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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 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
(State or other jurisdiction
of incorporation or organization)

45-1539785
(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 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 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
Non-accelerated filer

Accelerated filer
Smaller reporting company
Emerging growth company

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.

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

The registrant has 38,801,006 shares of common stock outstanding as of July 31, 2019.

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

PROCESSA PHARMACEUTICALS, INC.
TABLE OF CONTENTS

<u>PART I: FINANCIAL INFORMATION</u>	3
<u>ITEM 1: FINANCIAL STATEMENTS</u>	3
<u>ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	16
<u>ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	25
<u>ITEM 4. CONTROLS AND PROCEDURES</u>	25
<u>PART II. OTHER INFORMATION</u>	26
<u>ITEM 1. LEGAL PROCEEDINGS</u>	26
<u>ITEM 1A. RISK FACTORS</u>	26
<u>ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u>	26
<u>ITEM 3. DEFAULTS UPON SENIOR SECURITIES</u>	26
<u>ITEM 4. MINE SAFETY DISCLOSURES</u>	26
<u>ITEM 5. OTHER INFORMATION</u>	26
<u>ITEM 6. EXHIBITS</u>	26

PART 1: FINANCIAL INFORMATION

ITEM 1: FINANCIAL STATEMENTS

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

	<u>June 30, 2019</u>	<u>December 31, 2018</u>
ASSETS		
Current Assets		
Cash and cash equivalents	\$ 721,985	\$ 1,740,961
Due from related party	-	21,583
Prepaid expenses and other	267,922	257,832
Total Current Assets	<u>989,907</u>	<u>2,020,376</u>
Property And Equipment		
Software	19,740	19,740
Office equipment	9,327	9,327
Total Cost	29,067	29,067
Less: accumulated depreciation	15,915	11,692
Property and equipment, net	<u>13,152</u>	<u>17,375</u>
Other Assets		
Operating lease right of use assets, net of accumulated amortization	256,916	-
Intangible assets, net of accumulated amortization	10,040,118	10,437,782
Security deposit	5,535	5,535
Total Other Assets	<u>10,302,569</u>	<u>10,443,317</u>
Total Assets	<u>\$ 11,305,628</u>	<u>\$ 12,481,068</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Senior convertible notes	\$ 230,000	\$ 230,000
Current maturities of operating lease liability	77,544	-
Accrued interest	28,930	20,343
Accounts payable	143,351	292,102
Due to related parties	1,336	-
Accrued expenses	302,275	103,259
Total Current Liabilities	<u>783,436</u>	<u>645,704</u>
Non-current Liabilities		
Noncurrent operating lease liability	186,677	-
Net deferred tax liability	1,833,445	2,134,346
Total Liabilities	<u>2,803,558</u>	<u>2,780,050</u>
COMMITMENTS AND CONTINGENCIES		
Stockholders' Equity		
Preferred stock, par value \$0.0001, 10,000,000 shares authorized; no shares issued and outstanding	-	-
Common stock, par value \$0.0001, 350,000,000 shares authorized; 38,674,265 issued and outstanding at both June 30, 2019 and December 31, 2018	3,867	3,867
Additional paid-in capital	19,246,320	19,121,285
Subscription receivable	(1,404,073)	(1,800,000)
Accumulated deficit	(9,344,044)	(7,624,134)
Total Stockholders' Equity	<u>8,502,070</u>	<u>9,701,018</u>
Total Liabilities and Stockholders' Equity	<u>\$ 11,305,628</u>	<u>\$ 12,481,068</u>

