
**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 March 31, 2020

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 5,486,476 shares of common stock outstanding as of April 30, 2020.

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, 2020	December 31, 2019
ASSETS		
Current Assets		
Cash and cash equivalents	\$ 142,277	\$ 691,536
Due from related party	27,996	-
Prepaid expenses and other	186,252	315,605
Total Current Assets	<u>356,525</u>	<u>1,007,141</u>
Property and Equipment		
Software	19,740	19,740
Office equipment	9,327	9,327
Total Cost	<u>29,067</u>	<u>29,067</u>
Less: accumulated depreciation	<u>22,249</u>	<u>20,137</u>
Property and equipment, net	<u>6,818</u>	<u>8,930</u>
Other Assets		
Operating lease right-of-use assets, net of accumulated amortization	199,526	219,074
Intangible assets, net of accumulated amortization	9,443,622	9,642,454
Security deposit	5,535	5,535
Total Other Assets	<u>9,648,683</u>	<u>9,867,063</u>
Total Assets	<u>\$ 10,012,026</u>	<u>\$ 10,883,134</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Senior convertible notes, net of debt issuance costs	\$ 803,573	\$ 802,503
Current maturities of operating lease liability	78,013	77,992
Accrued interest	38,002	21,902
Accounts payable	93,216	75,612
Due to related parties	-	316
Accrued expenses	233,498	213,239
Total Current Liabilities	<u>1,246,302</u>	<u>1,191,564</u>
Non-current Liabilities		
Non-current operating lease liability	128,152	147,390
Net deferred tax liability	1,403,501	1,531,630
Total Liabilities	<u>2,777,955</u>	<u>2,870,584</u>
Commitments and Contingencies		
Stockholders' Equity		
Common stock, par value \$0.0001, 100,000,000 shares authorized; 5,486,476 issued and outstanding at both March 31, 2020 and December 31, 2019	549	549
Additional paid-in capital	19,089,865	18,994,008
Common stock deemed dividend payable: 28,971 shares at par value	3	3
Accumulated deficit	(11,856,346)	(10,982,010)
Total Stockholders' Equity	<u>7,234,071</u>	<u>8,012,550</u>
Total Liabilities and Stockholders' Equity	<u>\$ 10,012,026</u>	<u>\$ 10,883,134</u>

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, 2020 and 2019
(Unaudited)

	Three months ended March 31,	
	2020	2019
Operating Expenses		
Research and development expenses	\$ 501,771	\$ 484,750
General and administrative expenses	484,353	397,766
	(986,124)	(882,516)
Operating Loss		
Other Income (Expense)		
Interest expense	(17,170)	(4,600)
Interest income	829	5,985
	(1,002,465)	(881,131)
Net Operating Loss Before Income Tax Benefit		
Income Tax Benefit	128,129	130,299
	(874,336)	(750,832)
Net Loss	\$ (874,336)	\$ (750,832)
Net Loss Per Common Share - Basic and Diluted	\$ (0.16)	\$ (0.14)
Weighted Average Common Shares Used to Compute Net Loss Per Common Shares - Basic and Diluted	5,515,447	5,525,009

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, 2020 and 2019
(Unaudited)

	Common Stock		Additional Paid-In Capital	Common Stock Dividend Payable	Accumulated Deficit	Total
	Shares	Amount				
Balance at January 1, 2020	5,486,476	\$ 549	\$ 18,994,008	\$ 3	\$ (10,982,010)	\$ 8,012,550
Stock-based compensation	-	-	98,663	-	-	98,663
Transaction costs related to anticipated 2020 offering	-	-	(2,806)	-	-	(2,806)
Net loss	-	-	-	-	(874,336)	(874,336)
Balance, March 31, 2020	<u>5,486,476</u>	<u>\$ 549</u>	<u>\$ 19,089,865</u>	<u>\$ 3</u>	<u>\$ (11,856,346)</u>	<u>\$ 7,234,071</u>

	Common Stock		Additional Paid-In Capital	Subscription Receivable	Accumulated Deficit	Total
	Shares	Amount				
Balance at January 1, 2019	5,525,009	\$ 552	\$ 19,124,600	\$ (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	<u>5,525,009</u>	<u>\$ 552</u>	<u>\$ 19,183,159</u>	<u>\$ (1,685,000)</u>	<u>\$ (8,374,966)</u>	<u>\$ 9,123,745</u>

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, 2020 and 2019
(Unaudited)

