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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2019

or

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

For the transition period from ____ to ____

Commission File Number 333-184948

Processa Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

The registrant has 38,674,265 shares of common stock outstanding as of April 30, 2019.

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

PROCESSA PHARMACEUTICALS, INC.
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PART 1: FINANCIAL INFORMATION

ITEM 1: FINANCIAL STATEMENTS

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

	March 31, 2019	December 31, 2018
ASSETS		
Current Assets		
Cash and cash equivalents	$ 1,248,532	$ 1,740,961
Due from related party	47,165	21,583
Prepaid expenses and other	247,200	257,832
Total Current Assets	1,542,897	2,020,376
Property and equipment, net	15,264	17,375
Operating lease right-of-use assets, net	275,251	-
Intangible assets, net	10,238,950	10,437,782
Security deposit	5,535	5,535
Total Assets	$ 12,077,897	$ 12,481,068
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Senior convertible notes	$ 230,000	$ 230,000
Current maturities of operating lease liability	58,504	-
Accrued interest	24,943	20,343
Accounts payable	283,057	292,102
Accrued expenses	128,220	103,259
Total Current Liabilities	724,724	645,704
Non-current Liabilities		
Noncurrent operating lease liability	225,381	-
Net deferred tax liability	2,004,047	2,134,346
Total Liabilities	2,954,152	2,780,050
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 March 31, 2019 and December 31, 2018	3,867	3,867
Additional paid-in capital	19,179,844	19,121,285
Stock subscription receivable	(1,685,000)	(1,800,000)
Accumulated deficit	(8,374,966)	(7,624,134)
Total Stockholders' Equity	9,123,745	9,701,018
Total Liabilities and Stockholders' Equity	$ 12,077,897	$ 12,481,068

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

Processa Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
Three Months Ended March 31, 2019 and 2018
(Unaudited)

	Three Months Ended March 31,	
	2019	**2018**
Operating Expenses:		
Research and development	$ 484,750	$ 821,388
General and administrative	397,766	470,228
Operating Loss	(882,516)	(1,291,616)
Other Income (Expense):		
Interest expense	(4,600)	(87,740)
Interest income	5,985	1,024
Net Operating Loss Before Income Tax Benefit	(881,131)	(1,378,332)
Income Tax Benefit	130,299	281,534
Net Loss	$ (750,832)	$ (1,096,798)
Net Loss Per Common Share - Basic and Diluted	$ (0.02)	$ (0.03)
Weighted Average Common Shares Used to Compute Net Loss Per Common Shares - Basic and Diluted	38,674,265	35,272,626

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

Processa Pharmaceuticals, Inc.
Condensed Consolidated Statement of Changes in Stockholders' Equity
Three Months Ended March 31, 2019 and 2018
(Unaudited)

	Common Stock		Preferred Stock		Additional Paid-In	Subscription	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Receivable	Deficit	Total
Balance at 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

	Common Stock		Preferred Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance at January 1, 2018	35,272,626	$ 3,527	-	$ -	$ 4,228,723	$ (3,859,086)	$ 373,164
Recognize the fair value of the license 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

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

Processa Pharmaceuticals, Inc.
Condensed Consolidated Statements of Cash Flows
Three Months Ended March 31, 2019 and 2018
(Unaudited)

	2019	2018
Cash Flows From Operating Activities		
Net loss	$ (750,832)	$ (1,096,798)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	2,111	2,112
Amortization of right-of-use assets	17,947	-
Amortization of debt issuance costs	-	36,140
Amortization of intangible asset	198,832	25,435
Deferred income tax benefit	(130,299)	(281,534)
Stock-based compensation	58,559	-
Payments made directly to our Contract Research Organization by an investor in partial satisfaction of their stock subscription receivable	115,000	-
Net changes in operating assets and liabilities:		
Prepaid expenses	10,632	1,257
Current portion of operating lease liability	(19,276)	-
Accrued interest	4,600	51,600
Accounts payable	(9,045)	54,194
Due (from) to related parties	(25,582)	36,025
Accrued expenses	34,924	102,561
Net cash used in operating activities	(492,429)	(1,069,008)
Cash Flows From Investing Activities		
Purchase of intangible asset	-	(1,782)
Net cash provided by (used in) investing activities	-	(1,782)
Net Decrease in Cash	(492,429)	(1,070,790)
Cash and Cash Equivalents – Beginning of Period	1,740,961	2,847,429
Cash and Cash Equivalents – End of Period	$ 1,248,532	$ 1,776,639