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Operating Expenses				
Research and development expenses	\$ 726,904	\$ 1,077,643	\$ 1,211,655	\$ 1,865,921
General and administrative expenses	410,072	350,581	807,837	853,918
Total operating expenses	<u>1,136,976</u>	<u>1,428,224</u>	<u>2,019,492</u>	<u>2,719,839</u>
Operating Loss	(1,136,976)	(1,428,224)	(2,019,492)	(2,719,839)
Other Income (Expense)				
Interest expense	(6,102)	(58,314)	(10,702)	(146,054)
Interest income	3,398	2,681	9,383	3,706
Total other income (expense)	<u>(2,704)</u>	<u>(55,633)</u>	<u>(1,319)</u>	<u>(142,348)</u>
Net Operating Loss Before Income Tax Benefit	(1,139,680)	(1,483,857)	(2,020,811)	(2,862,187)
Income tax benefit	<u>170,602</u>	<u>277,783</u>	<u>300,901</u>	<u>559,317</u>
Net Loss	<u>\$ (969,078)</u>	<u>\$ (1,206,074)</u>	<u>\$ (1,719,910)</u>	<u>\$ (2,302,870)</u>
Net Loss per Common Share - Basic and Diluted	<u>\$ (0.03)</u>	<u>\$ (0.03)</u>	<u>\$ (0.04)</u>	<u>\$ (0.06)</u>
Weighted Average Common Shares Used to Compute Net Loss Applicable to Common Shares - Basic and Diluted	<u>38,674,265</u>	<u>36,623,697</u>	<u>38,674,265</u>	<u>35,951,894</u>

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

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

Six Months Ended June 30, 2019						
	Common Stock		Additional Paid-In Capital	Subscription Receivable	Accumulated Deficit	Total
	Shares	Amount				
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	-	-	-	-	(969,078)	(969,078)
Balance, June 30, 2019	38,674,265	\$ 3,867	\$ 19,246,320	\$ (1,404,073)	\$ (9,344,044)	\$ 8,502,070
Six Months Ended June 30, 2018						
	Common Stock		Additional Paid-In Capital	Subscription Receivable	Accumulated Deficit	Total
	Shares	Amount				
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 \$219,954	1,402,442	140	2,963,423	-	-	2,963,563
Issuance of common stock units for a future research funding commitment, net of costs of \$117,339	792,952	79	1,682,582	(1,800,000)	-	(117,339)
Net loss	-	-	-	-	(1,206,072)	(1,206,072)
Balance, June 30, 2018	38,674,265	\$ 3,867	\$ 19,264,976	\$ (1,800,000)	\$ (6,161,956)	\$ 11,306,887

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

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

	Six Months Ended June 30,	
	2019	2018
Cash Flows From Operating Activities		
Net Loss	\$ (1,719,910)	\$ (2,302,870)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	4,223	4,223
Amortization of right-of-use assets	36,282	-
Amortization of debt issuance costs	-	61,132
Amortization of intangible asset	397,664	222,559
Deferred income tax benefit	(300,901)	(559,317)
Stock-based compensation	125,035	-
Payments made directly to our Contract Research Organization for clinical trial expenses by an investor in partial satisfaction of their stock subscription receivable	395,927	-
Net changes in operating assets and liabilities:		
Prepaid expenses	(10,090)	(42,067)
Operating lease liability	(38,940)	-
Accrued interest	8,587	84,721
Accounts payable	(148,751)	200,713
Due (from)/to related parties	22,919	6,877
Accrued expenses	208,979	90,843
Net cash used in operating activities	<u>(1,018,976)</u>	<u>(2,233,186)</u>
Cash Flows From Investing Activities		
Purchase of intangible asset	-	(1,782)
Proceeds from (purchase of) certificates of deposit	-	(496,000)
Net cash used in investing activities	<u>-</u>	<u>(497,782)</u>
Cash Flows from Financing Activities		
Net proceeds from issuance of common stock	-	2,856,073
Transaction costs incurred on Senior Convertible Notes	-	(4,742)
Payment of placement agent and legal fees associated with clinical funding commitment	-	(117,339)
Net cash provided by financing activities	<u>-</u>	<u>2,733,992</u>
Net (Decrease)/Increase in Cash and Cash Equivalents	(1,018,976)	3,024
Cash and Cash Equivalents – Beginning of Period	1,740,961	2,847,429
Cash and Cash Equivalents – End of Period	\$ <u>721,985</u>	\$ <u>2,850,453</u>

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

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

	Six Months Ended June 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 \$2,350,000 of Senior Convertible Debt and related accrued interest into 1,206,245 shares of common stock and warrants	\$ -	\$ 2,395,111
Common stock and stock purchase warrants issued in connection with a clinical trial funding commitment	\$ -	\$ 1,800,000
Note receivable related to the sale of common stock and stock purchase warrants	\$ -	\$ 107,490