	2020	2019
Cash Flows From Operating Activities		
Net loss	\$ (874,336)	\$ (750,832)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	2,112	2,111
Non-cash lease expense for right-of-use assets	19,548	17,947
Amortization of debt issuance costs	1,070	-
Amortization of intangible asset	198,832	198,832
Deferred income tax benefit	(128,129)	(130,299)
Stock-based compensation	98,663	58,559
Net changes in operating assets and liabilities:		
Prepaid expenses and other	129,353	10,632
Operating lease liability	(19,217)	(19,276)
Accrued interest	16,100	4,600
Accounts payable	17,604	(9,045)
Due (from) to related parties	(28,312)	(25,582)
Accrued expenses	20,259	34,924
Net cash used in operating activities	<u>(546,453)</u>	<u>(607,429)</u>
Cash Flows From Financing Activities		
Proceeds received in satisfaction of stock subscription receivable	-	115,000
Transaction costs related to anticipated 2020 offering	(2,806)	-
Net cash (used in) provided by financing activities	<u>(2,806)</u>	<u>115,000</u>
Net Decrease in Cash	<u>(549,259)</u>	<u>(492,429)</u>
Cash and Cash Equivalents – Beginning of Period	<u>691,536</u>	<u>1,740,961</u>
Cash and Cash Equivalents – End of Period	<u>\$ 142,277</u>	<u>\$ 1,248,532</u>
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
Net	<u>\$ -</u>	<u>\$ -</u>

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

PCS499

Our lead product, PCS499, is an oral tablet that is a deuterated analog of the major metabolites of pentoxifylline (Trental[®]). The advantage of PCS499 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 PCS499 may result in clinical efficacy. The lead indication currently under development for PCS499 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.

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. PCS499 may provide a solution since PCS499 and its metabolites affect a number of biological pathways, several of which contribute to the pathophysiology associated with NL.

On June 22, 2018, the FDA granted orphan-drug designation for PCS499 for the treatment of NL. On September 28, 2018, the FDA cleared our IND for PCS499 in NL such that we could move forward with the Phase 2 trial multicenter, open-label prospective study designed to determine the safety and tolerability of PCS499 in patients with NL. The first enrolled NL patient in this Phase 2 clinical trial was dosed on January 29, 2019 and the study completed enrollment on August 23, 2019. The main objective of the trial is to evaluate the safety and tolerability of PCS499 in patients with NL and to use the collected safety and efficacy data to design future clinical trials. Based on toxicology studies and healthy human volunteer studies, Processa and the FDA agreed that a PCS499 dose of 1.8 grams/day would be the highest dose administered to NL patients in this Phase 2 trial. As anticipated, the PCS499 dose of 1.8 grams/day, 50% greater than the maximum tolerated dose of PTX, appeared to be well tolerated with no serious adverse events reported. Ten patients reported adverse events in the study, all of which have been mild in severity. As expected, gastrointestinal symptoms have been the most noted adverse events and reported in four patients, all of which were mild in severity and resolved within 1-2 weeks of starting dosing.

The two patients presenting with more severe ulcerated NL had ulcers for more than two months prior to dosing. At baseline, the reference ulcer in one of the two patients measured 3.5 cm² and had completely closed by Month 2 of treatment. The second patient had a baseline reference ulcer of 1.2 cm² which completely closed by Month 9. In addition, while in the trial one of these patients also developed small ulcers at other sites as a result of contact trauma to the site and these ulcers resolved within one month. The other ten patients presenting with mild to moderate NL and no ulceration had some improvement of the NL lesions but not as dramatic as the more serious ulcerated patients. Historically, less than 20% of all the patients with NL naturally progress to complete healing. Although the natural healing of the more severe NL patients with ulcers has not been evaluated independently, medical experts who treat NL patients believe that the natural progression of an open ulcerated wound to complete closure would be less than 5-10% if followed for approximately 12 months after presentation. In those patients without ulcers in our clinical trial, we have only seen a slight change in the NL lesion.

On March 25, 2020, we met with the FDA and discussed the clinical program, as well as the nonclinical and clinical pharmacology plans to support the submission of the PCS499 New Drug Application (NDA) in the U.S. for the treatment of ulcers in NL patients. With input from the FDA through a Special Protocol Assessment, we will be designing and conducting a Phase 3 trial to evaluate the ability of PCS499 to completely close ulcers in patients with NL. We initially planned to begin recruiting for this trial in the fourth quarter of 2020 but with the COVID-19 pandemic, we expect to begin recruiting patients in 2021. The FDA will determine if a second confirmatory Phase 3 trial is required after reviewing the results from this initial trial.

PCS100

On August 29, 2019, we entered into an exclusive license agreement with Akashi Therapeutics, Inc. (“Akashi”) to develop and commercialize an anti-fibrotic, anti-inflammatory drug, PCS100, which also promotes healthy muscle fiber regeneration. In previous clinical trials in Duchenne Muscular Dystrophy (DMD), PCS100 showed promising improvement in the muscle strength of non-ambulant pediatric patients. Although the FDA placed a clinical hold on the DMD trial after a serious adverse event in a pediatric patient, FDA has removed the drug off clinical hold and defined how PCS100 can resume clinical trials in DMD. Once we have obtained adequate funding, we plan to develop PCS100 in rare adult fibrotic related diseases such as focal segmental glomerulosclerosis, idiopathic pulmonary fibrosis or Scleroderma.

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 Article 8 of Regulation S-X.