Processa Pharmaceuticals, Inc.
Condensed Consolidated Statements of Cash Flows (continued)
Three Months Ended March 31, 2019 and 2018
(Unaudited)

	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 of Intangible asset	-	3,037,147
Recognize additional paid-in-capital for consideration paid from the transfer of 2,090,301 common shares of Processa released by Promet to CoNCERT for Processa	-	8,000,000
Net	$ -	$ -

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 searching for additional products for our portfolio.

Our lead product, PCS-499 is an oral tablet that is an analog of an active metabolite of an already approved FDA drug. The advantage of PCS-499 is that it potentially may work in many conditions because it has multiple pharmacological targets it affects that are important in the treatment of these conditions. Based on its pharmacological activity, we have identified multiple unmet medical need conditions where the use of PCS-499 may result in clinical efficacy. The lead indication currently under development for PCS-499 is Necrobiosis Lipoidica (NL). 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. As of May 1, 2019, we have enrolled nine patients in the trial with one of these patients discontinuing in the trial because of the inconvenience associated with a clinical trial. No adverse effects were noted in this patient. All eight of the other patients are receiving 1.8 gm of PCS-499 daily with no dose limiting side effects. One of these patients has been dosed for three months while two others will soon reach three months of treatment on PCS-499. As expected, we have not seen any significant change in the NL lesion in the one patient who has been treated for three months. Our expectation is that changes in the NL lesion will take at least six months to see any major effect. We anticipate all 12 patients planned for this trial will be enrolled on or before June 2019. In addition, we expect 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.

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

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.

Certain amounts have been reclassified in our March 31, 2018 statement of operations to confirm to the current year presentation.

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 three months ended March 31, 2019, we had an accumulated deficit of $8.4 million, incurred a net loss for the three months of $750,832 and used $492,429 in net cash from operating activities from continuing operations. At March 31, 2019, we had cash and cash equivalents totaling $1.2 million and a Clinical Trial Funding commitment from an investor (PoC Capital) of $1.7 million. During the three months ended March 31, 2019, PoC Capital paid $115,000 of costs on our behalf related to our Phase 2a trial for NL directly to our CRO. Subsequent to March 31, 2019, PoC Capital has paid an additional $216,965 directly to our CRO.

Based on our current plan and our available resources (including the Clinical Trial Funding commitment from PoC Capital), we will need to raise additional capital before the end of the second quarter of 2019 in order to fund our future operations. While we believe our current resources are adequate to complete our 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.

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

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 three months ended March 31, 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. 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 three months ended March 31, 2019 and 2018 excludes the impact of potentially dilutive common shares related to the conversion of our Senior 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 7, "Operating Leases."

Note 2 – Intangible Assets

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

	March 31, 2019	December 31, 2018
Gross intangible assets	$ 11,059,429	$ 11,059,429
Less: accumulated amortization	(820,479)	(621,647)
Total intangible assets, net	$ 10,238,950	$ 10,437,782

Amortization expense was $198,832 and $25,435 for the three months ended March 31, 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 March 31, 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 the Internal Revenue Code Section 351 Transaction. The Section 351 Transaction treats the acquisition of the license and Know-How for stock as a tax-free exchange. As a result, under ASC 740-10-25-51 *Income Taxes*, Processa recorded a deferred tax liability of $3,037,147 for the acquired temporary difference between intangible assets (see Note 2) for the financial reporting basis of $11,038,929 and the tax basis of $1,782. The deferred tax liability will be reduced for the effect of non-deductibility of the amortization of the intangible asset and may be offset by the deferred tax assets resulting from net operating tax losses.

