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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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 001-39531

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

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of Each Class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	PCSA	The Nasdaq Stock Market LLC

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 10,565,566 shares of common stock outstanding as of October 31, 2020.

PROCESSA PHARMACEUTICALS, INC.
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PART 1: FINANCIAL INFORMATION

ITEM 1: FINANCIAL STATEMENTS

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

	September 30, 2020	December 31, 2019
ASSETS		
Current Assets		
Cash and cash equivalents	$ 325,428	$ 691,536
Due from related party	7,605	-
Prepaid expenses and other	42,855	315,605
Total Current Assets (1)	375,888	1,007,141
Property and Equipment		
Property and equipment, net	2,596	8,930
Other Assets		
Operating lease right-of-use assets, net of accumulated amortization	159,199	219,074
Intangible assets, net of accumulated amortization	9,045,958	9,642,454
Security deposit	5,535	5,535
Total Other Assets	9,210,692	9,867,063
Total Assets	$ 9,589,176	$ 10,883,134
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Senior convertible notes, net of debt issuance costs	$ 762,229	$ 802,503
Line of credit payable – related party	700,000	-
Note payable – Paycheck Protection Program, current portion	90,329	-
Current maturities of operating lease liability	79,765	77,992
Accrued interest	89,704	21,902
Accounts payable	427,451	75,612
Due to related parties	110,796	316
Accrued expenses	397,598	213,239
Total Current Liabilities	2,657,872	1,191,564
Non-current Liabilities		
Note payable – Paycheck Protection Program	72,130	-
Non-current operating lease liability	86,736	147,390
Net deferred tax liability	1,245,209	1,531,630
Total Liabilities	4,061,947	2,870,584
Commitments and Contingencies	-	-
Stockholders' Equity		
Common stock, par value $0.0001, 30,000,000 and 100,000,000 shares authorized; 5,765,566 and 5,486,595 issued and outstanding at September 30, 2020 and December 31, 2019	577	549
Additional paid-in capital	21,187,697	18,994,008
Common stock deemed dividend payable: 28,971 shares at par value	-	3
Accumulated deficit	(15,661,045)	(10,982,010)
Total Stockholders' Equity	5,527,229	8,012,550
Total Liabilities and Stockholders' Equity	$ 9,589,176	$ 10,883,134

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

(1) As described in Note 17, on October 6, 2020, we closed an underwritten public offering of 4,800,000 shares of common stock for a public offering price of $4.00 per share. Net proceeds from the offering were approximately $17.1 million.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating Expenses				
Research and development expenses	$ 532,587	$ 584,979	$ 1,461,416	$ 1,804,169
Acquisition of in-process research and development	2,000,000	-	2,000,000	-
General and administrative expenses	422,958	419,028	1,282,239	1,219,329
Total operating expenses	2,955,545	1,004,007	4,743,655	3,023,498
Operating Loss	(2,955,545)	(1,004,007)	(4,743,655)	(3,023,498)
Other Income (Expense) (Note 5)	(186,197)	(768)	(221,801)	(2,087)
Net Operating Loss Before Income Tax Benefit	(3,141,742)	(1,004,775)	(4,965,456)	(3,025,585)
Income Tax Benefit	70,457	141,251	286,421	442,152
Net Loss	$ (3,071,285)	$ (863,524)	$ (4,679,035)	$ (2,583,433)
Net Loss per Common Share - Basic and Diluted	$ (0.55)	$ (0.16)	$ (0.84)	$ (0.47)
Weighted Average Common Shares Used to Compute Net Loss Applicable to Common Shares - Basic and Diluted	5,594,370	5,525,009	5,542,026	5,531,097

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

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

Nine Months Ended September 30, 2020

	Common Stock		Additional Paid-In	Common Stock Dividend	Accumulated	
	Shares	Amount	Capital	Payable	Deficit	Total
Balance at January 1, 2020	5,486,595	$ 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	5,486,595	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	5,515,566	552	19,182,228	-	(12,589,760)	6,593,020
Stock-based compensation	-	-	164,507	-	-	164,507
Shares issued in connection with Yuhan license agreement	250,000	25	1,999,975	-	-	2,000,000
Fair value of warrants issued in the sale of our 2019 Senior Notes	-	-	197,403	-	-	197,403
Transaction costs related to anticipated 2020 offering	-	-	(356,416)	-	-	(356,416)
Net loss	-	-	-	-	(3,071,285)	(3,071,285)
Balance, September 30, 2020	5,765,566	$ 577	$ 21,187,697	$ -	$ (15,661,045)	$ 5,527,229

Nine Months Ended September 30, 2019

	Common Stock		Additional Paid-In	Subscription	Accumulated	
	Shares	Amount	Capital	Receivable	Deficit	Total
Balance, January 1, 2019	5,525,128	$ 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	5,525,128	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	-	-	-	-	(969,077)	(969,077)
Balance, June 30, 2019	5,525,128	552	19,249,635	(1,404,073)	(9,344,043)	8,502,071
Conversion of Senior convertible notes for common stock and stock purchase warrants	18,107	2	258,928	-	-	258,930
Payments/reimbursements made by investor for clinical trial costs	-	-	-	504,073	-	504,073
Pledged shares of common stock forfeited upon revised agreement with clinical trial investor	(56,640)	(5)	(899,995)	900,000	-	-
Stock-based compensation	-	-	269,129	-	-	269,129
Net loss	-	-	-	-	(863,524)	(863,524)
Balance, September 30, 2019	5,486,595	$ 549	$ 18,877,697	$ -	$ (10,207,567)	$ 8,670,679

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

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

	2020	2019
Cash Flows From Operating Activities		
Net loss	$ (4,679,035)	$ (2,583,433)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	6,334	6,334
Non-cash lease expense for right-of-use assets	59,875	55,012
Non-cash acquisition of in-process research and development	2,000,000	-
Amortization of debt issuance costs (Note 5)	157,129	-
Amortization of intangible asset	596,496	596,496
Deferred income tax benefit	(286,421)	(442,152)
Stock-based compensation	357,039	394,164
Net changes in operating assets and liabilities:		
Prepaid expenses and other	272,750	37,552
Operating lease liability	(58,881)	(58,999)
Accrued interest	67,802	8,587
Accounts payable	351,839	(227,241)
Due (from) to related parties	102,875	46,647
Accrued expenses	184,359	30,374
Net cash used in operating activities	(867,839)	(2,136,659)
Cash Flows From Financing Activities		
Proceeds received in satisfaction of stock subscription receivable	-	900,000
Borrowings on line of credit from a related party	700,000	-
Proceeds received from our Paycheck Protection Program note payable	162,459	-
Transaction costs related to subsequent common stock offering	(360,728)	-
Net cash provided by financing activities	501,731	900,000
Net Decrease in Cash	(366,108)	(1,236,659)
Cash and Cash Equivalents – Beginning of Period	691,536	1,740,961
Cash and Cash Equivalents – End of Period	$ 325,428	$ 504,302
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 250,000 shares of common stock for the acquisition of in-process research and development in connection with the Yuhan License Agreement	$ 2,000,000	$ -
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

We are 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 or who have no alternative treatment. Our most advanced product candidate, PCS499, is an oral tablet that is a deuterated analog of one of the major metabolites of pentoxifylline (PTX or Trental®). We have completed the patient portion of the Phase 2A trial for PCS499 and are in the process of closing the trial, and we plan to begin recruiting for a Phase 2B trial in the first quarter of 2021. We have also begun the continued development of two newly acquired drugs, PCS12852 and PCS6422. We will continue to search for additional products for our portfolio that meet our portfolio 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 may be caused by a number of pathophysiological changes which has made it extremely difficult to develop effective treatments for this condition. Because PCS499 and its metabolites affect a number of biological pathways, several of which could contribute to the pathophysiology associated with NL, PCS499 may provide a novel treatment solution for NL, a condition for which there are currently no FDA-approved treatments.

