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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 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	**45-1539785**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

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

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

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

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

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

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 [X]

The registrant has 5,515,447 shares of common stock outstanding as of July 31, 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)

	June 30, 2020	December 31, 2019
ASSETS		
Current Assets		
Cash and cash equivalents	$ 452,654	$ 691,536
Due from related party	26,497	-
Prepaid expenses and other	97,682	315,605
Total Current Assets	576,833	1,007,141
Property and Equipment		
Property and equipment, net	4,707	8,930
Other Assets		
Operating lease right-of-use assets, net of accumulated amortization	179,591	219,074
Intangible assets, net of accumulated amortization	9,244,790	9,642,454
Security deposit	5,535	5,535
Total Other Assets	9,429,916	9,867,063
Total Assets	$ 10,011,456	$ 10,883,134
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Senior convertible notes, net of debt issuance costs	$ 804,643	$ 802,503
Line of credit payable – related party	500,000	-
Note payable – Paycheck Protection Program, current portion	72,203	-
Current maturities of operating lease liability	71,967	77,992
Accrued interest	58,483	21,902
Accounts payable	73,371	75,612
Due to related parties	-	316
Accrued expenses	317,252	213,239
Total Current Liabilities	1,897,919	1,191,564
Non-current Liabilities		
Note payable – Paycheck Protection Program	90,256	-
Non-current operating lease liability	114,595	147,390
Net deferred tax liability	1,315,666	1,531,630
Total Liabilities	3,418,436	2,870,584
Commitments and Contingencies	-	-
Stockholders' Equity		
Common stock, par value $0.0001, 30,000,000 and 100,000,000 shares authorized; 5,514,447 and 5,486,476 issued and outstanding at June 30, 2020 and December 31, 2019	552	549
Additional paid-in capital	19,182,228	18,994,008
Common stock deemed dividend payable: 28,971 shares at par value	-	3
Accumulated deficit	(12,589,760)	(10,982,010)
Total Stockholders' Equity	6,593,020	8,012,550
Total Liabilities and Stockholders' Equity	$ 10,011,456	$ 10,883,134

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

Processa Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
Three and Six Months Ended June 30, 2020 and 2019
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating Expenses				
Research and development expenses	$ 427,109	$ 726,904	$ 925,855	$ 1,211,655
General and administrative expenses	374,878	410,072	859,255	807,837
Total operating expenses	801,987	1,136,976	1,788,110	2,019,492
Operating Loss	(801,987)	(1,136,976)	(1,788,110)	(2,019,492)
Other Income (Expense)				
Interest expense	(19,280)	(6,102)	(36,450)	(10,702)
Interest income	18	3,398	846	9,383
Total other income (expense)	(19,262)	(2,704)	(35,604)	(1,319)
Net Operating Loss Before Income Tax Benefit	(821,249)	(1,139,680)	(1,823,714)	(2,020,811)
Income Tax Benefit	87,835	170,602	215,964	300,901
Net Loss	$ (733,414)	$ (969,078)	$ (1,607,750)	$ (1,719,910)
Net Loss per Common Share - Basic and Diluted	$ (0.13)	$ (0.18)	$ (0.29)	$ (0.31)
Weighted Average Common Shares Used to Compute Net Loss Applicable to Common Shares - Basic and Diluted	5,515,447	5,525,009	5,515,447	5,525,009

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

Processa Pharmaceuticals, Inc.
Condensed Consolidated Statements of Changes in Stockholders' Equity
Six Months Ended June 30, 2020 and 2019
(Unaudited)

Six Months Ended June 30, 2019

	Common Stock		Additional Paid-In	Common Stock Dividend	Accumulated	
	Shares	Amount	Capital	Payable	Deficit	Total
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	5,486,476	549	19,089,865	3	(11,856,346)	7,234,071
Stock-based compensation	-	-	93,869	-	-	93,869
Stock dividend distributed due to full-ratchet anti-dilution adjustment	28,971	3	-	(3)	-	-
Transaction costs related to anticipated 2020 offering	-	-	(1,506)	-	-	(1,506)
Net loss	-	-	-	-	(733,414)	(733,414)
Balance, June 30, 2020	5,515,447	$ 552	$ 19,182,228	$ -	$ (12,589,760)	$ 6,593,020

Six Months Ended June 30, 2019

	Common Stock		Additional Paid-In	Subscription	Accumulated	
	Shares	Amount	Capital	Receivable	Deficit	Total
Balance, 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	5,525,009	552	19,183,159	(1,685,000)	(8,374,966)	9,123,745
Stock-based compensation	-	-	66,476	-	-	66,476
Payments made directly by investor for clinical trial costs	-	-	-	280,927	-	280,927
Net loss	-	-	-	-	(969,078)	(969,078)
Balance, June 30, 2019	5,525,009	$ 552	$ 19,249,635	$ (1,404,073)	$ (9,344,044)	$ 8,502,070

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

Processa Pharmaceuticals, Inc.
Condensed Consolidated Statements of Cash Flows
Six Months Ended June 30, 2020 and 2019
(Unaudited)

	2020	2019
Cash Flows From Operating Activities		
Net loss	$ (1,607,750)	$ (1,719,910)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	4,223	4,223
Non-cash lease expense for right-of-use assets	39,483	36,282
Amortization of debt issuance costs	2,140	-
Amortization of intangible asset	397,664	397,664
Deferred income tax benefit	(215,964)	(300,901)
Stock-based compensation	192,532	125,035
Net changes in operating assets and liabilities:		
Prepaid expenses and other	217,923	(10,090)
Operating lease liability	(38,820)	(38,940)
Accrued interest	36,581	8,587
Accounts payable	(2,241)	(148,751)
Due (from) to related parties	(26,813)	22,919
Accrued expenses	104,013	208,979
Net cash used in operating activities	(897,029)	(1,414,903)
Cash Flows From Financing Activities		
Proceeds received in satisfaction of stock subscription receivable	-	395,927
Borrowings on line of credit payable from related party	500,000	-
Proceeds received from our Paycheck Protection Program note payable	162,459	-
Transaction costs related to anticipated 2020 offering	(4,312)	-
Net cash (used in) provided by financing activities	658,147	395,927
Net Decrease in Cash	(238,882)	(1,018,976)
Cash and Cash Equivalents – Beginning of Period	691,536	1,740,961
Cash and Cash Equivalents – End of Period	$ 452,654	$ 721,985
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	$ -	$ -
Issuance of 28,971 shares of common stock due to triggering, in December 2019, the full ratchet anti-dilution provision of common stock sold in our 2018 Private Placement Transactions	$ 3	$ -

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 is a clinical stage biopharmaceutical company focused on the 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 condition. Within this group of pharmaceutical products, we currently are developing one product for multiple indications (i.e., the use of a drug to treat a particular disease) and will begin developing our newly acquired drugs (PCS11T and PCS100) once adequate funding has been obtained. We continue searching for additional products for our portfolio that meet our criteria.