Under ACS 740-270 *Income Taxes – Interim Reporting*, we are required to project our annual federal and state effective income tax rate and apply it to the year to date ordinary operating tax basis loss before income taxes. Based on the projection, we expect to recognize the tax benefit from our projected ordinary tax loss, which can be used to offset the deferred tax liabilities related to the intangible assets and resulted in the recognition of a deferred tax benefit shown in the condensed consolidated statements of operations for three months ended March 31, 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

We did not grant any stock options to employees or non-employees during the three months ended March 31, 2019 or 2018. At March 31, 2019, we had outstanding options to purchase 384,400 shares of our common stock of which options for the purchase of 9,000 shares of our common stock were vested. We recorded $58,559 of stock-based compensation expense for the three months ended March 31, 2019 as general and administrative expense. No expense was recorded during the three months ended March 31, 2018 since we had not stock options outstanding at March 31, 2018.

Note 5 – Senior Convertible Notes

At March 31, 2019 and December 31, 2018, we had $230,000 of Senior Convertible Notes outstanding held by Canadian individuals that cannot be converted until the Alberta Securities Commission permits the issuance of our common stock units (consisting of shares of our common stock and stock purchase warrants) to these Canadian holders. If the Alberta Securities Commission does not allow us to convert this debt into common stock units, we will be required to repay the principal and related accrued interest of approximately $255,000.

Note 6 – 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 three months ended March 31, 2019 and 2018 was as follows:

	For the three months ended March 31,	
	2019	**2018**
Basic and diluted net loss per share:		
Net loss	$ (750,832)	$ (1,096,798)
Weighted-average number of common shares-basic and diluted	38,674,265	35,272,626
Basic and diluted net loss per share	$ (0.02)	$ (0.03)

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.

	2019	**2018**
Stock options and purchase warrants	3,917,763	-
Senior convertible notes	124,789	1,305,577

Note 7 - 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 $24,563 and $27,981 for the three months ended March 31, 2019 and 2018, respectively. The weighted average remaining lease terms and discount rate for our operating leases were as follows at March 31, 2019:

Weighted average remaining lease term (years) for our facility and equipment leases	3.35
Weighted average discount rate for our facility and equipment leases	8.00%

Maturities of our lease liabilities for all operating leases were as follows as of March 31, 2019:

2019	$	73,508
2020		92,603
2021		90,495
2022		69,741
Total lease payments		326,347
Less: Interest		(42,462)
Present value of lease liabilities		283,885
Less: current maturities		(58,504)
Non-current lease liability	$	225,381

Note 8 – 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. We did not receive reimbursements during the three months ended March 31, 2019 and 2018. Amounts due from CorLyst at March 31, 2019 and December 31, 2018 were $47,165 and $21,583, respectively.

Note 9 – 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 purchase obligations of approximately $23,000 at March 31, 2019.

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 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 March 31, 2019, we had an accumulated deficit of $8.4 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase significantly 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

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 three months ended March 31, 2019, we incurred a net loss from continuing operations of $750,832 and used $492,429 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 are planning on raising additional funds in the first half of 2019. In addition, we are seeking alternative options to add additional cash. However, no assurance can be given that we will be successful in securing adequate funds that may be required. If we are unable to raise additional capital 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 March 31, 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

Phase 2a Study and Orphan Drug Designation. On June 22, 2018, the FDA granted orphan-drug designation to our leading clinical compound 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 2 clinical trial on January 29, 2019. As of May 1, 2019, we have enrolled nine patients in the trial with one of these patients discontinuing in the trial because of the inconvenience associated with a clinical trial. No adverse effects were noted in this patient. All eight of the other patients are receiving 1.8 gm of PCS-499 daily with no dose limiting side effects. One of these patients has been dosed for three months while two others will soon reach three months of treatment on PCS-499. As expected, we have not seen any significant change in the NL lesion in the one patient who has been treated for three months. Our expectation is that changes in the NL lesion will take at least six months to see any major effect. We anticipate all 12 patients planned for this trial will be enrolled on or before June 2019. In addition, we expect 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 months ended March 31, 2019 and 2018

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

	Three Months Ended March 31,		
	2019	2018	Change
Operating Expenses			
Research and development costs	$ 484,750	$ 821,388	$ (336,638)
General and administrative expenses	397,766	470,228	(72,462)
Total operating expenses	882,516	1,291,616	(409,100)
Other Income (Expense)			
Interest expense	(4,600)	(87,740)	83,140
Interest income	5,985	1,024	4,961
Total other income (expense)	1,385	(86,716)	88,101
Net Operating Loss Before Income Tax Benefit	881,131	1,378,332	(497,201)
Income Tax Benefit	(130,299)	(281,534)	151,235
Net Loss	$ 750,832	$ 1,096,798	$ (345,966)

Revenues.