On June 18, 2018, the FDA granted orphan-drug designation for PCS499 for the treatment of NL. On September 28, 2018, the IND for PCS499 in NL was made effective by the FDA, 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 study initially had a six-month treatment phase and a six-month optional extension phase. In December 2019, we informed patients and sites that the study would conclude after the treatment phase and there would no longer be an extension phase. 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 last patient visit took place in February 2020. Due to COVID-19 related restrictions at certain sites, study closeout and database lock did not occur until October 2020. We are currently finalizing the data results and clinical study report.

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. All adverse events reported in the study were mild in severity. As expected, gastrointestinal symptoms were the most noted adverse events and reported in four patients, all of which were mild in severity and resolved within 1-2 weeks of starting dosing.

Two of the twelve patients in the study presented with more severe ulcerated NL and 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 during the patient's treatment extension period. In addition, while in the trial, both patients also developed small ulcers at other sites, possibly related to contact trauma, and these ulcers resolved within one month. However, the other ten patients, presenting with mild to moderate NL and no ulceration, had more limited improvement of the NL lesions during treatment. Historically, less than 20% of all the patients with NL naturally progress to complete healing over many 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 several years after NL presentation.

On March 25, 2020, we met with the FDA and discussed the clinical program, as well as the nonclinical and clinical pharmacology plans to ultimately 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. We initially planned to begin recruiting for the randomized, placebo-controlled trial in the fourth quarter of 2020, but we now expect to begin recruiting patients in 2021 due to delays in fundraising efforts. This PCS499 NL study will be a randomized, placebo-controlled Phase 2B study to better understand the potential response of NL patients on drug and on placebo. After obtaining the results from this Phase 2B study, we expect to meet with FDA to discuss our Phase 2B drug and placebo response findings while further discussing the next steps to obtain approval.

PCS12852

On August 19, 2020, we entered into a License Agreement ("Yuhan License Agreement") with Yuhan Corporation ("Yuhan"), pursuant to which we acquired an exclusive license to develop, manufacture and commercialize PCS12852 (formerly known as YH12852) globally, excluding South Korea.

We accounted for the Yuhan License Agreement as an asset acquisition since it did not meet the definition of a business, and therefore recorded the intangible asset at fair value, equal to the consideration paid of $2 million in the form of 500,000 shares of our common stock (see Note 12). Because the intangible asset represents in-process research and development with no alternative future use, we immediately expensed the fair value in the Statement of Operations. At September 30, 2020, only 250,000 shares had been issued.

PCS12852 is a novel, potent and highly selective 5-hydroxytryptamine 4 (5-HT4) receptor agonist. Other 5-HT receptor agonists with less 5-HT4 selectivity have been shown to successfully treat gastrointestinal (GI) motility disorders such as chronic constipation, constipation-predominant irritable bowel syndrome, functional dyspepsia and gastroparesis. Less selective 5-HT4 agonists, such as cisapride, have been either removed from the market or not approved because of the cardiovascular side effects associated with the drugs binding to other receptors, especially 5-HT receptors other than 5-HT4.

We plan to meet with the FDA in early 2021 to further define the clinical development program required for the PCS12852 product and discuss a Phase 2A proof of concept randomized, placebo-controlled study for PCS12852 in a gastrointestinal (GI) motility dysfunction disorder (e.g., gastroparesis, post-operative ileus also called gastrointestinal dysfunction (POGD), opioid induced constipation, chronic idiopathic constipation). The purpose of the Phase 2A trial would be to better define a dosage regimen of PCS128552 that could be potentially efficacious and safe in a larger pivotal study. The patients with these types of conditions have an abnormal pattern of GI motility in the absence of mechanical obstruction. For example, gastroparesis is characterized by postprandial fullness (early satiety), nausea, vomiting and bloating. It is known to occur in more than 4 million people in the US, but many still do not have access to medications that work or can be tolerated by the patients. The only FDA-approved product for gastroparesis is a dopamine D2 Antagonist metoclopramide (Gimoti®), which includes an FDA "Black Box" warning for tardive dyskinesia (TD), a serious movement disorder that is often irreversible. Because of this adverse effect, the treatment is limited to no more than 12 weeks. POGD is characterized by nausea, vomiting, abdominal distension and/or delated passage of flatus or stool, following surgery (most commonly with abdominal surgery). It is the most common cause of prolonged length of stay in hospital following GI surgery, leading to an increase in healthcare costs. The only FDA-approved drug to treat POGD is a mu-opioid receptor antagonist alvimopan (Entereg®), which is only available through a restricted program for short-term use due to the potential risk of myocardial infarction with long-term use.

Two clinical studies have been previously conducted by Yuhan with PCS12852. In the first-in-human clinical trial (Protocol YH12852-101), the initial safety and tolerability of PCS12852 were evaluated after single and multiple oral doses in healthy subjects. PCS12852 increased stool frequency with faster onset when compared to prucalopride, an FDA approved drug for the treatment of chronic idiopathic constipation. Compared to the group receiving prucalopride, the PCS12852 dose groups showed higher stool frequency for 24 hours following single dosing and had faster onset of spontaneous bowel movements (SBMs) with comparable or relatively higher Bristol Stool Form Scale score (lower stool consistency) for 24 hours following first dosing. In addition, based on an increase of ≥ 1 SBM/week from baseline during 7-day multiple dosing, the PCS12852 dose group had a higher percent of patients with an increase than the prucalopride group. All doses of PCS12852 were safe and well tolerated and no serious adverse events (SAE) occurred during the study. The most frequently reported adverse events (AEs) were headache, nausea and diarrhea which were temporal, manageable, and reversible within 24 hours. There were no clinically significant changes in platelet aggregation or ECG parameters including no sign of QTc prolongation in the study. The second study conducted was a Phase 1/2A clinical trial (Protocol YH12852-102) to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of PCS12852 immediate release (IR) formulation and delayed release (DR) formulation after multiple oral dosing. PCS12852 was safe and well tolerated after single and multiple administrations. The most frequent AEs for both the IR and DR formulations of PCS12852 were headache, nausea and diarrhea, but the incidences of these AEs were comparable with those of the prucalopride 2 mg group. These AEs, which were transient and mostly mild in severity, are also commonly observed with other 5-HT4 agonists. Both formulations of PCS12852 also showed pharmacologic activity as assessed using various pharmacodynamic parameters for stool assessment. In this study, PCS12852 also showed an enhanced gastric emptying rate in patients assessed by the Gastric Emptying Breath Test (GEBT). The change from baseline in gastric emptying rate increased in both 0.1 mg and 0.05 mg PCS12852 groups and showed a statistically significant change from baseline in the 0.1 mg group.

Yuhan had also conducted extensive toxicological studies for the product that demonstrated that the product is safe for use and can be moved quickly into Phase 2 studies.

PCS6422

On August 23, 2020, we entered into a License Agreement ("Elion License Agreement") with Elion Oncology, Inc. ("Elion"), pursuant to which we acquired an exclusive contingent license to develop, manufacture and commercialize PCS6422 globally. On October 6, 2020, in connection with the closing of our underwritten offering and listing on the Nasdaq Capital Market, the contingencies related to this license were met.