Accordingly, they do not include all the information and disclosures required by U.S. GAAP for complete financial statements. All material intercompany accounts and transactions have been eliminated in consolidation. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments necessary, which are of a normal and recurring nature, for the fair presentation of the Company’s financial position and of the results of operations and cash flows for the periods presented. These condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the SEC. 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 on private placements with a small group of accredited investors to finance our business and operations. On September 20, 2019, we entered into two separate line of credit agreements (“LOC Agreement”) with DKBK Enterprises, LLC (“DKBK”) and current shareholder CorLyst, LLC (“CorLyst”), both related parties (“Lenders”), which provide a revolving commitment of up to \$700,000 each (\$1.4 million total). Under the LOC Agreements, all funds borrowed will bear an 8% annual interest rate. The Lenders have the right to convert all or any portion of the debt and interest into Processa common shares. Our Chief Executive Officer (CEO) is also the CEO and Managing Member of both Lenders. CorLyst directly holds 1,073,050 shares of Processa common stock, representing approximately 19.6% of the Company’s outstanding shares of voting capital stock. On April 2, 2020, we borrowed \$200,000 under the LOC Agreement with DKBK.

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, 2020, we had an accumulated deficit of \$11.9 million, incurred a net loss for the three months of \$874,336 and used \$546,453 in net cash from operating activities from continuing operations. At March 31, 2020, we had cash and cash equivalents totaling \$142,277.

Based on our current plan, we will need to raise additional capital to fund our future operations. While we believe our current resources are adequate to complete our current Phase 2a trial for NL, we do not currently have resources to conduct other future trials, such as the Phase 3 clinical trial approved by the FDA, or develop PCS100 without raising additional capital. We believe that our existing cash and LOC Agreements will enable us to fund our operating expenses and capital expenditure requirements into the third quarter of 2020. 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.

We have begun the process to raise capital in an underwritten public offering, however, we have faced delays due to the global pandemic caused by the novel coronavirus, COVID-19. On May 5, 2020, we received \$162,459 under the Paycheck Protection Program.

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 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, 2020.

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, 2020 and 2019 excludes the impact of potentially dilutive common shares related to outstanding stock options and warrants and the conversion of our 2017 and 2019 Senior Notes since those shares would have an anti-dilutive effect on loss per share.

In 2019, we determined the sale of the 2019 Senior Notes triggered the full ratchet anti-dilution provision of the common stock we sold in 2018 Private Placement Transactions. As a result, those shareholders were entitled to 28,971 shares of common stock in the fourth quarter of 2019. We will issue 28,971 shares of common stock to these shareholders in 2020. For purposes of computing our basic and diluted EPS, we included the related shares which will be issued in 2020 in our weighted number of common shares outstanding for the three months ended March 31, 2020.

Our diluted net loss per share for the three months ended March 31, 2020 and 2019 excluded 782,923 and 660,511 of potentially dilutive common shares, respectively, related to outstanding stock options and warrants and the conversion of our Senior Notes since those shares would have had an anti-dilutive effect on loss per share during the years then ended.

Recent Accounting Pronouncements

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

Note 2 – Intangible Assets

Intangible assets at March 31, 2020 and December 31, 2019 consisted of the following:

	March 31, 2020	December 31, 2019
Gross intangible assets	\$ 11,059,429	\$ 11,059,429
Less: accumulated amortization	(1,615,807)	(1,416,975)
Total intangible assets, net	<u>\$ 9,443,622</u>	<u>\$ 9,642,454</u>

Amortization expense was \$198,832 for the three months ended March 31, 2020 and 2019 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 PCS499 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 PCS499, 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, 2020, and December 31, 2019, 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, 2020 and 2019. 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, 2020 or 2019. At March 31, 2020, we had outstanding options to purchase 175,466 shares of our common stock of which options for the purchase of 34,557 shares of our common stock were vested. We recorded \$98,663 and \$58,559 of stock-based compensation expense for the three months ended March 31, 2020 and 2019, respectively.

Note 5 – Notes Payable

Line of Credit Agreements

On September 20, 2019, we entered into two separate Line of Credit Agreements (“LOC Agreements”) with DKBK Enterprises, LLC (“DKBK”) and current shareholder CorLyst, LLC (“CorLyst”), both related parties (“Lenders”), which provide a revolving commitment of up to \$700,000 each (\$1.4 million total). Under the LOC Agreements, all funds borrowed will bear an 8% annual interest rate. The Lenders have the right to convert all or any portion of the debt and interest into shares of our common stock at a conversion price equal to the lower of (i) \$14.28 per share, (ii) a price per share equal to a 10% discount to the pre-money valuation of a Qualified Financing or an Equity State Transaction, or (iii) at an adjusted price; all as defined in the 2019 Senior Note agreement. The Lenders will also receive stock purchase warrants on a 1:1 basis to the number of shares of common stock received that have an exercise price equal to the greater of (i) the closing price of our common stock on the date of conversion or (ii) \$19.04 per share. Our Chief Executive Officer (CEO) is also the CEO and Managing Member of both Lenders. CorLyst directly holds 1,073,050 shares of Processa common stock, representing approximately 19.6% of the Company’s outstanding shares of voting capital stock at December 31, 2019.