The accompanying notes are an integral part of these 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) 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 2, 2019, our twelfth patient was screened and qualified for our study. We anticipate dosing the patient in late August, at which point our study will be fully enrolled. 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. Currently, eleven patients have been dosed with seven patients being on treatment for at least 3 months and three patients on treatment for 5 months. To date, six patients dosed at 1.8 g/day have reported only mild adverse events related to the treatment, which occurred mostly in the first month of treatment and were quickly resolved. As expected, gastrointestinal or central nervous system (CNS) adverse events were reported most often.

The degeneration of tissue occurring at the NL lesion site is caused by a number of pathophysiological changes, which has made it extremely difficult to develop effective treatments for this condition. PCS-499 may provide a solution since PCS-499 and its metabolites affect a number of biological pathways, several of which contribute to the pathophysiology associated with NL. As expected, we have not yet seen any significant change in the NL lesion of the trial participants. Our expectation is that changes in the NL lesion will take at least six months to see any major effect.

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.

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 consolidated financial statements include all adjustments necessary, which are of a normal and recurring nature, for the fair presentation of the Company's financial position and of the results of operations and cash flows for the periods presented. These consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto included in 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. We do not have any prospective arrangements or credit facilities as a source of future funds. We have not had any revenue since our inception. 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 six months ended June 30, 2019, we had an accumulated deficit of \$9.3 million, incurred a net loss for the six months of \$1.7 million and used \$1.0 million in net cash from operating activities from continuing operations. At June 30, 2019, we had cash and cash equivalents totaling \$721,985 and a Clinical Trial Funding commitment from an investor (PoC Capital) of \$1.4 million. During the six months ended June 30, 2019, PoC Capital paid \$395,927 of costs on our behalf related to our Phase 2a trial for NL directly to our CRO. Subsequent to June 30, 2019, PoC Capital has paid an additional \$193,299 directly to our CRO.

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. Subsequent to June 30, 2019, we have received \$435,000 from the sale of 8% Senior Notes to both new and existing investors and expect more in the coming weeks before we close the financing. We have also delayed some of our cash outflows, primarily through the deferral of salaries until such time as we have raised sufficient funding.

Based on our current plan, our available resources (including the Clinical Trial Funding commitment from PoC Capital) and the outcome of the additional 8% Senior Notes funding, we may need to raise additional capital before the end of the year in order 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 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 six months ended June 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 statements of operations based upon the underlying individual's role.

Net Loss Per Share

Basic loss per share is computed by dividing our net loss available to common shareholders by the weighted average number of shares of common stock outstanding during the year. Diluted loss per share is computed by dividing our net loss available to common shareholders by the diluted weighted average number of shares of common stock during the period. Since we experienced a net loss for both periods presented, basic and diluted net loss per share are the same. As such, diluted loss per share for the six months ended June 30, 2019 and 2018 excludes the impact of potentially dilutive common shares related to the conversion of our Senior Convertible Notes and outstanding stock options and warrants 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 8, "Operating Leases."

Note 2 – Intangible Assets

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

	June 30, 2019	December 31, 2018
Gross intangible assets	\$ 11,059,429	\$ 11,059,429
Less: Accumulated amortization	(1,019,311)	(621,647)
Total intangible assets, net	<u>\$ 10,040,118</u>	<u>\$ 10,437,782</u>

Amortization expense was \$397,664 and \$222,559 for the six months ended June 30, 2019 and 2018, respectively, and is included within research and development expense in the accompanying condensed consolidated statements of operations. Our estimated amortization expense for the next two years will be approximately \$795,000 per year and for annual periods thereafter approximately \$788,000 per year.

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 June 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 six months ended June 30, 2019 and 2018. No current income tax expense is expected for the foreseeable future as we expect to generate taxable net operating 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 did not grant any stock options to employees or non-employees during the six months ended June 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, 1/36th 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 June 30, 2019, we are only recognizing compensation cost for the awards related to completion of our current clinical trial. The clinical trial is progressing as planned with no significant adverse events, is nearly 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. As for the other two awards containing performance conditions, 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 two awards.