We have not accounted for the Elion License Agreement at September 30, 2020 since the contingency was not met until we closed our underwritten public offering and up-listed our common stock to the Nasdaq stock market, which occurred on October 6, 2020. We believe this license agreement represents an asset acquisition since it did not meet the definition of a business, and we plan to record the intangible asset acquired at fair value equal to the consideration paid of $3.3 million in the form of 825,000 shares of our common stock and $100,000 cash. Because the intangible assets represent in-process research and development with no alternative future use, we will immediately expense the fair value in the fourth quarter in our statement of operations.

Elion acquired the eniluracil (PCS6422) product from Fennec Pharmaceuticals (formerly known as Adherex Technologies) in 2016. PCS6422 is an oral, potent, selective, and irreversible inhibitor of dihydropyrimidine dehydrogenase (DPD), the enzyme that rapidly metabolizes 5-FU, a common chemotherapy drug, to inactive metabolites, such as α-fluoro-β-alanine (F-Bal). F-Bal is thought to cause the neurotoxicity and Hand–Foot Syndrome (HFS) associated with 5-FU, and greater formation of F-Bal appears to be associated with a decrease in the antitumor activity of 5-FU. HFS can affect daily living activities, quality of life, and requires dose interruptions/adjustments and even therapy discontinuation resulting in suboptimal tumor effects. We believe that the inhibition of DPD by PCS6422 may significantly improve exposure to 5-FU and reduce 5-FU side effects related to F-Bal. One dose of PCS6422 irreversibly blocks DPD activity for up to two weeks until DPD levels recover via de novo synthesis of the DPD enzyme. Thus, we believe inhibition of tumor DPD will result in higher 5-FU intra-tumoral concentration and potentially better tumor response along with the decrease in F-Bal.

Fluoropyrimidines (e.g., 5-FU) are still the cornerstone of treatment for many different types of cancers, either as monotherapy or in combination with other chemotherapy agents by an estimated two million patients annually. Xeloda®, an oral pro-drug of 5-FU, is approved as first-line therapy for metastatic colorectal and breast cancer. However, its use is limited by adverse effects such as the development of HFS in up to 60% of patients.

Elion evaluated the potential for the combination of PCS6422 with capecitabine (Xeloda®, and, together with PCS6422, known as ECAPE) as a treatment of advanced gastrointestinal (GI) tumors. Nonclinical efficacy data indicated that in colorectal cancer models, pretreatment with PCS6422 enhanced the antitumor activity of capecitabine. PCS6422 increased the antitumor potency of capecitabine while not increasing the toxicity. The antitumor efficacy of the combination of PCS6422 and capecitabine was tested in several xenograft animal models with human breast, pancreatic and colorectal cancer cells. These preclinical xenograft models demonstrate that PCS6422 potentiates the antitumor activity of capecitabine and significantly reduces the dose of capecitabine required to be efficacious.

Elion met with the FDA in 2019 and agreed upon the clinical development program required for the combination of PCS6422 and capecitabine as first-line therapy for metastatic colorectal cancer when treatment with fluoropyrimidine therapy alone is preferred. Subsequently, an IND has been granted safe to proceed by FDA on May 17, 2020, for the Phase 1B study. This Phase 1B study will evaluate the safety and tolerability of several dose combinations of PCS6422 and capecitabine in advanced GI tumor patients and should be initiated in the first half of 2021.

Other DPD enzyme inhibitors (e.g. Gimeracil used in Teysuno® approved only outside the US) act as competitive reversible inhibitors. These agents must be present when 5-FU or capecitabine are administered to inhibit 5-FU breakdown by DPD in order to improve the efficacy and safety profiles of 5-FU. Given the reversible nature of their effect on DPD, over time 5-FU metabolism to F-Bal will return, decreasing the amount of 5-FU in the cancer cells and decreasing the potential cytotoxicity on the cancer cells. There is also evidence that administering DPD inhibitors directly with 5-FU may also decrease the antitumor effect of the 5-FU. Because PCS6422 is an irreversible inactivator of DPD, it can be dosed the day before capecitabine administration and its effect on DPD can last longer than the reversible DPD inhibitors and beyond the time 5-FU exists in the cancer cell. We believe this can optimize the potential cytotoxic effect and minimize the metabolism of 5-FU.

Prior to Elion's involvement, two multicenter Phase 3 studies were conducted in patients with colorectal cancer (CRC) with PCS6422 administered in 10-fold excess to 5-FU. Unfortunately, we believe the dose of PCS6422 during these trials was not optimal, and that PCS6422 was not administered early enough to irreversibly affect the DPD enzyme, thus the regimen tended to produce less antitumor benefit than the control arm with the standard regimen of 5-FU/leucovorin (LV) without PCS6422. Later preclinical work suggested that when PCS6422 was present at the same time as and in excess to 5-FU, it diminished the antitumor activity of 5-FU, which we believe supports the proposal of exploring clinically dosing PCS6422 several hours before 5-FU to allow its clearance before the administration of 5-FU.

PCS11T

On May 24, 2020, we entered into an exclusive License Agreement with Aposense, Ltd., ("Aposense"), pursuant to which we were granted a contingent license in Aposense's patent rights and know-how to develop and commercialize their next generation irinotecan cancer drug, PCS11T (formerly known as ATT-11T). The grant of license was conditioned on (i) our closing of an equity financing and successful up-listing to Nasdaq which we completed on October 6, 2020 and (ii) Aposense obtaining the approval of the Israel Innovation Authority for the consummation of the transactions contemplated by the agreement, which was obtained on August 24, 2020.

We have not accounted for the License Agreement with Aposense at September 30, 2020 since the contingency was not met until we closed our underwritten public offering and up-listed our common stock to the Nasdaq stock market, which occurred on October 6, 2020. We believe this license agreement represents an asset acquisition since it did not meet the definition of a business, and we plan to record the intangible asset acquired at fair value equal to the consideration paid of $2.5 million in the form of 625,000 shares of our common stock. Because the intangible assets represent in-process research and development with no alternative future use, we will immediately expense the fair value in the fourth quarter in our statement of operations.

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 has been designed to allow 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 may make the therapeutic window of PCS11T wider than other irinotecan products such that the antitumor effect of PCS11T could occur at a much lower dose with a milder adverse effect profile 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, irinotecan has a narrow therapeutic window and includes an FDA "Black Box" warning for both neutropenia and severe diarrhea. 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. We believe 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 PCS11T demonstrated tumor eradication at much lower doses than irinotecan across various tumor xenograft 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, compared to irinotecan, which is known for its cholinergic-related side effects.

We are currently planning to manufacture the product at a GMP facility, conduct the toxicological studies required to file the IND and initiate the Phase 1B study in oncology patients with solid tumors in 2022-2023.

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 (formerly known as HT-100), 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 full clinical hold on the DMD trial after a serious adverse event in a pediatric patient, the FDA has partially removed the clinical hold and defined how PCS100 can resume clinical trials in DMD. 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.

Liquidity

On October 6, 2020, we closed an underwritten public offering of 4,800,000 shares of common stock for a public offering price of $4.00 per share. Net proceeds from the offering were approximately $17.1 million. We believe these funds, along with our existing cash on that day will provide us with sufficient capital to meet our anticipated operating and capital expenditure requirements into the fourth quarter of 2022. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our ultimate success depends on the outcome of our planned clinical trials and our research and development activities, as disclosed above. We expect to incur additional losses in the future and we anticipate the need to raise additional capital to fully implement our business plan if the cost of our planned clinical trials are greater than we expect or they take longer than anticipated. We also expect to incur increased general and administrative expenses at least through 2022 due in part to planned increased research and development activities as we conduct a Phase 2B trial for PCS499, a Phase 1B trial for PCS6422, and a Phase 2A clinical trial for PCS12852. In addition, there may be costs we incur as we develop these drug products that we do not currently anticipate requiring us to need additional capital sooner than currently expected.