2019 Senior Notes

During the fourth quarter of 2019 existing shareholders purchased \$805,000 of 8% Senior Convertible Notes (“2019 Senior Notes”) from us. The 2019 Senior Notes bear interest at 8% per year and if converted, the interest is payable in kind (in common stock). The 2019 Senior Notes mature on December 15, 2020. At March 31, 2020 and December 31, 2019, we had \$805,000 of 2019 Senior Notes outstanding.

The 2019 Senior Notes are convertible by the holder upon (i) completion of listing our common stock on either the Nasdaq Capital Market or the New York Stock Exchange or if we raise at least \$14 million, prior to December 15, 2020, the maturity date of the 2019 Senior Notes, in one or more qualified financings. If the 2019 Senior Notes are not paid or converted prior to their maturity date, the principal and any accrued interest will be automatically or mandatorily converted into our common stock. The 2019 Senior Notes, plus any accrued interest, is convertible into shares of our common stock at a conversion price equal to the lower of (i) \$14.28 per share or (ii) a price per share equal to a 10% discount to the pre-money valuation of a Qualified Financing or an Equity State Transaction, both as defined in the 2019 Senior Note agreement, occurring after the closing of the 2019 Senior Note financing. Upon either mandatory conversion or conversion at the holder’s option, the holder will also receive stock purchase warrants on a 1:1 basis to the number of shares of common stock received that have an exercise price equal to the greater of (i) the closing price of our common stock on the date of conversion or (ii) \$19.04 per share.

The 2019 Senior Notes provide the holders with (a) the option of receiving 110% of principal plus accrued interest in the event there is a change of control prior to conversion of the 2019 Senior Notes; (b) weighted-average anti-dilution protection in event of any sale of securities at a net consideration per share that is less than the applicable conversion price per share to the holder until we have raised an additional \$14 million from the sale of certain securities; and (c) certain preemptive rights pro rata to their respective interests through December 31, 2021.

The 2019 Senior Notes contains negative covenants that do not permit us to incur additional indebtedness or liens on property or assets owned, repurchase common stock, pay dividends, or enter into any transaction with affiliates of ours that would require disclosure in a public filing with the Securities and Exchange Commission. Upon an event of default, the outstanding principal amount of the Senior Notes, plus accrued but unpaid interest and other amounts owing in respect thereof through the date of acceleration, shall become immediately due and payable in cash at the holder’s election, if not cured within the cure period.

We incurred \$4,280 in debt issuance costs related to the 2019 Senior Notes. The debt issuance costs are amortized to interest expense using straight line amortization over the term of the 2019 Senior Notes.

Note 6 – Stockholders' Equity

On September 30, 2019, our Pledge Agreement with PoC Capital was amended to reduce the committed funds under this Agreement from \$1.8 million to \$900,000, which was paid in full as of December 31, 2019. As part of the Pledge Agreement amendment, PoC Capital forfeited the pledged collateral (56,640 shares of our common stock and warrants to purchase 56,640 shares of our common stock) in the amended agreement. The forfeited shares and warrants have been returned to us.

We have not had any sales of our preferred stock since we were incorporated on March 29, 2011 and there were no issued or outstanding shares of preferred stock at March 31, 2020 or December 31, 2019.

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 three months ended March 31, 2020 and 2019 was as follows:

	Three months ended March 31,	
	2020	2019
Basic and diluted net loss per share:		
Net loss	\$ (874,336)	\$ (750,832)
Weighted average number of common shares-basic and diluted	5,515,447	5,525,009
Basic and diluted net loss per share	<u>\$ (0.16)</u>	<u>\$ (0.14)</u>

We have determined the sale of the 2019 Senior Notes in late 2019, which are convertible into common stock at a conversion rate of \$14.28 per share, triggered the full ratchet anti-dilution provision of the common stock we sold in 2018 Private Placement Transactions. As a result, those shareholders were entitled to 28,971 shares of common stock in the fourth quarter of 2019. We will issue 28,971 shares of common stock to these shareholders in 2020. For purposes of computing our basic and diluted EPS, we included these shares in our weighted number of common shares outstanding for the three months ended March 31, 2020.

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.

	2020	2019
Stock options and purchase warrants	725,423	642,657
Senior convertible notes	57,500	17,854

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 condensed consolidated statement of operations totaled \$24,207 and \$24,573 for the three months ended March 31, 2020 and 2019, respectively. The weighted average remaining lease terms and discount rate for our operating leases were as follows at March 31, 2020:

Weighted average remaining lease term (years) for our facility and equipment leases	2.47
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, 2020:

2020	\$	69,321
2021		90,495
2022		69,741
Total lease payments		229,557
Less: Interest		(23,392)
Present value of lease liabilities		206,165
Less: current maturities		(78,013)
Non-current lease liability	\$	128,152

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. We did not receive reimbursements during the three months ended March 31, 2020. Amounts due from CorLyst at March 31, 2020 and December 31, 2019 were \$23,452 and \$0, respectively.