At June 30, 2019, we had outstanding options to purchase 1,293,630 shares of our common stock of which options for the purchase of 9,000 shares of our common stock were vested. We recorded \$66,476 and \$125,035 of stock-based compensation expense for the three and six months ended June 30, 2019, respectively. The allocation of stock-based compensation expense between research and development and general and administrative expense was as follows:

	Three months ended June 30, 2019	Six months ended June 30, 2019
Research and Development	\$ 3,404	\$ 3,404
General and Administrative	\$ 63,072	\$ 121,631
	<u>\$ 66,476</u>	<u>\$ 125,035</u>

No expense was recorded during the three and six months ended June 30, 2018 since we had no stock options outstanding at June 30, 2018.

Note 5 – Senior Convertible Notes

At June 30, 2019 and December 31, 2018, we had \$230,000 of Senior Convertible Notes outstanding 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 \$259,830 into 126,741 shares of common stock and 126,741 stock purchase warrants.

Note 6 – Stockholders' Equity

During the six months ended June 30, 2019 and 2018, there were no sales of our preferred stock. At June 30, 2019 and December 31, 2018, there were no issued or outstanding shares of preferred stock. During the six months ended June 30, 2019, PoC Capital (our clinical trial funding commitment investor), made payments directly to our CRO totaling \$395,927 for amounts being currently invoiced, thereby reducing the subscription receivable to \$1,404,073. Subsequent to June 30, 2019, PoC Capital has made additional payments totaling \$193,299 directly to our CRO. We paid \$239,129, \$158,000 of which is included in Prepaid and Other on our balance sheet, directly to our CRO at the beginning of our trial that we expect PoC Capital to repay us for. We will continue to reduce the subscription receivable in the period PoC Capital makes payment to our CRO or us.

Note 7 – Net Loss per Share of Common Stock

Basic net loss per share is computed by dividing net loss by the weighted average common shares outstanding. Diluted net loss per share is computed by dividing net loss by the weighted average common shares outstanding, which includes potentially dilutive effect of stock options, warrants and senior convertible notes. Since we experienced a loss for both 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 six months ended June 30, 2019 and 2018 was as follows:

	For the six months ended	
	June 30,	
	2019	2018
Basic and diluted net loss per share:		
Net loss from continuing operations	\$ (1,719,910)	\$ (2,302,870)
Weighted average number of common shares-basic and diluted	38,674,265	35,951,894
Basic and diluted net loss per share	\$ (0.04)	\$ (0.06)

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.

	June 30, 2019	December 31, 2018
Stock options and purchase warrants	4,906,417	3,997,187
Senior convertible notes and related accrued interest	126,741	122,537

Note 8 - 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 statement of operations totaled \$49,302 and \$53,302 for the six months ended June 30, 2019 and 2018, respectively. The weighted average remaining lease terms and discount rate for our operating leases were as follows at June 30, 2019:

Weighted average remaining lease term (years) for our facility and equipment leases	3.1
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 June 30, 2019:

2019	\$ 48,452
2020	92,603
2021	90,495
2022	69,741
Total lease payments	<u>301,291</u>
Less: Interest	<u>(37,070)</u>
Present value of lease liabilities	264,221
Less: current maturities	<u>(77,544)</u>
Non-current lease liability	\$ 186,677

Note 9 – 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 statement of operations. Reimbursements from CorLyst totaled \$52,464 and \$0 for rent and other costs during the six months ended June 30, 2019 and 2018, respectively. Amounts due from CorLyst at June 30, 2019 and December 31, 2018 were \$170 and \$21,583, respectively.

Note 10 – 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 June 30, 2019 and December 31, 2018, respectively.