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 (see Notes 11, 12 and 13). Amortization of intangibles used in research and development activities is a research and development cost.

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

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

Impairment of Long-Lived Assets and Intangibles Other Than Goodwill

We account for the impairment of long-lived assets in accordance with ASC 360, *Property, Plant and Equipment* and ASC 350, *Intangibles – Goodwill and Other,* which require that long-lived assets and certain identifiable intangibles be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to its expected future undiscounted net cash flows generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amounts of the assets exceed the fair value of the assets based on the present value of the expected future cash flows associated with the use of the asset. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. Based on management's evaluation, there was no impairment loss recorded during the nine months ended September 30, 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 net loss per share is computed by dividing our net loss available to common stockholders by the weighted average number of shares of common stock outstanding during the year. Diluted net loss per share is computed by dividing our net loss available to common stockholders by the diluted weighted average number of shares of common stock during the period. Since we experienced a net loss for all periods presented, basic and diluted net loss per share are the same. As such, diluted loss per share for the nine months ended September 30, 2020 and 2019 excludes the impact of 1,146,112 and 662,443 potentially dilutive common stock, respectively, related to outstanding stock options and warrants and the conversion of our 2017 and 2019 Senior Notes and line of credit agreement 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 condensed consolidated 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 as of September 30, 2020 and December 31, 2019 consisted of the following:

	September 30, 2020	December 31, 2019
Gross intangible assets	$ 11,059,429	$ 11,059,429
Less: accumulated amortization	(2,013,471)	(1,416,975)
Total intangible assets, net	$ 9,045,958	$ 9,642,454

Amortization expense was $198,832 for both three months ended September 30, 2020 and 2019, and $596,496 for both nine months ended September 30, 2020 and 2019. Amortization expense is included within research and development expense in the accompanying condensed consolidated statements of operations. Our estimated annual amortization expense in future periods will be approximately $790,000 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 September 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 we 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*, we recorded a deferred tax liability of $3,037,147 for the acquired temporary difference between intangible assets 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 ASC 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 nine months ended September 30, 2020 and 2019. No current income tax expense is expected for the foreseeable future as we expect to generate taxable net operating losses.

In September 2020, we acquired PCS12852 from Yuhan Corporation for an initial purchase price of $2 million. We also acquired PCS6422 from Elion Oncology, Inc. for an initial purchase price of $3.4 million and PCS11T from Aposense Ltd. for $2.5 million during the fourth quarter of 2020. Our total acquired research and development for 2020 is expected to be $7.9 million. The assets acquired were determined to represent in-process research and development with no alternative future use, so we immediately expensed the full $7.9 million for book purposes and capitalized the amount for tax purposes, creating deferred tax assets. We also established a full valuation allowance against these deferred tax assets.

Under ASC 350-30-35-17A, a research and development asset acquired must be considered an indefinite-lived intangible asset until completion or abandonment of the R&D efforts. Only at that time can one accurately determine the useful life of the research and development asset and begin amortization. Due to their current indefinite lives, we did not offset the acquired in-process research and development assets against our existing deferred tax liability from the CoNCERT transaction explained above. We will determine the useful life of the R&D assets when the research and development efforts are complete.

Note 4 – Stock-based Compensation

On August 5, 2020, we granted 324,360 restricted stock awards under the 2019 Omnibus Incentive Plan to our employees and directors, of which restricted stock awards for 214,078 shares of common stock vested on October 6, 2020 when we successfully completed our underwritten public offering, and the remaining 110,282 shares of common stock vest over two years.

During the nine months ended September 30, 2019, we granted 129,919 stock options to employees and non-employees under the 2019 Omnibus Incentive Plan. At September 30, 2020, we had outstanding options to purchase 169,329 shares of our common stock, of which options for the purchase of 63,272 shares of our common stock were vested.

We recorded stock-based compensation expense for the three and nine months ended September 30, 2020 and 2019 as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development	$ 40,715	$ 88,707	$ 64,170	$ 92,111
General and administrative	123,791	180,422	292,869	302,053
Total	$ 164,507	$ 269,129	$ 357,039	$ 394,164

Note 5 – 2019 Senior 8% Convertible Notes Payable

During the fourth quarter of 2019, accredited investors purchased $805,000 of 8% Senior Convertible Notes ("2019 Senior Notes") from us. For every $1,000 principal amount purchased, the note holders received 70 warrants to purchase our common stock. As a result, we granted 56,350 warrants to purchase our common stock at an exercise price of $19.04, which expire on December 19, 2023. 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 September 30, 2020 and December 31, 2019, we had $805,000 of 2019 Senior Notes outstanding.

As a result of the underwritten public offering in October 2020, the 2019 Senior Notes are currently convertible by the holder. 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 $3.60 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 $201,683 in debt issuance costs related to the 2019 Senior Notes – $4,280 in professional fees and $197,403 related to the warrants' calculated fair value. At the time the Senior Notes were issued, management believed the warrants were to be issued to the holders only if the notes were converted into shares of common stock. However, on September 4, 2020, we discovered the warrants should have been issued at the same time as the notes were issued and have subsequently been issued. We calculated the impact using the Black-Scholes valuation model and determined $197,403 should have been allocated to the warrants in December 2019. As such, we recorded $42,771 in unamortized debt issuance costs and $154,632 in interest expense related to the warrants for the nine months ended September 30, 2020. We amortized $154,989 and $157,129 in debt issuance costs for the three and nine months ended September 30, 2020. The debt issuance costs are amortized to interest expense using straight line amortization over the term of the 2019 Senior Notes. We did not have a similar expense during the same periods in 2019.

Note 6 – Related Party Line of Credit Agreements

On September 20, 2019, we entered into two separate LOC Agreements ("LOC Agreements") with DKBK Enterprises, LLC ("DKBK") and CorLyst, LLC ("CorLyst", and, together with DKBK, collectively, "Lenders"), both related parties, which provide a revolving commitment of up to $700,000 each ($1.4 million total). Under the LOC Agreements, all funds borrowed bear interest at an annual rate of 8%. The promissory notes issued in connection with the LOC Agreements provide that the Lenders have the right to convert all or any portion of the principal and accrued and unpaid interest into our common stock on the same terms as our 2019 Senior Convertible Notes.

Our Chief Executive Officer (CEO) is also the CEO and Managing Member of both lenders. As of September 30, 2020, DKBK directly held 16,166 shares of our common stock and CorLyst beneficially owned 1,095,649 shares of our 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.

On October 6, 2020, in connection with the closing of our underwritten public offering, DKBK converted the $700,000 principal amount and related interest outstanding under the LOC Agreement into 199,537 shares of our common stock at a conversion price of $3.60 per share, which, pursuant to the LOC Agreement, is a 10% discount on the underwritten public offering price.

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 September 30, 2020, $90,329 of the total $162,459 PPP-related debt is classified as a current liability on our condensed consolidated balances 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 stockholders 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.

On October 6, 2020, we closed an underwritten public offering of 4,800,000 shares of common stock for a public offering price of $4.00 per share. Net proceeds from this offering were approximately $17.1 million. As a result of this offering, we also issued an additional 3,270,095 shares as described in Note 17 – Subsequent Events.