At March 31, 2020, we also had approximately \$4,500 due from employees for health insurance contributions. We did not have comparable a similar receivable at December 31, 2019.

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 no purchase obligations at March 31, 2020.

Note 11 – Subsequent Event

As mentioned in Note 1 – Going Concern, on April 2, 2020, we borrowed \$200,000 under the LOC Agreement with DKBK. We also received \$162,459 on May 5, 2020 under the Paycheck Protection Program.

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; the impact of the global pandemic caused by the novel coronavirus, COVID-19, including its impact on our ability to obtain financing or complete clinical trials; 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, 2019, which is available on the SEC's website at www.sec.gov. All forward-looking statements are qualified in their entirety by this cautionary statement, and the Company undertakes no obligation to revise or update this Quarterly Report on Form 10-Q to reflect events or circumstances after the date hereof.

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

Overview

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

On October 4, 2017, we acquired all the net assets of Promet Therapeutics, LLC ("Promet") a private Delaware limited liability company, including the rights to the CoNCERT Agreement in exchange for 4,535,036 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. In March 2018, Promet released 298,615 shares to CoNCERT in connection with exercising the license and option agreement. Promet has since distributed the remaining 4,236,421 shares of the common stock it held to its partners. 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.

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 PCS499, 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, 2020, we had an accumulated deficit of \$11.9 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 PCS499 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 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 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 having 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 on private placements with a small group of accredited investors to finance our business and operations. On September 20, 2019, we entered into two separate Line of Credit Agreements ("LOC Agreements") with DKBK Enterprises, LLC ("DKBK") and current shareholder CorLyst, LLC ("CorLyst"), both related parties ("Lenders"), which provide a revolving commitment of up to \$700,000 each (\$1.4 million total). Under the LOC Agreements, all funds borrowed will bear an 8% annual interest rate. The Lenders have the right to convert all or any portion of the debt and interest into Processa common shares. Our Chief Executive Officer (CEO) is also the CEO and Managing Member of both Lenders. CorLyst directly holds 1,073,050 shares of Processa common stock, representing approximately 19.6% of the Company's outstanding shares of voting capital stock. As of April 30, 2020, we have borrowed \$200,000 under the LOC Agreement with DKBK.

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, 2020, we incurred a net loss from continuing operations of \$874,336 and used \$546,453 in net cash from operating activities. We expect our operating costs to be substantial as we incur costs related to the clinical trials for our product candidates and that we will operate at a loss for the foreseeable future. At March 31, 2020, we had cash and cash equivalents totaling \$142,277.

In December 2019, we closed our bridge financing and issued \$805,000 of the 2019 Senior Notes to accredited investors. In order to preserve cash, we have also delayed some of our cash outflows, primarily through the deferred payment of salaries (\$186,044, which has been accrued and included in accrued expenses at March 31, 2020) until such time as we have raised sufficient funding.

Based on our current plan, we will need to raise additional capital to fund our future operations. While we believe our current resources are adequate to complete our current Phase 2a trial for NL, we do not currently have resources to conduct other future trials, such as the Phase 3 clinical trial approved by the FDA, or develop PCS100 without raising additional capital. We believe that our existing cash and LOC Agreements will enable us to fund our operating expenses and capital expenditure requirements into the third quarter of 2020. 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.

We have begun the process to raise capital in an underwritten public offering, however, we have faced delays due to the global pandemic caused by the novel coronavirus, COVID-19. On May 5, 2020, we received \$162,459 under the Paycheck Protection Program.

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 three months ended March 31, 2020. The accompanying consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of recorded assets, or the amounts and classification of liabilities that might be different should the Company be unable to continue as a going concern based on the outcome of these uncertainties described above.

Status of our Phase 2a Clinical Trial in Necrobiosis Lipoidica

Our lead product, PCS499, is an oral tablet that is a deuterated analog of one of the major metabolites of pentoxifylline (Trental[®]). The advantage of PCS499 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 PCS499 may result in clinical efficacy. The lead indication currently under development for PCS499 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.

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. PCS499 may provide a solution since PCS499 and its metabolites affect a number of biological pathways, several of which contribute to the pathophysiology associated with NL.

On June 22, 2018, the FDA granted orphan-drug designation for PCS499 for the treatment of NL. On September 28, 2018, the FDA cleared our IND for PCS499 in NL such that we could move forward with the Phase 2 trial multicenter, open-label prospective study designed to determine the safety and tolerability of PCS499 in patients with NL. The first enrolled NL patient in this Phase 2 clinical trial was dosed on January 29, 2019 and the study completed enrollment on August 23, 2019. The main objective of the trial is to evaluate the safety and tolerability of PCS499 in patients with NL and to use the collected safety and efficacy data to design future clinical trials. Based on toxicology studies and healthy human volunteer studies, Processa and the FDA agreed that a PCS499 dose of 1.8 grams/day would be the highest dose administered to NL patients in this Phase 2 trial. As anticipated, the PCS499 dose of 1.8 grams/day, 50% greater than the maximum tolerated dose of PTX, appeared to be well tolerated with no serious adverse events reported. Ten patients reported adverse events in the study, all of which have been mild in severity. As expected, gastrointestinal symptoms have been the most noted adverse events and reported in four patients, all of which were mild in severity and resolved within 1-2 weeks of starting dosing.