Note 11 – Subsequent Events

Subsequent to June 30, 2019, we raised \$435,000 from the sale of 8% Senior Convertible Notes and we expect more within the coming weeks. Principal and interest under each Senior Note is due on the earlier of (i) upon raising a cumulative amount of \$14 million prior to December 15, 2020 which can occur over multiple financing transactions (i.e. Qualified Financing and/or Equity Stake transactions where net cash is obtained) or (ii) completion of the Company listing its common stock on either the Nasdaq Capital Market or the New York Stock Exchange or (iii) December 15, 2020 (“Maturity Date”). Holders of Senior Notes may elect to (i) convert all principal, together with accrued and unpaid interest under each Senior Note to Company common stock or (ii) be paid back all principal, together with accrued and unpaid interest under each Senior Note. The Company will grant investors stock purchase warrants on a 1:1 basis to the number of common stock shares issued, which will have an exercise price equal to the greater of (i) the reported closing price of the Common Stock on the OTCQB Venture Market on the closing day of the offering or (ii) \$2.72 (133% of the purchase price).

Also, as described in Note 5, on July 2, 2019 we converted the principal and related interest of outstanding Senior Convertible Notes totaling \$259,830 into 126,741 shares of common stock and 126,741 stock purchase warrants.

In August 2019, the Company reduced the number of authorized shares of its common stock from 350,000,000 shares to 100,000,000 shares and its preferred stock from 10,000,000 shares to 1,000,000 shares.

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) 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 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 June 30, 2019, we had an accumulated deficit of \$9.3 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;
- 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

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. Subsequent to June 30, 2019, we have received \$435,000 from the sale of 8% Senior Notes to both new and existing investors and expect more in the coming weeks before we close the financing. We have also delayed some of our cash outflows, primarily through the deferral of salaries until such time as we have raised sufficient funding.

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. We do not have any credit facilities as a source of future funds. 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 six months ended June 30, 2019, we incurred a net loss from continuing operations of \$1.7 million and used \$1.0 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.

We are looking at ways to add an additional revenue stream to offset some of our expenses. We may also need to raise additional funds depending on the outcome of the additional 8% Senior Notes funding. 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 June 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 2, 2019, our twelfth patient was screened and qualified for our study. We anticipate dosing in late August, at which point our study will be fully enrolled. 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. Currently, eleven patients have been dosed with seven patients being on treatment for at least 3 months and three patients on treatment for 5 months. 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 are continually evaluating the data we receive and believe that changes in the NL lesion could take at least six months to see any major effect.

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.

Results of Operations

Comparison of the three and six months ended June 30, 2019 and 2018

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

	Three Months Ended June 30,			Six Months Ended June 30,		
	2019	2018	Change	2019	2018	Change
Operating Expenses						
Research and development expenses	\$ 726,904	\$ 1,077,643	\$ (350,739)	\$ 1,211,655	\$ 1,865,921	\$ (654,266)
General and administrative expenses	410,072	350,581	59,491	807,837	853,918	(46,081)
Total operating expenses	1,136,976	1,428,224	(291,248)	2,019,492	2,719,839	(700,347)
Other Income (Expense)						
Interest Expense	(6,102)	(58,314)	52,212	(10,702)	(146,054)	135,352
Interest Income	3,398	2,681	717	9,383	3,706	5,677
Total other income (expense)	(2,704)	(55,633)	52,929	(1,319)	(142,348)	141,029
Net Operating Loss Before Income Tax Benefit	1,139,680	1,483,857	(344,177)	2,020,811	2,862,187	(841,376)
Income Tax Benefit	(170,602)	(277,783)	107,181	(300,901)	(559,317)	258,416
Net Loss	\$ 969,078	\$ 1,206,074	\$ (236,996)	\$ 1,719,910	\$ 2,302,870	\$ (582,960)

Revenues.

We had no revenue during the three and six months ended June 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) licensing of compounds for product testing and development, (ii) program and testing related expenses, (iii) amortization of the exclusive license intangible asset used in research and development activities, and (iv) internal research and development staff related payroll, taxes and employee benefits, external consulting and professional fees related to the product testing and our development activities. Non-refundable advance payments for goods and services to be used in future research and development activities are recorded as prepaid expenses and expensed when the research and development activities are performed.