PCS499

Our lead product, PCS499, is an oral tablet that is a deuterated analog of one of the major metabolites of pentoxifylline (PTX or Trental®). The advantage of PCS499 is that it potentially may work in many conditions because PCS499 and its metabolites act on multiple pharmacological targets that are important in the treatment of these conditions. Based on its pharmacological activity, we have identified 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 which can lead to more severe complications, such as deep tissue infections and osteonecrosis threatening life of the limb. Approximately 22,000 - 55,000 people in the United States and more than 120,000 people outside the United States are affected with ulcerated 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 the biological pathways 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 a Phase 2A trial multicenter, open-label prospective trial designed to determine the safety and tolerability of PCS499 in patients with NL. The first enrolled NL patient in this Phase 2A clinical trial was dosed on January 29, 2019 and the study completed enrollment on August 23, 2019. The main objective of the trial was 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 2A 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.

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 cm^2 and had completely closed by Month 2 of treatment. The second patient had a baseline reference ulcer of 1.2 cm^2 which completely closed by Month 9. In addition, while in the trial both 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 over the first one to two years after presenting with NL. 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 significantly less than the 20% reported as the maximum percentage of patients who naturally heal over the 12-24 months after NL presentation with the likelihood and time of healing possibly being dependent on the size of the ulcer. Although our study enrolled only two ulcerated patients, the existing ulcers and trauma ulcers in both patients completely closed supporting that the diverse pharmacology of PCS499 and its metabolites (similar to PTX) positively effects the open ulcers in NL. In addition, those patients without ulcers in our clinical trial also saw positive changes in their NL lesion, although to a much lesser extent than the closing of the more serious ulcers.

We have completed the patient portion of our Phase 2A trial of PCS499 in NL, with the last patient completing the trial during the first quarter of 2020. We are in the process of closing the trial, but the close out of our two sites has been delayed as a result of COVID-19.

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 we will be designing the next trial as a randomized, placebo controlled trial to evaluate the ability of PCS499 to completely close ulcers in patients with NL, along with an open labelled safety trial that will serve as an extension study for those in the randomized, placebo controlled trial. We initially planned to begin recruiting for the randomized, placebo-controlled trial in the fourth quarter 2020 but with the COVID-19 pandemic, we expect to begin recruiting patients in early 2021. The decision to conduct the study as a Phase 3 study with further input from the FDA via a Special Protocol Assessment, or to perform a smaller Phase 2B study, is still to be determined based on financial considerations, current pandemic concerns and other priorities within our portfolio. A Phase 2B or a Phase 3 trial would be of similar design but would differ in the number of patients. The FDA also noted that only a single pivotal clinical trial may be required for an NDA approval to treat ulcerated NL if the percent responders in the treatment arm is highly significant ($p << 0.05$) compared to the placebo arm. The FDA noted that the final determination of accepting only a single trial for approval would be dependent on the FDA review of the trial results.

PCS11T

On May 24, 2020, we entered into a condition precedent License Agreement (the "Aposense Agreement") with Aposense, LTD., ("Aposense"), pursuant to which we were granted a contingent license in the patent rights and the know-how to develop and commercialize their next generation irinotecan cancer drug, PCS-11T. Granting of the license is conditioned on the following being satisfied within 9 months of May 24, 2020 (or the Aposense Agreement shall terminate): (i) our closing of an equity financing and successful up-listing to Nasdaq and (ii) Aposense obtaining the approval of the Israel Innovation Authority for the consummation of the transactions contemplated by the Aposense Agreement.

PCS11T is a novel lipophilic anti-cancer pro-drug that is being developed for the treatment of the same solid tumors as prescribed for irinotecan. This pro-drug is a conjugate of a specific proprietary Aposense molecule connected to SN-38, the active metabolite of irinotecan. The proprietary molecule in PCS11T allows PCS11T to bind to cell membranes to form an inactive pro-drug depot on the cell with SN-38 preferentially accumulating in the membrane of tumors cells and the tumor core. This unique characteristic is expected to make the therapeutic window of PCS11T wider than all other irinotecan products such that the anti-tumor effect of PCS11T will occur at a much lower dose with a milder adverse effect profile than irinotecan. Irinotecan serves as a water-soluble pro-drug of SN-38, with SN-38 being significantly more potent as a topoisomerase I inhibitor than irinotecan. Despite the widespread use of commercially marketed irinotecan products in the treatment of metastatic colorectal cancer and other cancers resulting in peak annual sales of approximately $1.1 billion dollars, irinotecan has a narrow therapeutic window and includes an FDA "Black Box" warning for both neutropenia and severe diarrhea. Its adverse effects include diarrhea, neutropenia, leucopenia, lymphocytopenia, and anemia, which are major impediments to optimal dosing for efficacy since the dose must often be reduced with repeated treatment cycles. There is, therefore, a substantial unmet need to overcome the limitations of the current commercially marketed irinotecan products, improving efficacy and reducing the severity of treatment emergent adverse events. The potential wider therapeutic window of PCS11T will likely lead to more patients responding with less side effects when on PCS11T compared to other irinotecan products.

