure controls and procedures as of the end of the period covered by this Report were not effective in providing reasonable assurance in the reliability of our report as of the end of the period covered by this report.

In our 2018 Annual Report on Form 10-K, we identified the following material weaknesses in our internal control over financial reporting, which are common in many small companies with limited staff including: (i) lack of certain entity level controls; (ii) inadequate segregation of duties throughout the entire year; and (iii) insufficient documentation of certain policies and procedures for transaction processing, accounting and financial reporting with respect to the requirements and application of both U.S. GAAP and SEC guidelines, their related controls and the operation thereof. These material weaknesses continue to be present at September 30, 2019.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during our quarter ended September 30, 2019, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We are continuing to take remediation actions to rectify our control deficiencies (including material weaknesses) through the adoption and implementation of written policies and procedures for transaction processing, accounting and financial reporting, as well as strengthening our supervisory review processes.

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

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, 2018.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

(a) Recent Sale of Unregistered Securities

We are currently in the process of raising additional funds through the private sale of 8% Senior Convertible Notes ("8% Senior Notes") to accredited investors. As of November 5, 2019, we have received into escrow $745,000 from the sale of 8% Senior Notes. We have not recorded these amounts in the accompanying condensed consolidated financial statements at September 30, 2019 since these investors, in connection with the revision of our agreement with PoC Capital and our entering into the LOC agreements, had the opportunity through October 18, 2019 to rescind their investment. No investors indicated their plan to rescind any investment and we plan to close the escrow account in the fourth quarter of 2019, at which time we will record the proceeds.

Upon completion of listing our common stock on either the Nasdaq Capital Market or the New York Stock Exchange, our 8% Senior Notes are mandatorily convertible into shares of our common stock at a conversion price equal to the lower of (i) $2.04 per share or (ii) a price per share equal to a 10% discount to the pre-money valuation of a Qualified Financing or an Equity State Transaction, both as defined in the 8% Senior Note agreement, occurring after the closing of the 8% Senior Note financing. Upon maturity (December 15, 2020), the 8% Senior Note holders have the option to convert the 8% Senior Note into shares of our common stock at the lower of $2.04 per share or an adjusted price as set forth in the 8% Senior Note agreement. Upon either mandatory conversion or conversion at the holder's option, the holder will also receive stock purchase warrants on a 1:1 basis to the number of shares of common stock received that have an exercise price equal to the greater of (i) the closing price of our common stock on the date of conversion or (ii) $2.72 per share.

The 8% Senior Notes and warrants were issued pursuant to the exemptions provided in Section 4(a)(2) of the Securities Act of 1933, as amended, and Regulation D.

(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 nine months ended September 30, 2019.

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
3	Fourth Amended and Restated Certificate of Incorporation of Processa Pharmaceuticals, Inc. (incorporated by reference to exhibit 3 accompanying Form 10-Q filed on August 14, 2019)
10.1	Line of Credit Agreement dated September 20, 2019 between Processa Pharmaceuticals and DKBK Enterprises, LLC (incorporated by reference to exhibit 10.1 accompanying Form 8-K filed on October 2, 2019)
10.2	Line of Credit Agreement dated September 20, 2019 between Processa Pharmaceuticals and CorLyst, LLC (incorporated by reference to exhibit 10.2 accompanying Form 8-K filed on October 2, 2019)
10.3	Amendment to the Agreement between PoC Capital and Processa Pharmaceuticals, Inc. dated September 30, 2019 (incorporated by reference to exhibit 10.3 accompanying Form 8-K filed on October 2, 2019)
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 14, 2019

By: */s/ James Stanker*
James Stanker
Chief Financial Officer
(Principal Financial and Accounting Officer)
Dated: November 14, 2019

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. for the quarter ended September 30, 2019;

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 14, 2019

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. for the quarter ended September 30, 2019;

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 14, 2019

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

Exhibit 32.1

Written Statement of the Chief Executive Officer and Chief 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, 2019 (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 14, 2019

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, 2019 (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 14, 2019

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