During the three months ended June 30, 2019 and 2018, we incurred total research and development expenses of \$726,904 and \$1.1 million, respectively, for the continued development and testing of our lead product, PCS-499. Research and development expenses were approximately \$1.2 million and \$1.9 million for the six months ended June 30, 2019 and 2018, respectively. Costs for the three and six months ended June 30, 2019 and 2018 were as follows:

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
Amortization of intangible assets	\$ 198,832	\$ 197,124	\$ 397,664	\$ 222,559
Research and development salaries and benefits	160,992	172,722	319,848	338,227
Preclinical, clinical trial and other costs	367,080	707,797	494,143	1,305,135
Total	\$ 726,904	\$ 1,077,643	\$ 1,211,655	\$ 1,865,921

Overall, during the three months ended June 30, 2019, our research and development costs decreased by \$350,739 as compared to the three months ended June 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 \$197,124 of amortization expense during the three months ended June 30, 2019 and 2018, respectively. The increase in amortization expense of approximately \$1,700 was from the software license, which began recognition in the third quarter of 2018. Our research and development salaries and benefits decreased by approximately \$12,000 for the three months ended June 30, 2019 when compared to the same period in 2018 related to one of our research and development team members having a reduced level of involvement. The majority of the reduction related to lower research and development expenses for preclinical, clinical trial and other costs of \$340,717 during the three months ended June 30, 2019 when compared to the same period in 2018. During the three months ended June 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 six months ended June 30, 2019, our research and development costs decreased by \$654,266 as compared to the six months ended June 30, 2018. The decrease is due to a reduction of approximately \$811,000 in preclinical, clinical trial, and other costs and a reduction of approximately \$19,000 in salaries, benefits, and other related payroll costs when comparing the six months ended June 30, 2019 to the same period in 2018. The decrease was offset by an increase of approximately \$175,000 in amortization expense for the software license and CoNCERT license agreement.

We incurred \$333,157 of costs related to our Phase 2a trial during the six months ended June 30, 2019 and expect to spend approximately an additional \$230,000 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 \$1.6 to \$1.8 million and anticipate our Clinical Trial Funding commitment of \$1.8 million executed in June 2018 will be sufficient to fund the costs of this trial. The funding necessary to bring a drug candidate to market is, however, subject to numerous uncertainties. Once a drug candidate is identified, the further development of that drug candidate can be halted or abandoned at any time due to a number of factors. These factors include, but are not limited to, funding constraints, safety or a change in market demand. For each of our drug candidate programs, we periodically assess the scientific progress and merits of the programs to determine if continued research and development is economically viable. Certain of our programs may be terminated due to the lack of scientific progress and lack of prospects for ultimate commercialization. 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.

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 six months ended June 30, 2019, PoC Capital made payments directly to our CRO totaling \$395,927 for amounts being currently invoiced, thereby reducing the subscription receivable to \$1,404,073. Subsequent to June 30, 2019, PoC Capital has made additional payments totaling \$193,299 directly to our CRO. We expect PoC Capital to repay us, as well as continue to make payments to our CRO for outstanding and future invoices related to our Phase 2a trial. We will continue to reduce the subscription receivable in the period the investor makes payment to our CRO or us.

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 June 30, 2019 increased by \$59,491 to \$410,072 from \$350,581 for the three months ended June 30, 2018. The increase related mostly to increased payroll and related costs of approximately \$110,000 (including stock-based compensation of \$63,072) 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 \$22,000 in other administrative costs such as insurance, office, and travel expenses. Our tax expense increased by approximately \$66,000 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. Currently, we are 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 (38,674,265 at June 30, 2019). This resulted in a high tax bill for 2018 and requires us to pay quarterly estimated taxes for 2019. We filed a definitive information statement Schedule 14c to decrease the number of authorized shares in July 2019 and submitted our Certificate of Amendment with the State of Delaware – Division of Corporations on August 8, 2019, following the required 20-day period for the action to become effective. These increases were offset by decreases of approximately \$10,000 in training, repairs and maintenance, and telephone/internet expenses, as well as reductions of \$129,000 in professional fees for legal, accounting, advisory and consulting costs as we establish in-house capabilities.