Pre-clinical studies conducted to date showed that that PCS11T has an efficacy advantage over Irinotecan as demonstrated by tumor eradication at much lower doses than irinotecan across various tumor xenograft models. PCS11T produced a marked, dose-related sustained tumor growth inhibition (TGI) in all the evaluated models. TGI in all of these models was significantly improved in comparison to irinotecan. Tumor regression was also observed in several models. PCS11T does not affect acetyl choline esterase (AChE) activity in human and rat plasma in vitro, which would suggest that PCS11T will show an improved safety profile, unlike irinotecan, which is known for its cholinergic related side-effects.

Prior to the License Agreement, Aposense had met with the FDA at a Pre-IND meeting. At that meeting, agreement was reached related to the necessary manufacturing and toxicological study requirements for filing the IND and the subsequent design of the Phase 1B study for PCS11T in the treatment of solid tumors. Depending upon our available funds, we are currently planning to manufacture the product at a GMP facility, conduct the required toxicological studies required to file the IND and initiate the Phase 1B study in oncology patients with solid tumors in late 2021.

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, the 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. At the present time we are evaluating the potential GMP manufacturing facilities and the potential indications for PCS100.

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 pharmaceutical company 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 primarily on private placements with a small group of accredited investors to finance our business and operations. As described in more detail below, we entered into two line of credit agreements last year with related parties providing a revolving commitment of an aggregate of up to $1.4 million. 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. At June 30, 2020, we had an accumulated deficit of $12.6 million, and during the six months ended June 30, 2020, we incurred a net loss of $1,607,750 and used $897,029 in net cash from operating activities from continuing operations. At June 30, 2020, we had cash and cash equivalents totaling $452,654.

On September 20, 2019, we entered into two separate Line of Credit Agreements ("LOC Agreements") to borrow up to $700,000 with current shareholders and related parties: DKBK Enterprises, LLC ("DKBK") and CorLyst, LLC ("CorLyst") ($1.4 million total). Under the LOC Agreements, all funds borrowed 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. Our Chief Executive Officer (CEO) is also the CEO and Managing Member of both lenders. DKBK directly holds 16,166 shares of our common stock, less than 1% of our outstanding common stock, and CorLyst beneficially owns 1,095,649 shares, representing 19.9% of our outstanding common stock. In April and June 2020, we drew $500,000 under the LOC Agreement with DKBK. On July 21, 2020, we drew an additional $200,000, bringing the total amount drawn under the LOC Agreement with DKBK to $700,000.

In December 2019, we closed our bridge financing and issued $805,000 of 2019 Senior Notes to accredited investors. In order to preserve cash, in August 2019 we began delaying some cash outflows, primarily through the deferred payment of certain salaries ($210,800 has been included in accrued expenses at June 30, 2020) until such time as we have raised sufficient funding.

In May 2020, we entered into a promissory note in favor of the Bank of Americaunder the Small Business Administration Paycheck Protection Program of the Coronavirus Aid, Relief and Economic Security Act of 2020 (the "CARES Act") for a $162,459 loan ("the PPP Loan"). We plan to use the loan proceeds for payroll costs, rent and utilities in accordance with the relevant terms and conditions of the CARES Act.

We have begun the process of raising capital in an underwritten public offering, however, we have faced delays due to the global pandemic caused by the novel coronavirus, COVID-19. 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 the closeout of our current Phase 2A trial for NL, we do not currently have resources to conduct other future trials, such as the Phase 2B/3 clinical trial approved by the FDA, or to develop our other drug candidates 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.

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 trial plans, 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 six months ended June 30, 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. For awards that contain performance vesting conditions, we do not recognize compensation expense until achieving the performance condition is probable. Stock-based awards with graded-vesting schedules are recognized on a straight-line basis over the requisite service period for each separately vesting portion of the award. We estimate the fair value of stock option grants using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. Stock-based compensation costs are recorded as general and administrative or research and development costs in the statements of operations based upon the underlying individual's role.

Net Loss Per Share

Basic loss per share is computed by dividing our net loss available to common shareholders by the weighted average number of shares of common stock outstanding during the year. Diluted loss per share is computed by dividing our net loss available to common shareholders by the diluted weighted average number of shares of common stock during the period. Since we experienced a net loss for both periods presented, basic and diluted net loss per share are the same. As such, diluted loss per share for the six months ended June 30, 2020 and 2019 excludes the impact of 740,899 and 719,083 potentially dilutive common shares, respectively, 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.

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 June 30, 2020 and December 31, 2019 consisted of the following:

	June 30, 2020	December 31, 2019
Gross intangible assets	$ 11,059,429	$ 11,059,429
Less: accumulated amortization	(1,814,639)	(1,416,975)
Total intangible assets, net	$ 9,244,790	$ 9,642,454

Amortization expense was $397,664 for the six months ended June 30, 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 year 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 June 30, 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 six months ended June 30, 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 our employees or non-employees during the six months ended June 30, 2020. During the six months ended June 30, 2019, we granted 129,919 stock options to employees and non-employees under the 2019 Omnibus Incentive Plan. At June 30, 2020, we had outstanding options to purchase 169,329 shares of our common stock of which options for the purchase of 56,853 shares of our common stock were vested. We recorded $192,532 and $125,035 of stock-based compensation expense for the six months ended June 30, 2020 and 2019, respectively.

Note 5 – 2019 Senior 8% Convertible Notes Payable

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 June 30, 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 – Related Party 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 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 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 Stake 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 at the time of conversion.

Our Chief Executive Officer (CEO) is also the CEO and Managing Member of both lenders. DKBK directly holds 16,166 shares of our common stock, representing less than 1% of our outstanding common stock, and CorLyst beneficially owns 1,095,649 shares of our common stock, representing 19.9% of our outstanding common stock at June 30, 2020. In April and June 2020, we drew $500,000 under the LOC Agreement with DKBK. On July 21, 2020, we drew an additional $200,000, bringing the total amount drawn under the LOC Agreement with DKBK to $700,000.