The two patients presenting with more severe ulcerated NL had ulcers for more than two months prior to dosing. At baseline, the reference ulcer in one of the two patients measured 3.5 cm² and had completely closed by Month 2 of treatment. The second patient had a baseline reference ulcer of 1.2 cm² which completely closed by Month 9. In addition, while in the trial one of these patients also developed small ulcers at other sites as a result of contact trauma to the site and these ulcers resolved within one month. The other ten patients presenting with mild to moderate NL and no ulceration had some improvement of the NL lesions but not as dramatic as the more serious ulcerated patients. Historically, less than 20% of all the patients with NL naturally progress to complete healing. Although the natural healing of the more severe NL patients with ulcers has not been evaluated independently, medical experts who treat NL patients believe that the natural progression of an open ulcerated wound to complete closure would be less than 5-10% if followed for approximately 12 months after presentation. In those patients without ulcers in our clinical trial, we have only seen a slight change in the NL lesion.

On March 25, 2020, we met with the FDA and discussed the clinical program, as well as the nonclinical and clinical pharmacology plans to support the submission of the PCS499 New Drug Application (NDA) in the U.S. for the treatment of ulcers in NL patients. With input from the FDA through a Special Protocol Assessment, we will be designing and conducting a Phase 3 trial to evaluate the ability of PCS499 to completely close ulcers in patients with NL. We initially planned to begin recruiting for this trial in the fourth quarter 2020 but with the COVID-19 pandemic, we expect to begin recruiting patients in 2021. The FDA will determine if a second confirmatory Phase 3 trial is required after reviewing the results from this initial trial.

Additional information about our business and operations is contained in our Annual Report on Form 10-K for the year ended December 31, 2019.

License Agreement for PCS100

On August 29, 2019, we entered into an exclusive license agreement with Akashi Therapeutics, Inc. (“Akashi”) to develop and commercialize an anti-fibrotic, anti-inflammatory drug, PCS100, which also promotes healthy muscle fiber regeneration. In previous clinical trials in Duchenne Muscular Dystrophy (DMD), PCS100 showed promising improvement in the muscle strength of non-ambulant pediatric patients. Although the FDA placed a clinical hold on the DMD trial after a serious adverse event in a pediatric patient, FDA has removed the drug off clinical hold and defined how PCS100 can resume clinical trials in DMD. Once we have obtained adequate funding, we plan to develop PCS100 in rare adult fibrotic related diseases such as focal segmental glomerulosclerosis, idiopathic pulmonary fibrosis or Scleroderma.

The Akashi Agreement provides us with a worldwide license to research, develop, make and commercialize products comprising or containing PCS100. As partial consideration for the license, we paid \$10,000 to Akashi upon full execution of the license agreement. This upfront payment was expensed as a research and development cost. As additional consideration, we will pay Akashi development and regulatory milestone payments (up to \$3.0 million per milestone) upon the achievement of certain milestones, which primarily consist of having a drug indication approved by a regulatory authority in the United States or another country. In addition, we must pay Akashi one-time sales milestone payments based on the achievement during a calendar year of one or more thresholds for annual sales for products made and pay royalties based on annual licensing sales. We are also required to split any milestone payments we receive with Akashi based on any sub-license agreement we may enter into.

We are required to use commercially reasonable efforts, at our sole cost and expense, to research, develop and commercialize products in one or more countries, including meeting specific diligence milestones that consist of (i) requesting a meeting with the FDA for a first indication within 18 months of the date of the agreement, (ii) submitting an IND for a drug indication on or before June 30, 2022 and (iii) initiating a Phase 1 or 2 trial for a drug indication on or before December 30, 2022. Either party may terminate the agreement in the event of a material breach of the license agreement that has not been cured following written notice and a 60-day opportunity to cure such breach (which is shortened to 15 days for a payment breach).

Results of Operations

Comparison of the three months ended March 31, 2020 and 2019

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

	Three months ended March 31,		Change
	2020	2019	
Operating Expenses			
Research and development expenses	\$ 501,771	\$ 484,750	\$ 17,021
General and administrative expenses	484,353	397,766	86,587
Operating Loss	(986,124)	(882,516)	
Other Income (Expense)			
Interest expense	(17,170)	(4,600)	(12,570)
Interest income	829	5,985	(5,156)
Net Operating Loss Before Income Tax Benefit	(1,002,465)	(881,131)	
Income Tax Benefit	128,129	130,299	(2,170)
Net Loss	<u>\$ (874,336)</u>	<u>\$ (750,832)</u>	

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, 2020 and 2019, we incurred total research and development expenses of \$501,771 and \$484,750, respectively, for the continued development and testing of our lead product, PCS499. Costs for the three months ended March 31, 2020 and 2019 were as follows:

	Three months ended March 31,	
	2020	2019
Amortization of intangible assets	\$ 198,832	\$ 198,832
Research and development salaries and benefits	140,298	158,855
Preclinical, clinical trial and other costs	162,641	127,063
Total	<u>\$ 501,771</u>	<u>\$ 484,750</u>

Overall, during the three months ended March 31, 2020, our research and development costs increased by \$17,021 as detailed below.