There were no issued or outstanding shares of preferred stock at September 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 stock outstanding. Diluted net loss per share is computed by dividing net loss by the weighted average common stock 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 stock 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 nine months ended September 30, 2020 and 2019 was as follows:

	Nine months ended September 30,	
	2020	**2019**
Basic and diluted net loss per share:		
Net loss	$ (4,679,035)	$ (2,583,433)
Weighted average number of common stock-basic and diluted	5,542,026	5,531,097
Basic and diluted net loss per share	$ (0.84)	$ (0.47)

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	703,288	662,443
Shares of common stock that would be issued on the conversion of our 2019 Senior Notes and LOC Agreement with DKBK, plus related accrued interest	442,824	-
	1,146,112	662,443

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 $24,029 and $24,319 for the three months ended September 30, 2020 and 2019, respectively, and $72,230 and $73,621 for the nine months ended September 30, 2020 and 2019, respectively. The weighted average remaining lease terms and discount rate for our operating leases were as follows at September 30, 2020:

Weighted average remaining lease term (years) for our facility and equipment leases	2
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 September 30, 2020:

2020	$	22,416
2021		90,495
2022		69,741
Total lease payments		182,652
Less: Interest		(16,151)
Present value of lease liabilities		166,501
Less: current maturities		(79,765)
Non-current lease liability	$	86,736

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. On October 6, 2020, we satisfied the conditions and are currently working with Aposense to issue 625,000 shares of our common stock, which was determined by dividing $2.5 million by the $4.00 per share price in our underwritten public offering. 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 – License Agreement with Yuhan Corporation

On August 19, 2020, we entered into a License Agreement (the "Yuhan License Agreement") with Yuhan, pursuant to which we acquired an exclusive license to develop, manufacture and commercialize PCS12852 globally, excluding South Korea.

As consideration for the Yuhan License Agreement, we issued to Yuhan 250,000 shares of common stock (based upon an $8.00 per share price). Per the Yuhan License Agreement and related Share Issuance Agreement, we will issue an additional 250,000 shares based on the $4.00 per share price in the underwritten public offering, which closed on October 6, 2020. As additional consideration, we will pay Yuhan development and regulatory milestone payments (a portion of which are payable in shares of our common stock based on the volume weighted average trading price during the period prior to such achievement and a portion of which are payable in cash) upon the achievement of certain milestones, which primarily consist of dosing a patient in pivotal trials or having a drug indication approved by a regulatory authority in the United States or another country. The amount of future development and regulatory milestone payments payable to Yuhan is based on a Yuhan affiliate purchasing 750,000 shares of common stock for $3,000,000 in our underwritten public offering. In addition, we must pay Yuhan 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 received with Yuhan based on any sub-license agreement we may enter into.

We are required to use commercially reasonable efforts, at our sole cost and expense, in conjunction with a joint Processa-Yuhan Board to oversee such commercialization efforts, to research, develop and commercialize products in one or more countries, including meeting specific diligence milestones that consist of: (i) preparing a first draft of the product development plan within 90 days; (ii) requesting an FDA pre-IND meeting for a product within 6 months; (iii) dosing a first patient in a Phase 2A clinical trial with a product within 24 months; and (iv) dosing a first patient with a product in a Phase 2B clinical trial, Phase 3 clinical trial or other pivotal clinical trial with a product within 48 months. Either party may terminate the agreement in the event of a material breach of the 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).

Note 13 – License Agreement with Elion Oncology, Inc.

On August 23, 2020, we entered into the Elion License Agreement with Elion, pursuant to which we acquired an exclusive license to develop, manufacture and commercialize PCS6422 globally.

The grant of license was conditioned on the closing of our underwritten public offering and successful up-listing to Nasdaq, which closed on October 6, 2020. Following the satisfaction of the conditions, we paid Elion $100,000 and will issue Elion 825,000 shares of our common stock, based on the $4.00 per share price in our underwritten public offering. Such shares will be subject to a lock-up, with 50% of such shares released from such lock up after six months and the remaining 25% tranches to be released following 9 months and 12 months, respectively.

As additional consideration, we will pay Elion development and regulatory milestone payments (a portion of which are payable in shares of our common stock and a portion of which are payable in cash) upon the achievement of certain milestones, which include the first two annual anniversaries of the effective date of the agreement, FDA or other regulatory approval and dosing a patient. In addition, we must pay Elion 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 received with Elion 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) dosing a first patient in a Phase 1B clinical trial with a product within 12 months; and (ii) dosing a first patient with a product in a Phase 2 or 3 clinical trial within 48 months. Either party may terminate the agreement in the event of a material breach of the 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 14 – 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 $76,979 and $79,058 of reimbursements during the nine months ended September 30, 2020 and 2019, respectively. No amounts were due from CorLyst at September 30, 2020 and December 31, 2019. In September 2020, CorLyst prepaid shared expenses to us for the fourth quarter of 2020 through the second quarter of 2021. Similarly, in August 2019, CorLyst prepaid us for shared expenses for Q4 2019. At September 30, 2020, we recognized $110,796 in prepaid reimbursements as due to related parties in the accompanying condensed consolidated balance sheet.

At September 30, 2020, we had approximately $7,600 due from certain employees for health insurance contributions. We did not have comparable a similar receivable at December 31, 2019.

Note 15 – 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 September 30, 2020.

Note 16 – Impact of COVID-19

In December 2019, a novel strain of coronavirus, SARS-CoV-2, causing the Coronavirus Disease 2019, also known as COVID-19, was reported to have surfaced in Wuhan. Since then, the SARS-CoV-2 virus has spread to multiple countries worldwide, including the United States, where we have planned and have ongoing preclinical studies and clinical trials. On March 11, 2020, the World Health Organization declared the outbreak of the SARS-CoV-2 virus to be a global pandemic.

Our clinical development timelines and plans could be affected by the SARS-CoV-2 virus pandemic. Site initiation and patient enrollment could be delayed or suspended due to prioritization of hospital resources toward the SARS-CoV-2 virus pandemic. In addition, some patients may not be able to comply with clinical trial protocols and the ability to conduct follow up visits with treated patients may be limited if quarantines impede patient movement or interrupt healthcare services. We cannot assure the SARS-CoV-2 virus will not have an adverse impact on our future planned clinical trials. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to SARS-CoV-2 virus pandemic could be adversely impacted.

If the SARS-CoV-2 virus pandemic continues to spread in the United States and elsewhere, we may experience disruptions, including those that could severely impact our business, preclinical studies, and planned clinical trials.

Note 17 – Subsequent Events

On October 6, 2020, we closed on our underwritten public offering of 4,800,000 shares of common stock for a public offering price of $4.00 per share. Net proceeds from the offering were approximately $17.1 million. In addition to closing our underwritten public offering, the following additional transactions occurred subsequent to September 30, 2020:

- As a result of closing our public offering, we triggered the full ratchet anti-dilution provision of shares sold in PIPE transactions in 2018, and as a result we will issue 1,156,480 shares of common stock to those stockholders. The full ratchet anti-dilution provisions expired following closing of the offering.
- DKBK, our line of credit lender, converted $700,000 principal amount outstanding and related accrued interest into 199,537 shares of common stock on October 6, 2020.
- The conditions for finalizing our agreements with Aposense and Elion were met upon the close of our public offering and up-list to the Nasdaq Capital Market. We made a payment of $100,000 to Elion and issued 625,000 and 825,000 shares of common stock to Aposense and Elion, respectively, pursuant to the agreements.
- We issued an additional 250,000 number of shares of common stock to Yuhan pursuant to the agreement we entered into with them.
- Restricted stock awards for 214,078 shares of our common stock vested on the completion of our public offering and up-list to the Nasdaq Capital Market on October 6, 2020.