Note 7 – Paycheck Protection Program Loan

In May 2020, we entered into a $162,459 Paycheck Protection Promissory Note (the "PPP Loan") with the Bank of America. The PPP Loan was made under, and is subject to the terms and conditions of, the PPP which was established under the CARES Act and is administered by the U.S. Small Business Administration. The current terms of the loan is two years with a maturity date of May 5, 2022 and it contains a favorable fixed annual interest rate of 1.00%. Payments of principal and interest on the PPP Loan is deferred for the first six months of the term of the PPP Loan until November 5, 2020. Principal and interest are payable monthly and may be prepaid by us at any time prior to maturity with no prepayment penalties. Under the terms of the CARES Act, recipients can apply for and receive forgiveness for all, or a portion of the loan granted under the PPP. Such forgiveness will be determined, subject to limitations, based on the use of loan proceeds for certain permissible purposes as set forth in the PPP, including, but not limited to, payroll costs, mortgage interest, rent or utility costs (collectively, "Qualifying Expenses"), and on the maintenance of employee and compensation levels during a certain time period following the funding of the PPP Loan. We have used the proceeds of our PPP Loan for payroll costs. However, no assurance is provided that we will be able to obtain forgiveness of the PPP Loan in whole or in part. As of June 30, 2020, $72,203 of the total $162,459 PPP-related debt is classified as a current liability on our condensed consolidated balance sheets.

Note 8 – 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 of our common stock and stock purchase warrants have been returned to us.

We 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 common stock we sold in our 2018 Private Placement Transactions. As a result, those shareholders were entitled to 28,971 shares of common stock in the fourth quarter of 2019, which we issued on June 18, 2020. We accounted for these shares at December 31, 2019 as a deemed dividend payable at their par value.

On June 25, 2020, we amended our Certificate of Incorporation reducing the number of authorized shares of our common stock from 100,000,000 to 30,000,000. We believe 100,000,000 authorized shares of common stock was disproportionately large in relation to the Company's outstanding common stock and our anticipated future needs, and the reduction will reduce our future Delaware franchise tax.

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 June 30, 2020 or December 31, 2019.

Note 9 – Net Loss per Share of Common Stock

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

The computation of net loss per share for the six months ended June 30, 2020 and 2019 was as follows:

	Six months ended June 30,	
	2020	**2019**
Basic and diluted net loss per share:		
Net loss	$ (1,607,750)	$ (1,719,910)
Weighted average number of common shares-basic and diluted	5,515,447	5,524,895
Basic and diluted net loss per share	$ (0.29)	$ (0.31)

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	646,938	700,976
Senior convertible notes and LOC, plus related accrued interest	93,961	18,107
	740,899	719,083

Note 10 – 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 $23,995 and $24,729 for the three months ended June 30, 2020 and 2019, respectively, and $48,201 and $49,302 for the six months ended June 30, 2020 and 2019, respectively. The weighted average remaining lease terms and discount rate for our operating leases were as follows at June 30, 2020:

Weighted average remaining lease term (years) for our facility and equipment leases	2.23
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 June 30, 2020:

2020	$	45,869
2021		90,495
2022		69,741
Total lease payments		206,105
Less: Interest		(19,543)
Present value of lease liabilities		186,562
Less: current maturities		(71,967)
Non-current lease liability	$	114,595

Note 11 – License Agreement with Aposense, Ltd.

On May 24, 2020 we executed a condition precedent License Agreement (“Aposense Agreement”) with Aposense under which they will provide us with an exclusive worldwide license (excluding China) to research, develop and commercialize products comprising or containing PCS11T. The grant of license is conditioned on the following being satisfied within 9 months of May 24, 2020 (or the Aposense Agreement shall terminate): (i) our closing of an equity financing and successful up-listing to Nasdaq and (ii) Aposense obtaining the approval of the Israel Innovation Authority for the consummation of the transactions contemplated by the Aposense Agreement. Within five business days of satisfying the conditions, we must issue Aposense a number of shares of common stock determined by dividing $2.5 million by the price per share paid by such investors in equity financing. Such shares will be subject to a lock-up, with 40% of such shares released from such lock up after six months and the remaining two 30% tranches to be released upon completion of the next two subsequent quarters. As additional consideration, we will pay Aposense 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 Aposense 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 Aposense 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) submitting an IND for a drug indication within 30 months following the satisfaction of the license conditions above; (ii) dosing of a first patient with a product within 42 months following the satisfaction of the license conditions above; (iii) dosing of a first patient with a product in a pivotal clinical trial within 72 months following the satisfaction of the license conditions above and (iv) an NDA submission within 120 months following the satisfaction of the license conditions above. Either party may terminate the Aposense Agreement in the event of a material breach of the license agreement that has not been cured following written notice and a 90-day opportunity to cure such breach (which is shortened to 15 days for a payment breach).

Note 12 – Related Party Transactions

CorLyst 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 recorded $25,928 and $52,464 of reimbursements during the six months ended June 30, 2020 and 2019, respectively. Amounts due from CorLyst at June 30, 2020 and December 31, 2019 were $24,713 and $0, respectively.

At June 30, 2020, we also had approximately $1,700 due from certain employees for health insurance contributions. We did not have comparable a similar receivable at December 31, 2019.

Note 13 – 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 June 30, 2020.

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) and will begin developing newly acquired drugs (PCS11T and PCS100) once adequate funding has been obtained. We continue searching for additional products for our portfolio that meet our criteria.

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, PCS11T, PCS100; organizing and staffing our company; business planning; raising capital; establishing our intellectual property portfolio and conducting clinical trials. We do not have any drug candidates approved for sale and have not yet generated any revenue from drug sales. We have funded our operations through the private sale of equity and equity-linked securities to accredited investors. Since inception, we have incurred operating losses. As of June 30, 2020, we had an accumulated deficit of $12.6 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;
- begin developing PCS11T and PCS100;
- hire additional research and development and general and administrative personnel;
- maintain, expand and protect our intellectual property portfolio;
- evaluate opportunities for the development of additional drug candidates; and
- incur additional costs associated with operating as a public company.