The increase in research and development expenses was due to an increase in preclinical, clinical trial and other costs of \$35,578 during the three months ended March 31, 2020 when compared to the same period in 2019. This increase was attributable to regulatory filing and consulting fees as we prepared for our meeting with the FDA, as well as increased costs related to our Phase 2a clinical trial. The increase was offset by a decrease in research and development salaries and benefits of \$18,557 for the three months ended March 31, 2020 when compared to the same period in 2019 related to the departure of two research and development team members in the first quarter of 2020.

We anticipate our research and development costs to increase in the future as we complete our Phase 2a clinical trial activities for NL in 2020. We incurred \$98,883 of costs related to our Phase 2a trial during the three months ended March 31, 2020 and expect to spend an additional \$335,000 for the remainder of the trial. We believe, based on our estimates, the total cost of our current Phase 2a trial to be approximately \$1.5 million. We had a clinical trial funding investor pay for \$900,000 of the clinical trial costs and we will cover the remaining \$600,000 with funds received from the sale of our 2019 Senior Notes and our LOC Agreements, as necessary.

The funding necessary to bring a drug candidate to market is, however, subject to numerous uncertainties. Once a drug candidate is identified, the further development of that drug candidate can be halted or abandoned at any time due to a number of factors. These factors include, but are not limited to, funding constraints, safety or a change in market demand. For each of our drug candidate programs, we periodically assess the scientific progress and merits of the programs to determine if continued research and development is economically viable. Certain of our programs may be terminated due to the lack of scientific progress and lack of prospects for ultimate commercialization. We anticipate our research and development costs to increase in the future as we complete our Phase 2a clinical trial activities, prepare a Special Protocol Assessment and beginning designing and conducting a Phase 3 trial to evaluate the ability of PCS499 to completely close ulcers in patients with NL and initiate any research activities related to PCS100. We expect to begin recruiting patients for our Phase 3 trial for NL in 2021. The FDA will determine if a second confirmatory Phase 3 trial is required after reviewing the results from this initial trial.

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, 2020 increased by \$86,587 to \$484,353 from \$397,766 for the three months ended March 31, 2019. The majority of the increase was due to a \$116,000 increase in our Delaware franchise tax as a result of our 1-for-7 reverse stock split in December 2019. We are currently evaluating options to decrease our franchise tax liability in the future.

We also experienced an increase in our insurance and office expenses of \$11,000 and increased payroll and related costs of approximately \$18,000. These increases were offset by reductions in professional fees for legal, accounting, advisory and consulting costs, as well as decreases in travel, utilities, training and repairs and maintenance of approximately \$60,000. Reimbursements from CorLyst of \$24,747 for rent and other costs during the three months ended March 31, 2020 were approximately \$1,200 less than the same period in 2019.

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 and Interest Income

Interest expense was \$17,170 and \$4,600 for the three months ended March 31, 2020 and 2019, respectively, related to our \$805,000 and \$2.58 million of 8% Senior Notes sold in 2019 and 2017, respectively. Included in interest expense is the amortization of debt issuance costs totaling \$1,070 and \$0 for the three months ended March 31, 2020 and 2019, respectively.

Interest income was \$829 and \$5,985 for the three months ended March 31, 2020 and 2019, respectively. Interest income represents interest earned on money market funds.

Income Tax Benefit.

An income tax benefit of \$128,129 was recognized for the three months ended March 31, 2020 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, 2020, we had \$142,277 in cash. Net cash used in our operating activities during the three months ended March 31, 2020 totaled \$546,453 compared to \$607,429 for the three months ended March 31, 2019.

Our total assets decreased by approximately \$871,000 to \$10.0 million at March 31, 2020 compared to \$10.9 million at December 31, 2019. This decrease is a result of the operating costs we have incurred during the three months ended March 31, 2020 since December 31, 2019.

At March 31, 2020, our total liabilities, not including the impact of deferred income taxes, increased \$35,500 to \$1,374,454 when compared to \$1,338,954 at December 31, 2019. This increase is due to increases in accounts payable, accrued expenses related to accrued salary liability and accrued interest related to the 2019 Senior Notes.

In December 2019, we closed our bridge financing and issued \$805,000 of the 2019 Senior Notes to accredited investors.