The following pro forma table shows the number of issued and outstanding shares of our common stock as a result of the underwritten offering, which closed on October 6, 2020 as if the shares were all issued and outstanding as of September 30, 2020:

	September 30, 2020
Actual shares issued and outstanding	5,765,566
Shares sold in the underwritten common stock offering which closed on October 6, 2020	4,800,000
Conversion of the $700,000 LOC with DKBK and related accrued interest on October 6, 2020	199,537
Shares to be issued as a result of triggering the anti-dilution provision of previously issued shares of common stock	1,156,480
Shares to be issued to Yuhan Corporation, Elion Oncology, Inc. and Aposense Ltd. in connection with the respective license agreements.	1,700,000
Restricted stock awards that vested on the completion of our underwritten offering and up-list to the Nasdaq Capital Market on October 6, 2020	214,078
Pro forma shares issued and outstanding	13,835,661

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, our 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 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 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 or who have no alternative treatment. Our most advanced product candidate, PCS499, is an oral tablet that is a deuterated analog of one of the major metabolites of pentoxifylline (PTX or Trental®). We have completed the patient portion of the Phase 2A trial for PCS499 and are in the process of closing the trial, and we plan to begin recruiting for a Phase 2B trial in the first quarter of 2021. We have also begun the continued development of two newly acquired drugs, PCS12852 and PCS6422. We will continue to search for additional products for our portfolio that meet our portfolio criteria.

Our Strategy

Our vision is to develop drugs with potentially high return on investment and lower risk of development failure. Our portfolio drugs are focused on treating patients who do not have adequate treatment options for their conditions and have some clinical evidence supporting the efficacy of the drug, whether it be evidence with the drug itself or a drug with similar pharmacological properties. Given the prior success of our development team, the regulatory science approach that we employ not only allows us to develop drugs focused on FDA approval, but also allows us to select drugs for our portfolio which may have a greater chance for approval in a population of patients who need treatment options. The key pillars of our strategy to achieve our vision include:

(i) identifying drugs that have potential efficacy in patients with an unmet medical need, as demonstrated by some clinical evidence that the targeted pharmacology of the drug provides clinical efficacy in the targeted patient population;

(ii) identifying drug products that have been developed or approved for other indications but can be repurposed to treat those patients who have an unmet medical need; and

(iii) identifying drugs that can be quickly developed such that within 2-4 years, critical value-added clinical milestones can be achieved while advancing the drug closer to commercialization.

In order to add significant value to our in-licensed drugs within 2 to 4 years, the drugs must be in the clinical development stage and not in discovery stage, and during those 2 to 4 years we must be able to obtain clinical data to support the added value. The additional clinical data could range from a clinical proof-of-concept data to further demonstrate that the proposed pharmacology occurs clinically in the targeted patient population to a pivotal well-designed randomized controlled trial.

Our portfolio specifically includes drugs that (i) already have clinical proof-of-concept data demonstrating the desired pharmacological activity in humans or, minimally, clinical evidence in the form of case studies or clinical experience demonstrating the drug or a similar drug pharmacologically can successfully treat patients with the targeted indication, (ii) target indications for which the FDA believes that a single positive pivotal study demonstrating efficacy provides enough evidence that the clinical benefits of the drug and its approval outweighs the risks associated with the drug or the present standard of care (e.g., some orphan indications, many serious life-threatening conditions, some serious quality of life conditions), and/or (iii) target indications where the prevalence of the condition and the likelihood of patients enrolling in a study meet the desired time-frame to demonstrate that the drug can, at some level, treat or potentially treat patients with the condition.

To advance our mission, we have assembled an experienced and talented management and product development team. Our team is experienced in developing drug products through all principal regulatory tiers from IND enabling studies to NDA submission. Our combined scientific, development and regulatory experience has resulted in more than 30 drug approvals by the FDA, over 100 meetings with the FDA and involvement with more than 50 drug development programs, including drug products targeted to patients who have an unmet medical need. Although we believe that the skills and experience of our team in drug development and commercialization is an important indicator of our future success, the past successes of our team in developing and commercializing pharmaceutical products does not guarantee that they will successfully develop and commercialize drugs for us. In addition, the growth in revenues of companies at which our executive officers and directors served in was due to many factors and does not guarantee that they will successfully operate or manage us or that we will experience similar growth in revenues, even if they continue to serve as executive officers and/or directors.

Our ability to generate meaningful revenue from any products depends on our ability to out-license the drugs in the U.S. and/or ex-U.S. before or after we obtain FDA NDA approval. Even if our products are authorized and approved by the FDA, it should be noted that the products must still meet the challenges of successful marketing, distribution and consumer acceptance.

Status of our 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®). PCS499 is classified by FDA as a new molecular entity. PCS499 and its metabolites act on multiple pharmacological targets that are important in a variety of conditions. We have identified Necrobiosis Lipoidica (NL) as our lead indication for PCS499. 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 occurs more often in people with diabetes. Ulceration occurs in approximately 30% of NL patients, which can lead to more severe complications, such as deep tissue infections and osteonecrosis threatening the 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 may be caused by a number of pathophysiological changes, which has made it extremely difficult to develop effective treatments for this condition. Because PCS499 and its metabolites affect a number of biological pathways, several of which could contribute to the pathophysiology associated with NL, PCS499 may provide a novel treatment solution for NL, a condition for which there are currently no FDA-approved treatments.

On June 18, 2018, the FDA granted orphan-drug designation for PCS499 for the treatment of NL. On September 28, 2018, the IND for PCS499 in NL became effective, 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 study initially had a six-month treatment phase and a six-month optional extension phase. In December 2019, we informed patients and sites that the study would conclude after the treatment phase and there would no longer be an extension phase. 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 last patient visit took place in February 2020. Due to COVID-19 related restrictions at certain sites, study closeout and database lock did not occur until October 2020. We are finalizing the data results and clinical study report.

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. All adverse events reported in the study were mild in severity. As expected, gastrointestinal symptoms were the most noted adverse events and reported in four patients, all of which were mild in severity and resolved within 1-2 weeks of starting dosing.

Two of the twelve patients in the study presented with more severe ulcerated NL and 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 during the patient's treatment extension period. In addition, while in the trial, both patients also developed small ulcers at other sites, possibly related to contact trauma, and these ulcers resolved within one month. However, the other ten patients, presenting with mild to moderate NL and no ulceration, had more limited improvement of the NL lesions during treatment. Historically, less than 20% of all the patients with NL naturally progress to complete healing over many 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 several years after NL presentation.

On March 25, 2020, we met with the FDA and discussed the clinical program, as well as the nonclinical and clinical pharmacology plans to ultimately 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. We initially planned to begin recruiting for the randomized, placebo-controlled trial in the fourth quarter of 2020, but we now expect to begin recruiting patients in 2021 due to delays in fundraising efforts. This PCS499 NL study will be a randomized, placebo-controlled Phase 2B study to better understand the potential response of NL patients on drug and on placebo. After obtaining the results from this Phase 2B study, we expect to meet with FDA to discuss our Phase 2B drug and placebo response findings while further discussing the next steps to obtain approval.

New Licenses Entered into in Third Quarter

License Agreement with Yuhan Corporation. - On August 19, 2020, we entered into a License Agreement (the "Yuhan License Agreement") with Yuhan, pursuant to which we acquired an exclusive license to develop, manufacture and commercialize PCS12852 globally, excluding South Korea.