Going Concern and Management's Plan

Our condensed consolidated financial statements 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 pharmaceutical 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 primarily on private placements with a small group of accredited investors to finance our business and operations. As described in more detail below, we recently entered into two line of credit agreements with related parties providing a revolving commitment of an aggregate of up to $1.4 million. 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. At June 30, 2020, we had an accumulated deficit of $12.6 million, and during the six months ended June 30, 2020, we incurred a net loss for the six months of $1,607,750 and used $897,029 in net cash from operating activities from continuing operations. At June 30, 2020, we had cash and cash equivalents totaling $452,654.

On September 20, 2019, we entered into two separate Line of Credit Agreements ("LOC Agreements") to borrow up to $700,000 with current shareholders and related parties DKBK Enterprises, LLC ("DKBK") and CorLyst, LLC ("CorLyst") ($1.4 million total). Under the LOC Agreements, all funds borrowed 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. Our Chief Executive Officer (CEO) is also the CEO and Managing Member of both lenders. DKBK directly holds 16,166 shares of our common stock, less than 1% of our outstanding common stock, and CorLyst beneficially owns 1,095,649 shares, representing 19.9% of our outstanding common stock. In April and June 2020, we drew $500,000 under the LOC Agreement with DKBK. On July 21, 2020, we drew an additional $200,000, bringing the total amount drawn under the LOC Agreement with DKBK to $700,000.

In December 2019, we closed our bridge financing and issued $805,000 of 2019 Senior Notes to accredited investors. In order to preserve cash, in August 2019 we began delaying some cash outflows, primarily through the deferred payment of certain salaries ($210,800 has been included in accrued expenses at June 30, 2020) until such time as we have raised sufficient funding.

In May 2020, we entered into a promissory note in favor of the Bank of Americaunder the Small Business Administration Paycheck Protection Program of the Coronavirus Aid, Relief and Economic Security Act of 2020 ("the CARES Act"), for a $162,459 loan ("the PPP Loan"). We have used the loan proceeds for payroll costs in accordance with the relevant terms and conditions of the CARES Act.

We have begun the process of raising capital in an underwritten public offering, however, we have faced delays due to the global pandemic caused by the novel coronavirus, COVID-19. 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 the closeout of our current Phase 2A trial for NL, we do not currently have resources to conduct other future trials, such as the Phase 2B/3 clinical trial approved by the FDA, or to develop our other drug candidates 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.

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 trial plans, 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.

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 (PTX or Trental®). The advantage of PCS499 is that it potentially may work in many conditions because PCS499 and its metabolites act on multiple pharmacological targets that are important in the treatment of these conditions. Based on its pharmacological activity, we have identified 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 occurs in approximately 30% of NL patients, which can lead to more severe complications, such as deep tissue infections and osteonecrosis threatening life of the limb. Approximately 22,000 - 55,000 people in the United States and more than 120,000 people outside the United States are affected with ulcerated 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 a Phase 2A multicenter, open-label prospective trial designed to determine the safety and tolerability of PCS499 in patients with NL. The first enrolled NL patient in this Phase 2A clinical trial was dosed on January 29, 2019 and the study completed enrollment on August 23, 2019. The main objective of the trial was 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 2A 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.

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 cm^2 and had completely closed by Month 2 of treatment. The second patient had a baseline reference ulcer of 1.2 cm^2 which completely closed by Month 9. In addition, while in the trial both 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 over the first one to two years after presenting with NL. 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 significantly less than the 20% reported as the maximum percentage of patients who naturally heal over the 12-24 months after NL presentation with the likelihood and time of healing possibly being dependent on the size of the ulcer. Although our study enrolled only two ulcerated patients, the existing ulcers and trauma ulcers in both patients completely closed supporting that the diverse pharmacology of PCS499 and its metabolites (similar to PTX) positively effects the open ulcers in NL. In addition, those patients without ulcers in our clinical trial also saw positive changes in their NL lesion, although to a much lesser extent than the closing of the more serious ulcers.

We have completed the patient portion of our Phase 2A trial of PCS499 in NL, with the last patient completing the trial during the first quarter of 2020. We are in the process of closing the trial, but the close out of our two sites has been delayed as a result of COVID-19.

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, we will be designing the next trial as a randomized, placebo controlled trial to evaluate the ability of PCS499 to completely close ulcers in patients with NL, along with an open labelled safety trial that will serve as an extension study for those in the randomized, placebo-controlled trial. We initially planned to begin recruiting for the randomized, placebo controlled trial in the fourth quarter 2020 but with the COVID-19 pandemic, we expect to begin recruiting patients in early 2021. The decision to conduct the study as a Phase 3 study with further input from the FDA via a Special Protocol Assessment, or to perform a smaller Phase 2B study, is still to be determined based on financial considerations, current pandemic concerns and other priorities within our portfolio. A Phase 2B or a Phase 3 trial would be of similar design but would differ in the number of patients. The FDA also noted that only a single pivotal clinical trial may be required for an NDA approval to treat ulcerated NL if the percent responders in the treatment arm is highly significant ($p << 0.05$) compared to the placebo arm. The FDA indicated that the final determination of accepting only a single trial for approval would be dependent on the FDA review of the trial results.

License Agreement with Akashi Therapeutics, Inc.

On August 29, 2019, we entered into an exclusive license agreement (the "Akashi 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, the 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 Akashi 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 Akashi 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 Akashi 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).

License Agreement with Aposense, Ltd.