For the six months ended June 30, 2019, general and administrative expenses decreased by \$46,081 to \$807,837 from \$853,918 for the six months ended June 30, 2018. The decrease related to a cybersecurity fraud loss of approximately \$144,000, for which we did not have insurance coverage, during the six months ended June 30, 2018. We also saw reductions in professional fees for legal, accounting, advisory and consulting costs of approximately \$201,000, as well as reductions of approximately \$18,000 in rent, repairs and maintenance and continuing education. The overall decrease in our general and administrative expenses during the six months ended June 30, 2019 was also offset by increases of approximately \$209,000 in payroll and related costs (including stock-based compensation of \$121,631) and approximately \$108,000 in administrative costs such as insurance, office expenses, continuing education, and travel.

Reimbursements from CorLyst of \$26,500 and \$52,464 for rent and other costs during the three and six months ended June 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 \$6,102 and \$58,314 for the three months ended June 30, 2019 and 2018, respectively, and \$10,702 and \$146,054 for the six months ended June 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. Subsequent to June 30, 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 \$24,992 for the three months ended June 30, 2019 and 2018, respectively, and \$0 and \$61,132 for the six months ended June 30, 2019 and 2018, respectively.

Interest Income.

Interest income was \$3,398 and \$2,681 for the three months ended June 30, 2019 and 2018, respectively, and \$9,383 and \$3,706 for the six months ended June 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 \$170,602 and \$277,783 was recognized for the three months ended June 30, 2019 and 2018, respectively, and \$300,901 and \$559,317 for the six months ended June 30, 2019 and 2018, respectively, as a result of our recording and amortizing the deferred tax liability created in connection with our acquisition of CoNCERT's license and "Know-How" in exchange for Processa stock that had been issued in an Internal Revenue Code Section 351 transaction on March 19, 2018. The Section 351 transaction treated the acquisition of the Know-How for stock as a tax-free exchange. As a result, under ASC 740-10-25-51 *Income Taxes*, Processa recorded a deferred tax liability of \$3,037,147 for the acquired temporary difference between the financial reporting basis of \$11,038,929 and the tax basis of \$1,782. The deferred tax liability will be reduced for the effect of the non-deductibility of the amortization of the intangible asset and may be offset by the deferred tax assets resulting from net operating tax losses. This offset results in the recognition of a deferred tax benefit shown in the consolidated statements of operations.

Financial Condition

At June 30, 2019, we had \$721,985 in cash and \$1.4 million remaining in our commitment from PoC Capital to fund our Phase 2a clinical trial for NL. Net cash used in our operating activities during the six months ended June 30, 2019 totaled \$1,018,976 compared to \$2,233,186 for the six months ended June 30, 2018.

Our total assets decreased by approximately \$1.2 million to \$11.3 million at June 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 six months ended June 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 June 30, 2019, our total liabilities, not including the impact of deferred income taxes, increased \$324,409 to \$970,113 when compared to \$645,704 at December 31, 2018. This increase is due primarily to changes in accrued expenses as we continue the development of PCS-499 and conduct our Phase 2a clinical trial, as well as the recognition of operating lease liabilities in accordance with the adoption of ASC 842.

At June 30, 2019, we had \$230,000 of Senior Convertible Notes outstanding 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. Subsequent to June 30, 2019, we have received \$435,000 from the sale of 8% Senior Notes to both new and existing investors and expect more in the coming weeks before we close the financing. We have also delayed some of our cash outflows, primarily through the deferral of salaries until such time as we have raised sufficient funding.

At June 30, 2019, we had \$721,985 in cash and cash equivalents compared to \$1.7 million at December 31, 2018. We also received a Clinical Trial Funding commitment of \$1.8 million to fund clinical trial expenses, of which \$1.4 million has not been used as of June 30, 2019. We believe the clinical trial committed funds will be sufficient to fund our current Phase 2a clinical trial of PCS-499 in patients with NL. We do not have any credit facilities as a source of future funds, and there can be no assurance that we will be able to raise sufficient additional capital on acceptable terms, or at all. As a result, substantial doubt exists about our ability to continue as a going concern within one year after the date that this Form 10-Q is filed with the SEC.