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 the effect of the non-deductibility of the amortization of the intangible asset and 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, 2020, we had \$142,277 in cash and cash equivalents compared to \$691,536 at December 31, 2019. In December 2019, we closed our bridge financing and issued \$805,000 of the 2019 Senior Notes to accredited investors. In order to preserve cash, we have also delayed some of our cash outflows, primarily through the deferred payment of salaries (\$186,044, which has been accrued and included in accrued expenses on the condensed consolidated balance sheet at March 31, 2020) until such time as we have raised sufficient funding.

On September 20, 2019, we entered into two separate LOC Agreements with DKBK and current shareholder CorLyst, both related parties, which provide a revolving commitment of up to \$700,000 each (\$1.4 million total). Under the LOC Agreements, all funds borrowed will bear an 8% annual interest rate. The Lenders have the right to convert all or any portion of the debt and interest into Processa common shares. Our Chief Executive Officer (CEO) is also the CEO and Managing Member of both Lenders. CorLyst directly holds 1,073,050 shares of Processa common stock, representing approximately 19.6% of the Company's outstanding shares of voting capital stock. As of April 30, 2020, we have drawn \$200,000 under the LOC Agreement with DKBK.

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 PCS499 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, we will need to raise additional capital to fund our future operations. While we believe our current resources are adequate to complete our current Phase 2a trial for NL, we do not currently have resources to conduct other future trials, such as the Phase 3 clinical trial approved by the FDA, or develop PCS100 without raising additional capital. We believe that our existing cash and LOC Agreements will enable us to fund our operating expenses and capital expenditure requirements into the third quarter of 2020. 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.

We have begun the process to raise capital in an underwritten public offering, however, we have faced delays due to the global pandemic caused by the novel coronavirus, COVID-19. On May 5, 2020, we received \$162,459 under the Paycheck Protection Program.

Cash Flows

The following table sets forth our sources and uses of cash and cash equivalents for the three months ended March 31, 2020 and 2019:

	Three months ended March 31,	
	2020	2019
Net cash (used in) provided by:		
Operating activities	\$ (546,453)	\$ (607,429)
Investing activities	-	-
Financing activities	(2,806)	115,000
Net decrease in cash	<u>\$ (549,259)</u>	<u>\$ (492,429)</u>

Net cash used in operating activities

We used net cash in our operating activities of \$546,453 and \$607,429 during the three months ended March 31, 2020 and 2019, respectively. The decrease in cash used in operating activities during the first quarter of 2020 compared to the comparable period in 2019 was related to a decreased amount of direct cash costs incurred, such as salaries. Our net loss for the three months ended March 31, 2020 was \$123,504 greater than the comparable period in 2019. This was due primarily to our increased clinical trial costs and accrued interest related to the 2019 Senior Notes.

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, 2020 or 2019.

Net cash (used in) provided by financing activities

We used net cash in our financing activities of \$2,806 related to the anticipated capital offering during the three months ended March 31, 2020. Net cash provided by financing activities during the three months ended March 31, 2019 is \$115,000 we received from our clinical trial funding investor in partial satisfaction of his stock subscription receivable that he paid directly to our CRO.

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, 2019.

Off Balance Sheet Arrangements

At March 31, 2020, 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

We have evaluated recently issued accounting pronouncements and determined that there is no material impact on our financial position or results of operations.

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 2019 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, 2020.

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, 2020, 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

The following additional risk factor related to COVID-19 should be read in conjunction with the risk factors set forth under “Item 1A. Risk Factors” in our 2019 Form 10-K. Except as described herein, there have been no material changes with respect to the risk factors disclosed in our 2019 Form 10-K.

The ongoing COVID-19 pandemic may disrupt our operations and affect our ability to successfully conduct clinical studies and raise capital.

In March 2020, the World Health Organization declared COVID-19 a pandemic. The COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains, and created significant volatility and disruption in the financial and capital markets. We are unable to accurately predict the full impact that the ongoing COVID-19 pandemic will have on our results from operations, financial condition, and scientific and clinical activities due to numerous factors that are not within our control, including the duration and severity of the outbreak, stay-at-home orders, business closures, travel restrictions, supply chain disruptions and employee illness or quarantines, which could result in disruptions to our operations and adversely impact our results from operations and financial condition. In addition, the COVID-19 pandemic has resulted in ongoing volatility in the financial and capital markets. If our access to capital is restricted or associated borrowing costs increase as a result of developments in financial markets relating to the COVID-19 pandemic, our operations and financial condition could be adversely impacted. In addition, we may experience delays in conducting our clinical trials as a result of stay-at-home orders or otherwise, which would delay our drug development process.

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, 2020.

(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, 2020.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

<u>SEC Ref. No.</u>	<u>Title of Document</u>
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 15, 2020

By: /s/ James Stanker
James Stanker
Chief Financial Officer
(Principal Financial and Accounting Officer)
Dated: May 15, 2020

CERTIFICATION

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, 2020;
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: May 15, 2020

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

CERTIFICATION

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, 2020;
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: May 15, 2020

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 March 31, 2020 (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 15, 2020

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, 2020 (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 15, 2020

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