As consideration for the Yuhan License Agreement and related Share Issuance Agreement, we issued to Yuhan 250,000 shares of common stock (based upon an $8.00 per share price). Per the Yuhan License Agreement, we will issue an additional 250,000 shares based on the $4.00 per share price in the underwritten public offering, which closed on October 6, 2020. As additional consideration, we will pay Yuhan development and regulatory milestone payments (a portion of which are payable in shares of our common stock based on the volume weighted average trading price during the period prior to such achievement and a portion of which are payable in cash) upon the achievement of certain milestones, which primarily consist of dosing a patient in pivotal trials or having a drug indication approved by a regulatory authority in the United States or another country. The amount of future development and regulatory milestone payments payable to Yuhan is based in part on a Yuhan affiliate purchasing 750,000 shares of common stock for $3,000,000 in our underwritten public offering. In addition, we must pay Yuhan 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 received with Yuhan based on any sub-license agreement we may enter into.

We are required to use commercially reasonable efforts, at our sole cost and expense, in conjunction with a joint Processa-Yuhan Board to oversee such commercialization efforts, to research, develop and commercialize products in one or more countries, including meeting specific diligence milestones that consist of: (i) preparing a first draft of the product development plan within 90 days; (ii) requesting an FDA pre-IND meeting for a product within 6 months; (iii) dosing a first patient in a Phase 2A clinical trial with a product within 24 months; and (iv) dosing a first patient with a product in a Phase 2B clinical trial, Phase 3 clinical trial or other pivotal clinical trial with a product within 48 months. Either party may terminate the agreement in the event of a material breach of the 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 Elion Oncology, Inc - On August 23, 2020, we entered into the Elion License Agreement with Elion, pursuant to which we acquired an exclusive license to develop, manufacture and commercialize PCS6422 globally.

The grant of license was conditioned on the closing of our underwritten public offering and successful up-listing to Nasdaq, which closed on October 6, 2020. Following the satisfaction of the conditions, we paid Elion $100,000 and will issue Elion 825,000 shares of our common stock, based on the $4.00 per share price in our underwritten public offering. Such shares will be subject to a lock-up, with 50% of such shares released from such lock up after six months and the remaining 25% tranches to be released following 9 months and 12 months, respectively.

As additional consideration, we will pay Elion development and regulatory milestone payments (a portion of which are payable in shares of our common stock and a portion of which are payable in cash) upon the achievement of certain milestones, which include the first two annual anniversaries of the effective date of the agreement, FDA or other regulatory approval and dosing a patient. In addition, we must pay Elion 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 received with Elion 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) dosing a first patient in a Phase 1B clinical trial with a product within 12 months; and (ii) dosing a first patient with a product in a Phase 2 or 3 clinical trial within 48 months. Either party may terminate the agreement in the event of a material breach of the 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).

Recent Developments

Underwritten Public Offering - On October 6, 2020, we closed on our underwritten public offering of 4,800,000 shares of common stock for a public offering price of $4.00 per share. Net proceeds from the offering were approximately $17.1 million.

Conversion of our Line of Credit with DKBK Enterprises, LLC - On October 6, 2020, the Lender converted $700,000 due under the line of credit and accrued interest of $18,333 into 199,537 shares of common.

Results of Operations

Comparison of the three and nine months ended September 30, 2020 and 2019

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2020	2019	Change	2020	2019	Change
Operating Expenses						
Research and development expenses	$ 532,587	$ 584,979	$ (52,392)	$ 1,461,416	$ 1,804,169	$ (342,573)
Acquisition of in-process research and development	2,000,000	-	2,000,000	2,000,000	-	2,000,000
General and administrative expenses	422,958	419,028	3,930	1,282,239	1,219,329	62,910
Operating Loss	(2,955,545)	(1,004,007)		(4,743,655)	(3,023,498)	
Other Income (Expense)	(186,197)	(768)	(185,429)	(221,801)	(2,087)	(219,714)
Net Operating Loss Before Income Tax Benefit	(3,141,742)	(1,004,775)		(4,965,456)	(3,025,585)	
Income Tax Benefit	70,457	141,251	(70,794)	286,421	442,152	(155,731)
Net Loss	$ (3,071,285)	$ (863,524)		$ (4,679,035)	$ (2,583,433)	

Revenues.

We had no revenue during the three and nine months ended September 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 September 30, 2020 and 2019, we incurred total research and development expenses of $532,587 and $584,979, respectively, for the continued development and testing of our lead product, PCS499. Research and development expenses were approximately $1.5 and $1.8 million for the nine months ended September 30, 2020 and 2019, respectively. Costs for the three and nine months ended September 30, 2020 and 2019 were as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Amortization of intangible assets	$ 198,832	$ 198,832	$ 596,496	$ 596,496
Research and development salaries and benefits	156,195	245,053	411,020	564,935
Preclinical, clinical trial and other costs	177,560	141,094	453,900	642,738
Total	$ 532,587	$ 584,979	$ 1,461,416	$ 1,804,169

Overall, during the three months ended September 30, 2020, our research and development costs decreased by $52,392 as compared to the three months ended September 30, 2019. The decrease in research and development expenses was due to a decrease in research and development salaries and benefits of $88,858 for the three months ended September 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. The decrease was offset by an increase in preclinical, clinical trial and other costs of $36,466, which was primarily due to an increase in professional fees.

During the nine months ended September 30, 2020, our research and development costs decreased by $342,753 as compared to the nine months ended September 30, 2019. The decrease in research and development expenses was due to a decrease in preclinical, clinical trial and other costs of $188,838 and in research and development salaries and benefits of $153,915 during the nine months ended September 30, 2020 when compared to the same period in 2019 for the same reasons as stated above.

We incurred $297,020 of costs related to our Phase 2A trial during the nine months ended September 30, 2020 and expect to spend an additional $188,000 as we close out the trial. We believe, based on our estimates, the total cost of our Phase 2A trial in NL will total approximately $1.5 million.

We anticipate our research and development costs to increase significantly in the future as we continue manufacturing drug products and conduct future clinical trials related to our current drug portfolio as we start clinical trials for PCS499, PCS6422 and PCS12852.

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. As noted above, we anticipate our research and development costs to increase in the future as we finalize our Phase 2A clinical trial activities and beginning designing and conducting a Phase 2B trial to evaluate the ability of PCS499 to completely close ulcers in patients with NL, begin a Phase 1B clinical trial for PCS6422 and a Phase 2A study for PCS12852. We expect to begin recruiting patients for these three clinical trials during the first half of 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 contract research organizations (CROs) that conduct and manage clinical trials on our behalf.

We estimate manufacturing 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.

Acquisition of In-Process Research and Development.

In connection with the Yuhan License Agreement, we recorded $2 million of acquired in-process research and development expense during the three and nine month periods ended September 30, 2020. We believe the in-process research and development assets acquired have no alternative future use. We did not acquire any in-process research and development assets in 2019.

General and Administrative Expenses.

Our general and administrative expenses for the three months ended September 30, 2020 increased by $3,930 to $422,958 from $419,028 for the three months ended September 30, 2019. We experienced an increase in professional fees for legal, accounting, advisory and consulting costs of approximately $24,524 and in administrative expenses such as taxes, insurance and office expenses of $21,828. The increase was offset by reductions in payroll and related costs of $42,679 (primarily due to a decrease in stock-based compensation of $56,631). Reimbursements from CorLyst, a related party, were $26,337 and $26,594 for rent and other costs during the nine months ended September 30, 2020 and 2019, respectively.