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

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

Based on our current plan, our available resources (including the remaining Clinical Trial Funding Commitment of \$1.4 million from PoC Capital) and the outcome of the additional 8% Senior Notes funding, we may need to raise additional capital before the end of the year in order to fund our future operations. While we believe our current resources, through our Clinical Trial Funding Commitment, are adequate to complete our Phase 2a trial, we do not currently have resources to conduct other future trials without raising additional capital. As noted above, the timing and extent of our spending will depend on the cost associated with, and the results of our 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.

Cash Flows

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

	Six months ended	
	June 30,	
	2019	2018
Net cash provided by (used in):		
Operating activities	\$ (1,018,976)	\$ (2,233,186)
Investing activities	-	(497,782)
Financing activities	-	2,733,992
Net increase in cash and cash equivalents	<u>\$ (1,018,976)</u>	<u>\$ 3,024</u>

Net cash used in operating activities

We used net cash in our operating activities of \$1,018,976 and \$2,233,186 during the six months ended June 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 six months ended June 30, 2019 was \$582,960 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 six months ended June 30, 2019 was further reduced as PoC Capital directly paid \$395,927 to our CRO related to our Phase 2a clinical trial. We also incurred amortization expense of \$397,664 (versus \$222,559 for the comparable period in 2018) and \$125,035 of stock-based compensation during the six months ended June 30, 2019. During the six months ended June 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 six months ended June 30, 2019. Net cash used during the six months ended June 30, 2018 was \$497,782 related to the purchase of certificates of deposit (CDs) and transaction costs incurred to acquire the exclusive license of PCS-499 in 2018.

Net cash provided by financing activities

We had no cash sources or uses for financing activities during the six months ended June 30, 2019. Net cash provided from financing activities was approximately \$2.7 million for the six months ended 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 June 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 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) 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 GAAP and SEC guidelines, their related controls and the operation thereof. These material weaknesses continue to be present at June 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 June 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

At June 30, 2019, we had \$230,000 of Senior Convertible Notes outstanding 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. The shares and warrants were issued pursuant to the exemptions provided in Section 4(a)(2) of the Securities Act of 1933, as amended, and Regulation S.

(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 six months ended June 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.
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: August 14, 2019

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

CERTIFICATE OF AMENDMENT

AMENDMENT TO FOURTH AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
PROCESSA PHARMACEUTICALS, INC.

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

1. The name of the corporation is Processa Pharmaceuticals, Inc. The date of the filing of its original Certificate of Incorporation with the Secretary of State of the State of Delaware was March 29, 2011. The Certificate of Incorporation was restated on April 15, 2011, October 25, 2011, and July 24, 2012, was amended on June 28, 2011, and June 21, 2013, and restated and amended on September 27, 2017 and amended on October 23, 2017.

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

3. This Amendment to the Fourth Amended and Restated Certificate of Incorporation amends the text of the Fourth paragraph to read as herein set forth in full:

FOURTH: The total number of shares of all classes of stock which the Corporation shall have authority to issue is (i) 100,000,000 shares of Common Stock, \$0.0001 par value per share ("Common Stock") and (ii) 1,000,000 shares of Preferred Stock, \$0.0001 par value per share ("Preferred Stock").

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

A. COMMON STOCK

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

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

3. Dividends. Dividends may be declared and paid on the Common Stock from funds lawfully available therefor as and when determined by the Board of Directors and subject to any preferential dividend or other rights of any then outstanding Preferred Stock.
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4. Liquidation. Upon the dissolution or liquidation of the Corporation, whether voluntary or involuntary, holders of Common Stock will be entitled to receive all assets of the Corporation available for distribution to its stockholders, subject to any preferential or other rights of any then outstanding Preferred Stock.

B. PREFERRED STOCK

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

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

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

EXECUTED on August 8, 2019

By: /s/ James Stanker
Name: James Stanker
Title: Chief Financial Officer

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 June 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 Rules 13a-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: August 14, 2019

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

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 June 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 Rules 13a-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: August 14, 2019

By: /s/ James Stanker

James Stanker
Chief Financial Officer
(Principal Financial and Accounting Officer)

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 June 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: August 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 June 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: August 14, 2019

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