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

Research and Development Expenses.

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

During the three months ended March 31, 2019 and 2018, we incurred total research and development expenses of $484,750 and $821,388, respectively, for the continued development and testing of our lead product, PCS-499. Costs for the three months ended March 31, 2019 and 2018 were as follows:

	Three months ended March 31,	
	2019	2018
Amortization of intangible assets	$ 198,832	$ 25,435
Research and development salaries and benefits	158,855	165,512
Preclinical, clinical trial and other costs	127,063	630,441
Total	$ 484,750	$ 821,388

Overall, during the three months ended March 31, 2019, our research and development costs decreased by $336,638 as detailed below.

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 $25,435 of amortization expense during the three months ended March 31, 2019 and 2018, respectively. Our research and development salaries and benefits decreased by $6,657 for the three months ended March 31, 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. A majority of the reduction related to lower research and development expenses for preclinical, clinical trial and other costs of $503,378 during the three months ended March 31, 2019 when compared to the same period in 2018. During the three months ended March 31, 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.

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. In the second quarter of 2019, we expect to incur additional costs to manufacture additional clinical material since we do not have enough product to complete our Phase 2a clinical trial. We incurred $83,562 of costs related to our Phase 2a trial during the three months ended March 31, 2019 and expect to spend an additional $395,000 during the remainder of 2019 and $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.

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 three months ended March 31, 2019, PoC Capital made payments directly to our CRO totaling $115,000 for amounts being currently invoiced, thereby reducing the subscription receivable to $1,685,000. Subsequent to March 31, 2019, PoC Capital has made additional payments totaling $216,965 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 March 31, 2019 decreased by $72,462 to $397,766 from $470,228 for the three months ended March 31, 2018. The decrease related primarily to a cybersecurity fraud loss of approximately $144,000, for which we did not have insurance coverage, during the three months ended March 31, 2018. We also saw reductions in professional fees for legal, accounting, advisory and consulting costs as we establish in-house capabilities as well as decreases in rent, repairs and maintenance, of approximately $47,000. We experienced increased payroll, and related costs of approximately $98,000 (including stock-based compensation of $58,559) as we build our finance team in the later part of 2018, including hiring a Chief Financial Officer and a Director of Finance and Accounting in the latter half of 2018 to support our growth and public company reporting and compliance requirements. The overall decrease in our general and administrative expenses during the three months ended March 31, 2019 was also offset by increases of approximately $20,000 in administrative costs such as insurance, office expenses, continuing education, and travel. Reimbursements from CorLyst of $25,964 for rent and other costs during the three months ended March 31, 2019 were comparable for the same period 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 $4,600 and $87,740 for the three months ended March 31, 2019 and 2018, respectively, related to our $2.58 million of 8% Senior 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. Included in interest expense is the amortization of debt issuance costs totaling $0 and $36,140 for the three months ended March 31, 2019 and 2018, respectively.

Interest Income.

Interest income was $5,985 and $1,024 for the three months ended March 31, 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 $130,299 was recognized for the three months ended March 31, 2019 as a result of our recording and amortizing the deferred tax liability created in connection with our acquisition of CoNCERT's license and "Know-How" in exchange for Processa stock that had been issued in the Internal Revenue Code Section 351 transaction on March 19, 2018. The Section 351 transaction treated the acquisition of the Know-How for stock as a tax-free exchange. As a result, under ASC 740-10-25-51 *Income Taxes*, Processa recorded a deferred tax liability of $3,037,147 for the acquired temporary difference between the financial reporting basis of $11,038,929 and the tax basis of $1,782. The deferred tax liability 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 March 31, 2019, we had $1,248,532 in cash and a $1.7 million commitment for PoC Capital to fund our Phase 2a clinical trial for NL. Net cash used in our operating activities during the three months ended March 31, 2019 totaled $492,429 compared to $1,069,008 for the three months ended March 31, 2018.