On May 24, 2020, we entered into a condition precedent License Agreement (the "Aposense Agreement") with Aposense, pursuant to which we were granted a contingent license in the patent rights and the know-how to develop and commercialize their next generation irinotecan cancer drug, PCS-11T. Granting of the license is conditioned on the following being satisfied within 9 months of May 24, 2020 (or the Aposense Agreement shall terminate): (i) our closing of an equity financing and successful up-listing to Nasdaq and (ii) Aposense obtaining the approval of the Israel Innovation Authority for the consummation of the transactions contemplated by the Aposense Agreement. Within five business days of satisfying the conditions, we must issue Aposense shares of common stock, the number being determined by dividing $2.5 million by the price per share paid by such investors in the equity financing. Such shares will be subject to a lock-up, with 40% of such shares released from such lock up after six months and the remaining two 30% tranches to be released upon completion of the next two subsequent quarters. As additional consideration, we will pay Aposense 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 Aposense 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 Aposense 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) submitting an IND for a drug indication within 30 months following the satisfaction of the license conditions above; (ii) dosing of a first patient with a product within 42 months following the satisfaction of the license conditions above; (iii) dosing of a first patient with a product in a pivotal clinical trial within 72 months following the satisfaction of the license conditions above and (iv) an NDA submission within 120 months following the satisfaction of the license conditions above. Either party may terminate the Aposense Agreement in the event of a material breach of the license agreement that has not been cured following written notice and a 90-day opportunity to cure such breach (which is shortened to 15 days for a payment breach).

Results of Operations

Comparison of the three and six months ended June 30, 2020 and 2019

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

	Three Months Ended June 30,			Six Months Ended June 30,		
	2020	2019	Change	2020	2019	Change
Operating Expenses						
Research and development expenses	$ 427,109	$ 726,904	$ (299,795)	$ 928,855	$ 1,211,655	$ (282,800)
General and administrative expenses	374,878	410,072	(35,194)	859,255	807,837	51,418
Operating Loss	(801,987)	(1,136,976)		(1,788,110)	(2,019,492)	
Other Income (Expense)						
Interest expense	(19,280)	(6,102)	(13,178)	(36,450)	(10,702)	(25,748)
Interest income	18	3,398	(3,380)	846	9,383	(8,537)
Net Operating Loss Before Income Tax Benefit	(821,249)	(1,139,680)		(1,823,714)	(2,020,811)	
Income Tax Benefit	87,835	170,602	(82,767)	215,964	300,901	(84,937)
Net Loss	$ (733,414)	$ (969,078)		$ (1,607,750)	$ (1,719,910)	

Revenues.

We had no revenue during the three and six months ended June 30, 2020 and 2019. 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 PCS499 license intangible asset used in research and development activities, and (iv) internal research and development staff related payroll, taxes and employee benefits, external consulting and professional fees related to the product testing and our development activities. Non-refundable advance payments for goods and services to be used in future research and development activities are recorded as prepaid expenses and expensed when the research and development activities are performed.

During the three months ended June 30, 2020 and 2019, we incurred total research and development expenses of $427,109 and $726,904, respectively, for the continued development and testing of our lead product, PCS499. Research and development expenses were approximately $929 thousand and $1.2 million for the six months ended June 30, 2020 and 2019, respectively. Costs for the three and six months ended June 30, 2020 and 2019 were as follows:

	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Amortization of intangible assets	$ 198,832	$ 198,832	$ 397,664	$ 397,664
Research and development salaries and benefits	114,579	160,992	254,851	319,848
Preclinical, clinical trial and other costs	113,698	367,080	276,340	494,143
Total	$ 427,109	$ 726,904	$ 928,855	$ 1,211,655

Overall, during the three months ended June 30, 2020, our research and development costs decreased by $299,795 as detailed below. The decrease in research and development expenses was due to a decrease in preclinical, clinical trial and other costs of $253,382 during the three months ended June 30, 2020 when compared to the same period in 2019. This decrease was attributable to decreased costs related to our Phase 2A clinical trial, as we have completed the patient portion of the study. We also had a decrease in research and development salaries and benefits of $46,413 for the three months ended June 30, 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.

During the six months ended June 30, 2020, our research and development costs decreased by $282,800 as compared to the six months ended June 30, 2019. The decrease in research and development expenses was due to a decrease in preclinical, clinical trial and other costs of $217,803 and in research and development salaries and benefits of $64,997 during the six months ended June 30, 2020 when compared to the same period in 2019 for the same reasons as stated above.

We anticipate our research and development costs to increase significantly in the future as we continue pre-clinical studies and conduct future clinical trials related to our current drug portfolio. We incurred $181,751 of costs related to our Phase 2A trial during the six months ended June 30, 2020 and expect to spend an additional $305,000 for the remainder of the trial. We believe, based on our estimates, the total cost of our current Phase 2A trial in NL to be approximately $1.5 million. We had a clinical trial funding investor pay for $900,000 of the clinical trial costs and we are covering 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 finalize our Phase 2A clinical trial activities, prepare a Special Protocol Assessment and beginning designing and conducting a Phase 2B/3 trial to evaluate the ability of PCS499 to completely close ulcers in patients with NL and initiate any research activities related to PCS11T and PCS100. We expect to begin recruiting patients for our Phase 2B/3 trial for NL in early 2021.

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

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

General and Administrative Expenses.

Our general and administrative expenses for the three months ended June 30, 2020 decreased by $35,194 to $374,878 from $410,072 for the three months ended June 30, 2019. We experienced reductions in professional fees for legal, accounting, advisory and consulting costs of approximately $40,000, as well as decreases in other administrative costs such as office expenses, travel, and taxes and licenses of approximately $25,000. These decreases were offset by an increase in insurance and telephone expenses of $3,800 and increased payroll and related costs of approximately $26,000 (primarily due to an increase in stock-based compensation of approximately $23,000). Reimbursements from CorLyst of $25,894 for rent and other costs during the six months ended June 30, 2020 were comparable to the same period in 2019.

For the six months ended June 30, 2020, general and administrative expenses increased by $51,418 to $859,255 from $807,837 for the six months ended June 30, 2019. The majority of the increase was due to a $109,000 increase in taxes and licenses, primarily due to our Delaware franchise tax as a result of our 1-for-7 reverse stock split in December 2019. Delaware used the assumed par value method to compute their franchise tax. The reverse stock split increased the assumed par value per share which was assessed on the number of authorized shares to compute the franchise tax. On June 25, 2020, we amended our articles of incorporation to reduce the number of authorized shares in part to decrease our future Delaware franchise tax.