For the nine months ended September 30, 2020, general and administrative expenses increased by $62,910 to $1,282,239 from $1,219,329 for the nine months ended September 30, 2019. The majority of the increase was due to a $126,003 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 an increase in insurance of $24,469 and in payroll and related costs of $1,291. These increases were offset by a decrease of $70,106 in professional fees for legal, accounting, advisory and consulting costs, and $20,826 in other administrative expenses such as office expenses, travel, and repairs and maintenance. Reimbursements from CorLyst of $76,979 for rent and other costs during the nine months ended September 30, 2020 were $2,079 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.

Other Income and Expense.

Interest expense was $186,209 and $2,271 for the three months ended September 30, 2020 and 2019, respectively, and $222,660 and $12,973 for the nine months ended September 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 $157,129 and $0 for the nine months ended September 30, 2020 and 2019, respectively. As noted in Note 5 – 2019 Senior Notes, we did not recognize $197,403 in debt issuance costs related to the warrants issuable to the Note Holders until September 2020, and as such, did not amortize the debt issuance costs in previous periods.

Interest income was $12 and $1,503 for the three months ended September 30, 2020 and 2019, respectively, and $859 and $10,886 for the nine months ended September 30, 2020 and 2019, respectively. Interest income represents interest earned on money market funds.

Income Tax Benefit.

We recognized an income tax benefit of $70,457 and $141,251 for the three months ended September 30, 2020 and 2019, respectively, and $286,421 and $442,152 for the nine months ended September 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.

Liquidity and Capital Resources

At September 30, 2020, we had $325,428 in cash. Net cash used in our operating activities during the nine months ended September 30, 2020 totaled $867,839 compared to $2,136,659 for the nine months ended September 30, 2019. On October 6, 2020, we closed on our underwritten public offering of 4,800,000 shares of common stock for a public offering price of $4.00 per share. Net proceeds from the offering were approximately $17.1 million.

We had no revenue during the three and nine months ended September 30, 2020 and 2019, and do not have any revenue under contract or any immediate sales prospects. Our primary uses of cash are to fund our planned clinical trials, research and development expenditures and operating expenses. Cash used to fund operating expenses is impacted by the timing of when incur and pay these expenses.

On October 6, 2020, we closed an underwritten public offering of 4,800,000 shares of common stock for a public offering price of $4.00 per share. Net proceeds from the offering were approximately $17.1 million. We believe these funds, along with our existing cash on that day will provide us with sufficient capital to meet our anticipated operating and capital expenditure requirements into the fourth quarter of 2022. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our ultimate success depends on the outcome of our planned clinical trials and our research and development activities, as disclosed above. We expect to incur additional losses in the future and we anticipate the need to raise additional capital to fully implement our business plan if the cost of our planned clinical trials are greater than we expect or they take longer than anticipated. We also expect to incur increased general and administrative expenses at least through 2022 due in part to planned increased research and development activities as we conduct a Phase 2B trial for PCS499, a Phase 1B trial for PCS6422, and a Phase 2A clinical trial for PCS12852. In addition, there may be costs we incur as we develop these drug products that we do not currently anticipate requiring us to need additional capital sooner than currently expected.

Prior to our underwritten public offering in October 2020, our business and operations were funded primarily through the private placement of equity securities and senior secured convertible notes. We have taken the following actions to address our liquidity:

- Starting in August 2019, we began deferring the salaries of certain employees. At September 30, 2020 we have deferred a total of $289,873 (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 stockholders 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 shares of our common stock. Our CEO is also the CEO and Managing Member of both Lenders. As of September 30, 2020DKBK directly holds 16,166 shares of our common stock, and CorLyst beneficially owns 1,095,649 shares. 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. On October 6, 2020, DKBK converted the debt and related interest into 199,537 shares of our common stock in connection with the closing of our underwritten public offering.

- 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.

- On October 6, 2020, we closed our underwritten capital raise, receiving net proceeds of $17.1 million and our common stock was approved for listing on the Nasdaq Capital Market, which began trading under the symbol “PCSA” on October 2, 2020.

If we need to raise additional capital to fund our operations in the future, 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 one or more of our preclinical studies 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 collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Cash Flows

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

	Nine months ended September 30,	
	2020	2019
Net cash (used in) provided by:		
Operating activities	$ (867,839)	$ (2,136,659)
Investing activities	-	-
Financing activities	501,731	900,000
Net decrease in cash	$ (366,108)	$ (1,236,659)

Net cash used in operating activities

We used net cash in our operating activities of $867,839 and $2,136,659 during the nine months ended September 30, 2020 and 2019, respectively. The decrease in cash used in operating activities during the first nine 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 $273,000, $172,000 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 nine months ended September 30, 2020 or 2019.

Net cash provided by financing activities

Net cash provided by financing activities during the nine months ended September 30, 2020 of $501,731 was from borrowings totaling $700,000 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 $360,728 related to our underwritten public offering. During the nine months ended September 30, 2019, net cash provided by financing activities of $900,000 were funds received from our clinical trial funding investor in partial satisfaction of his stock subscription receivable that he paid directly to our CRO.

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 September 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 September 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 September 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 have experienced delays in completing the closeout of our Phase 2A clinical trial for PCS499 and any future delays 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.

Our licenses are subject to termination by the licensor in certain circumstances.

Our rights to practice the inventions claimed in the licensed patents and patent applications are subject to our licensors abiding by the terms of those licenses and not terminating them. Our licenses may be terminated by the licensor if we are in material breach of certain terms or conditions of the license agreement or in certain other circumstances. Our license agreements each include provisions that allow the licensor to terminate the license if (i) we breach any payment obligation or other material provision under the agreement and fail to cure the breach within a fixed time following written notice of termination, (ii) we or any of our affiliates, licensees or sublicensees directly or indirectly challenge the validity, enforceability, or extension of any of the licensed patents, or (iii) we declare bankruptcy or dissolve. The majority of license agreements require us to satisfy due diligence milestones that relate to the development of new products containing the licensed drug or the agreement may be terminated by such counterparty. Our rights under these licenses are subject to our continued compliance with the terms of the license, including the milestone and royalty payments due under the license. Termination of any of these licenses could prevent us from marketing some or all of our products. Because of the complexity of our products and the patents we have licensed, determining the scope of the license and related royalty obligations can be difficult and can lead to disputes between us and the licensor. An unfavorable resolution of such a dispute could lead to an increase in the royalties payable pursuant to the license. If a licensor believed we were not paying the royalties due under the license or were otherwise not in compliance with the terms of the license, the licensor might attempt to revoke the license. If such an attempt were successful, we might be barred from producing and selling some or all of our products.

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

(a) Recent Sale of Unregistered Securities

In September 2020, we issued 250,000 shares of common stock to Yuhan Corporation, an accredited investor, in connection with a license agreement. The sale of shares was exempt from the registration requirements of the Securities Act of 1933, as amended (the "Securities Act"), in reliance on Section 4(a)(2) of the Securities Act. See Note 12 for additional information about the license agreement with Yuhan Corporation. There were no other sales of unregistered securities during the three months ended September 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 three months ended September 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
10.1	License Agreement with Yuhan Corporation (incorporated by reference to Form S-1 filed September 30, 2020)
10.2	Share Issuance Agreement pursuant to License Agreement with Yuhan Corporation (incorporated by reference to Form S-1 filed September 30, 2020)
10.3	License Agreement with Elion Oncology, Inc. (incorporated by reference to Form S-1 filed September 30, 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: November 12, 2020

By: */s/ James Stanker*
James Stanker
Chief Financial Officer
(Principal Financial and Accounting Officer)
Dated: November 12, 2020

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 quarterly period ended September 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:November 12, 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 quarterly period ended September 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:November 12, 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 September 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:November 12, 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 September 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:November 12, 2020

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