Our total assets decreased by approximately $400,000 to $12.1 million at March 31, 2019 compared to $12.5 million at December 31, 2018. This decrease is a result of the operating costs we have incurred during the three months ended March 31, 2019, offset by the recording of right of use assets in conjunction with the adoption of ASC 842, and the tax effects resulting from the temporary difference between the book and tax basis of the intangible asset and transaction costs.

At March 31, 2019, our total liabilities, not including the impact of deferred income taxes, increased $304,401 to $950,105 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.

We continue to have $230,000 of Senior Convertible Notes outstanding that are held by Canadian individuals that, even though all the conditions for automatic conversion have been met, cannot be converted until the Alberta Securities Commission permits the issuance of our common stock units (consisting of shares of our common stock and stock purchase warrants) to these Canadian holders. If the Alberta Securities Commission does not allow us to convert this debt into common stock units, we will be required to repay the principal and related accrued interest of approximately $255,000.

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. At March 31, 2019, we had $1.2 million 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 $1.7 million has not been used as of March 31, 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 and our available resources (including the remaining Clinical Trial Funding commitment of $1.7 million from PoC Capital), we will need to raise additional capital before the end of the second quarter of 2019 in order to fund our future operations. While we believe our current resources are adequate to complete our upcoming Phase 2a trial, we do not currently have resources to conduct other future trials without raising additional capital. As noted above, the timing and extent of our spending will depend on the cost associated with, and the results of our 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 three months ended March 31, 2019 and 2018:

	Three months ended March 31,	
	2019	2018
Net cash provided by (used in):		
Operating activities	$ (492,429)	$ (1,069,008)
Investing activities	-	(1,782)
Financing activities	-	-
Net increase in cash and cash equivalents	$ (492,429)	$ (1,070,790)

Net cash used in operating activities

We used net cash in our operating activities of $492,429 and $1,069,008 during the three months ended March 31, 2019 and 2018, respectively. The decrease in cash used in operating activities during the first quarter of 2019 compared to the comparable period in 2018 was related to a decreased amount of direct cash costs incurred. Our net loss for the three months ended March 31, 2019 was $345,966 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 and that PoC Capital made direct payments to our CRO of $115,000 related to our Phase 2a trial. We also incurred a full quarter of amortization expense or $198,832 (versus $25,425 for the comparable period in 2018) and $58,559 of stock-based compensation during the three months ended March 31, 2019. During the three months ended March 31, 2018, we incurred a one-time cybersecurity fraud loss of approximately $144,000 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 three months ended March 31, 2019. Net cash used during the three months ended March 31, 2018 was $1,782 related to the transaction costs incurred to acquire the exclusive license of PCS-499 in 2018.

Net cash provided by (used in) financing activities

There were no financing activities for the three months ended March 31, 2019 and 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 March 31, 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 March 31, 2019.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during our quarter ended March 31, 2019, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We are continuing to take remediation actions to rectify our control deficiencies (including material weaknesses) through the adoption and implementation of written policies and procedures for transaction processing, accounting and financial reporting, as well as strengthening our supervisory review processes.

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

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

There are no material changes to the Company's risk factors as described in Item 1A of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

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

(a) Recent Sale of Unregistered Securities

We did not have any sales of unregistered securities during the three months ended March 31, 2019.

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

None.

(c) Issuer Purchases of Equity Securities

We did not repurchase any shares of our common stock during the three months ended March 31, 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
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: May 14, 2019

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

Exhibit 31.1

CERTIFICATIONS

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

1. I have reviewed this quarterly report on Form 10-Q of PROCESSA PHARMACEUTICALS, INC. for the three months ended March 31, 2019;

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

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

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

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

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

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

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

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

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

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

Date: May 14, 2019

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

Exhibit 31.2

CERTIFICATIONS

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

1. I have reviewed this quarterly report on Form 10-Q of PROCESSA PHARMACEUTICALS, INC. for the three months ended March 31, 2019;

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

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

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

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

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

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

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

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

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

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

Date: May 14, 2019

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

Exhibit 32.1

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

Solely for the purposes of complying with 18 U.S.C. §1350, I, the undersigned Chief Executive Officer of Processa Pharmaceuticals, Inc. (the "Company"), hereby certify, to the best of my knowledge, that the quarterly report on Form 10-Q of the Company for the quarter ended March 31, 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: May 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 March 31, 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: May 14, 2019

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