We also experienced increases of approximately $44,000 in payroll and related costs (due to an increase in stock-based compensation of approximately $47,000) and approximately $12,000 in administrative costs for items such as insurance and telephone expenses. The overall increase was offset by decreases in professional fees for legal, accounting, advisory and consulting costs of approximately $95,000, as well as reductions of approximately $20,000 in office expenses, travel, continuing education, utilities and repairs and maintenance. Reimbursements from CorLyst of $50,642 for rent and other costs during the six months ended June 30, 2020 were $1,800 less than the same period in 2019.

We expect the general and administrative expenses to increase in the future 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 $19,280 and $6,102 for the three months ended June 30, 2020 and 2019, respectively, and $36,450 and $10,702 for the six months ended June 30, 2020 and 2019, respectively, related to our $805,000 and $2.58 million of 8% Senior Notes sold in 2019 and 2017, respectively, and to the 2020 borrowings on the LOC Agreement with DKBK. Included in interest expense is the amortization of debt issuance costs totaling $2,140 and $0 for the six months ended June 30, 2020 and 2019, respectively.

Interest income was $18 and $3,398 for the three months ended June 30, 2020 and 2019, respectively, and $846 and $9,383 for the six months ended June 30, 2020 and 2019, respectively. Interest income represents interest earned on money market funds.

Income Tax Benefit.

We recognized an income tax benefit of $87,835 and $170,602 for the three months ended June 30, 2020, respectively, and $215,964 and $300,901 for the six months ended June 30, 2020 and 2019, respectively, as a result of our recording and amortizing the deferred tax liability created in connection with our acquisition of CoNCERT's license and "Know-How" in exchange for Processa stock that had been issued in 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 condensed consolidated statements of operations.

Financial Condition

At June 30, 2020, we had $452,654 in cash. Net cash used in our operating activities during the six months ended June 30, 2020 totaled $897,029 compared to $1,414,903 for the six months ended June 30, 2019.

Our total assets decreased by approximately $872,000 to $10 million at June 30, 2020 compared to $10.9 million at December 31, 2019. This decrease is a result of the operating costs we incurred during the six months ended June 30, 2020.

At June 30, 2020, our total liabilities, not including the impact of deferred income taxes, increased approximately $764,000 to $2,102,770 when compared to $1,338,954 at December 31, 2019. This increase is due to increases in accrued expenses related to accrued salary liability, accrued interest related to the 2019 Senior Notes and other borrowings, funds drawn under the LOC Agreement with DKBK and the promissory note we entered into with the Bank of America under the Paycheck Protection Program.

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 combination of the tax 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 June 30, 2020, we had $452,654 in cash compared to $691,536 at December 31, 2019. We have taken the following actions to address our liquidity:

- Starting in August 2019, we began deferring the salaries of certain employees. At June 30, 2020 we have deferred a total of $210,800 (which has been included in accrued expenses on the condensed consolidated balance sheet) until such time as we have raised sufficient funding.

- On September 20, 2019, we entered into two separate LOC Agreements with current shareholders and related parties DKBK and CorLyst, 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 CEO is also the CEO and Managing Member of both Lenders. DKBK directly holds 16,166 shares of our common stock, representing less than 1% of our outstanding common stock, and CorLyst beneficially owns 1,095,649 shares, representing 19.9% of our outstanding common stock. In April and June 2020, we drew $500,000 under the LOC Agreement with DKBK. On July 21, 2020, we drew an additional $200,000, bringing the total amount drawn under the LOC Agreement with DKBK to $700,000. We have not drawn any funds under the LOC Agreement with CorLyst.

- In December 2019, we closed a bridge financing raising $805,000 through the issuance of 2019 Senior Notes to accredited investors.

- In May 2020, we received $162,459 from a loan with Bank of America under the Paycheck Protection Program.

- We have initiated an underwritten capital raise and have applied to up-list of our common stock to the Nasdaq Capital Market.

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 the closeout of our current Phase 2A trial in NL, we do not currently have resources to conduct other future trials, such as the Phase 2B/3 clinical trial approved by the FDA, or develop our other drug candidates 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. There may be costs we incur as we close our Phase 2A trial in NL that we do not currently anticipate in order to complete the trial, requiring us to need additional capital sooner than currently expected.

Cash Flows

The following table sets forth our sources and uses of cash and cash equivalents for the six months ended June 30, 2020 and 2019:

	Six months ended June 30,	
	2020	2019
Net cash (used in) provided by:		
Operating activities	$ (897,029)	$ (1,414,903)
Investing activities	-	-
Financing activities	658,147	395,927
Net decrease in cash	$ (238,882)	$ (1,018,976)

Net cash used in operating activities

We used net cash in our operating activities of $897,029 and $1,414,903 during the six months ended June 30, 2020 and 2019, respectively. The decrease in cash used in operating activities during the first six months of 2020 compared to the comparable period in 2019 was related to a decreased amount of direct cash costs incurred, such as salaries and clinical trial costs. Additionally, prepaid expenses decreased by approximately $218,000. $155,000 of which related to costs for our Phase 2A clinical trial.

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

Net cash used in investing activities

We had no cash sources or uses for investing activities during the six months ended June 30, 2020 or 2019.

Net cash (used in) provided by financing activities

Net cash provided by financing activities during the six months ended June 30, 2020 of $658,147 was from borrowings totaling $500,000 under our LOC Agreement with DKBK and $162,459 we received from the Bank of America pursuant to a promissory note under the Paycheck Protection Program, less transaction costs of $4,312 related to our anticipated 2020 offering. During the six months ended June 30, 2019, net cash provided by financing activities of $395,927 were funds 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 June 30, 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 June 30, 2020.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during our quarter ended June 30, 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.

We have incurred indebtedness under the CARES Act, which will be subject to review, may not be forgivable in whole or in part and may eventually have to be repaid.

We received funds under the Paycheck Protection Program in May 2020 in the amount of $162,459, serviced by the Bank of America. The application for these funds requires us to, in good faith, certify that the current economic uncertainty made the loan request necessary to support our ongoing operations. This certification further requires us to take into account our current business activity and our ability to access other sources of liquidity sufficient to support ongoing operations in a manner that is not significantly detrimental to the business. The receipt of these funds, and the forgiveness of the loan attendant to these funds, is dependent on us having initially qualified for the loan and qualifying for the forgiveness of such loan based on our future adherence to the forgiveness criteria.

Under the terms of the CARES Act and the corresponding promissory note, the use of the proceeds of the loan is restricted to payroll costs (as defined in the CARES Act), covered rent, covered utility payments and certain other expenditures that, while permitted, would not result in forgiveness of a corresponding portion of the loan. Following recent amendments to the Paycheck Protection Program, after an eight- or twenty-four-week period starting with the disbursement of the loan proceeds, we may apply for forgiveness of some or all of the loan, with the amount which may be forgiven equal to the sum of eligible payroll costs, mortgage interest (not applicable to us), covered rent, and covered utility payments, in each case incurred by us during the eight- or twenty-four-week period following the date of first disbursement. Certain reductions in our payroll costs or full-time equivalent employees (when compared against the applicable measurement period) may reduce the amount of the Loan eligible for forgiveness. The Payroll Protection Program has been amended twice with the latest series of amendments significantly altering the timeline associated with the Payroll Protection Program spending and loan forgiveness. While we believe we have acted in good faith and has complied with all requirements of the Payroll Protection Program, if Treasury or SBA determined that our loan application was not made in good faith or that the we did not otherwise meet the eligibility requirements of the Payroll Protection Program, we may not receive forgiveness of the loan (in whole or in part) and we could be required to return the loan or a portion thereof. Further, there is no guarantee that we will receive forgiveness for any amount and forgiveness will be subject to review by our Bank of information and documentation that we submit, as required by SBA and the lender.

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 six months ended June 30, 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 six months ended June 30, 2020.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

SEC Ref. No.	Title of Document
3*	Amendment to Fourth Amended and Restated Certificate of Incorporation of Processa Pharmaceuticals, Inc. dated June 25, 2020
10.1	License Agreement with Aposense, LTD dated May 24, 2020 (incorporated by reference to Form 8-K filed June 1, 2020)
10.2	Promissory Note, dated May 1, 2020, with Processa Pharmaceuticals, Inc. and Bank of America, N.A., under the Small Business Administration Paycheck Protection Program of the Coronavirus Aid, Relief and Economic Securities Act of 2020 (incorporated by reference to exhibit 10.10 to Form S-1A filed on July 17, 2020)
31.1*	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*++	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
99.1	XBRL Files

* Filed herewith.

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

PROCESSA PHARMACEUTICALS, INC.

By: */s/ David Young*
David Young
Chief Executive Officer
(Principal Executive Officer)
Dated: August 5, 2020

By: */s/ James Stanker*
James Stanker
Chief Financial Officer
(Principal Financial and Accounting Officer)
Dated: August 5, 2020

Exhibit 3

CERTIFICATE OF AMENDMENT
TO
FOURTH AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
PROCESSA PHARMACEUTICALS, INC.
(a Delaware corporation)

Processa Pharmaceuticals, Inc. (the "Corporation"), a corporation organized and existing under the General Corporation Law of the State of Delaware (the "DGCL"), hereby certifies as follows:

1. This Certificate of Amendment (the "Certificate of Amendment") amends the provisions of the Corporation's Fourth Amended and Restated Certificate of Incorporation filed with the Secretary of State of the State of Delaware on September 27, 2017, as amended on October 23, 2017, as amended on August 12, 2019, and as amended on December 23, 2019 (the "Certificate of Incorporation").

2. The Board of Directors of the Corporation has duly adopted a resolution pursuant to Section 242 of the DGCL setting forth a proposed amendment to the Certificate of Incorporation and declaring said amendment to be advisable. The Certificate of Amendment amends the Certificate of Incorporation as follows:

The FOURTH paragraph of the Certificate of Incorporation is hereby deleted in its entirety and replaced with the following:

FOURTH: The total number of shares of all classes of stock which the Corporation shall have authority to issue is (i) 30,000,000 shares of Common Stock, $0.0001 par value per share ("Common Stock") and (ii) 1,000,000 shares of Preferred Stock, $0.0001 par value per share ("Preferred Stock").

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

A. COMMON STOCK

1. General. The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights of the holders of the Preferred Stock of any series as may be designated by the Board of Directors upon any issuance of the Preferred Stock of any series.

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

   The number of authorized shares of Common Stock may be increased or decreased (but not below the number of share thereof then outstanding) by the affirmative vote of the holders of a majority of the stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law of the State of Delaware.

3. Dividends. Dividends may be declared and paid on the Common Stock from funds lawfully available therefor as and when determined by the Board of Directors and subject to any preferential dividend or other rights of any then outstanding Preferred Stock.

4. Liquidation. Upon the dissolution or liquidation of the Corporation, whether voluntary or involuntary, holders of Common Stock will be entitled to receive all assets of the Corporation available for distribution to its stockholders, subject to any preferential or other rights of any then outstanding Preferred Stock.

B. PREFERRED STOCK

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

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

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

3. The requisite stockholders of the Corporation have duly approved this Certificate of Amendment in accordance with Section 242 of the DGCL.

4. This Certificate of Amendment shall be effective at 5:00 p.m. Eastern Time on June 25, 2020.

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Amendment to be executed as of the date set forth below.

Dated: June 25, 2020

PROCESSA PHARMACEUTICALS, INC.

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

Exhibit 31.1

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 six months ended June 30, 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 Rules13a-15(f) and 15d-15 (f)) for the registrant and have:

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

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

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

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

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

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

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

Date: August 5, 2020

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

Exhibit 31.2

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 six months ended June 30, 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 Rules13a-15(f) and 15d-15 (f)) for the registrant and have:

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

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

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

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

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

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

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

Date: August 5, 2020

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

Exhibit 32.1

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

Solely for the purposes of complying with 18 U.S.C. §1350, I, the undersigned Chief Executive Officer of Processa Pharmaceuticals, Inc. (the "Company"), hereby certify, to the best of my knowledge, that the quarterly report on Form 10-Q of the Company for the quarter ended June 30, 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: August 5, 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 June 30, 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: August 5, 2020

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