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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2021

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 ☒ 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See definition 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	☒
		Emerging growth company	☐

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

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

The number of outstanding shares of the registrant's common stock as of November 2, 2021 was15,715,996.

PROCESSA PHARMACEUTICALS, INC.
TABLE OF CONTENTS

PART 1: FINANCIAL INFORMATION
ITEM 1: FINANCIAL STATEMENTS

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

	September 30, 2021	December 31, 2020
ASSETS		
Current Assets		
Cash and cash equivalents	$ 19,093,188	$ 15,416,224
Due from related party	-	154,730
Due from tax agencies	70,274	77,024
Prepaid expenses and other	1,506,603	554,708
Total Current Assets	20,670,065	16,202,686
Property and Equipment, net	-	484
Other Assets		
Operating lease right-of-use assets, net of accumulated amortization	95,934	158,558
Intangible assets, net of accumulated amortization	8,253,761	8,847,126
Security deposit	5,535	5,535
Total Other Assets	8,355,230	9,011,219
Total Assets	$ 29,025,295	$ 25,214,389
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Note payable – Paycheck Protection Program, current portion	$ -	$ 117,574
Current maturities of operating lease liability	92,769	87,200
Accrued interest	-	950
Accounts payable	354,977	320,694
Due to licensor	400,000	400,000
Due to related parties	-	69,858
Accrued expenses	378,660	224,676
Total Current Liabilities	1,226,406	1,220,952
Non-current Liabilities		
Note payable – Paycheck Protection Program	-	44,885
Non-current operating lease liability	8,773	78,463
Non-current due to licensor	400,000	400,000
Net deferred tax liability	181,752	530,611
Total Liabilities	1,816,931	2,274,911
Commitments and Contingencies	-	-
Stockholders' Equity		
Common stock, par value $0.0001, 30,000,000 shares authorized: 15,599,062 and 14,187,984 issued and outstanding at September 30, 2021 and December 31, 2020, respectively	1,560	1,419
Additional paid-in capital	60,846,342	48,333,857
Accumulated deficit	(33,639,538)	(25,395,798)
Total Stockholders' Equity	27,208,364	22,939,478
Total Liabilities and Stockholders' Equity	$ 29,025,295	$ 25,214,389

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

Processa Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating Expenses				
Research and development expenses	$ 1,722,364	$ 532,587	$ 4,806,845	$ 1,461,416
Acquisition of in-process research and development	50,953	2,000,000	566,583	2,000,000
General and administrative expenses	1,338,113	422,958	3,391,105	1,282,239
Operating Loss	(3,111,430)	(2,955,545)	(8,764,533)	(4,743,655)
Other Income (Expense)				
Forgiveness of PPP loan and related accrued interest	-	-	163,771	-
Interest expense	-	(186,209)	(362)	(222,660)
Interest income	1,771	12	8,525	859

Net Operating Loss Before Income Tax Benefit	(3,109,659)	(3,141,742)	(8,592,599)	(4,965,456)
Income Tax Benefit	122,442	70,457	348,859	286,421
Net Loss	$ (2,987,217)	$ (3,071,285)	$ (8,243,740)	$ (4,679,035)
Net Loss per Common Share - Basic and Diluted	$ (0.19)	$ (0.55)	$ (0.54)	$ (0.84)
Weighted Average Common Shares Used to Compute Net Loss Applicable to Common Shares - Basic and Diluted	15,531,442	5,594,370	15,177,306	5,542,026

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

Processa Pharmaceuticals, Inc.
Condensed Consolidated Statement of Changes in Stockholders' Equity
(Unaudited)

Nine Months Ended September 30, 2021

	Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance at January 1, 2021	14,187,984	$ 1,419	$ 48,333,857	$ (25,395,798)	$ 22,939,478
Stock-based compensation	12,500	1	620,590	-	620,591
Shares issued in private placement, net of transaction costs	1,321,132	132	9,875,418	-	9,875,550
Net loss	-	-	-	(2,099,480)	(2,099,480)
Balance, March 31, 2021	15,521,616	1,552	58,829,865	(27,495,278)	31,336,139
Stock-based compensation	38,300	4	762,592	-	762,596
Shares issued in connection with license agreement	44,689	4	299,996	-	300,000
Net loss	-	-	-	(3,157,043)	(3,157,043)
Balance, June 30, 2021	15,604,605	1,560	59,892,453	(30,652,321)	29,241,692
Stock-based compensation	(1,030)	-	981,869	-	981,869
Shares withheld to pay income taxes on stock-based compensation	(4,513)	-	(27,980)	-	(27,980)
Net loss	-	-		(2,987,217)	(2,987,217)
Balance, September 30, 2021	15,599,062	$ 1,560	$ 60,846,342	$ (33,639,538)	$ 27,208,364

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

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, 2021 and 2020
(Unaudited)

	2021	2020
Cash Flows From Operating Activities		
Net loss	$ (8,243,740)	$ (4,679,035)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	484	6,334
Non-cash lease expense for right-of-use assets	62,624	59,875
Non-cash acquisition of in-process research and development	300,000	2,000,000
Amortization of debt issuance costs	-	157,129

Amortization of intangible asset	593,365	596,496
Deferred income tax benefit	(348,859)	(286,421)
Stock-based compensation	2,257,863	357,039
Forgiveness of PPP loan and related accrued interest	(163,771)	-
Net changes in operating assets and liabilities:		
Prepaid expenses and other	(664,417)	272,750
Operating lease liability	(64,121)	(58,881)
Accrued interest	362	67,802
Accounts payable	34,283	351,839
Due to related parties	84,872	102,875
Other receivables	6,750	-
Accrued expenses	153,984	184,359
Net cash used in operating activities	(5,990,321)	(867,839)
Cash Flows From Financing Activities		
Net proceeds from private placement	9,875,550	-
Borrowings on line of credit payable from related party	-	700,000
Proceeds received from our Paycheck Protection Program note payable	-	162,459
Shares withheld to pay taxes on stock-based compensation	(27,980)	-
Other	(180,285)	(360,728)
Net cash provided by financing activities	9,667,285	501,731
Net Increase (Decrease) in Cash	3,676,964	(366,108)
Cash and Cash Equivalents – Beginning of Period	15,416,224	691,536
Cash and Cash Equivalents – End of Period	$ 19,093,188	$ 325,428

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

Processa Pharmaceuticals, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

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 provide treatment for patients who have a high unmet medical need condition that effects survival or the patient's quality of life and for which few or no treatment options currently exist. We currently have five drugs: four in various stages of clinical development (PCS499, PCS12852, PCS3117 and PCS6422) and one in nonclinical development (PCS11T). We group our drugs into non-oncology (PCS499 and PCS12852) and oncology (PCS3117, PCS6422 and PCS11T). A summary of each of our five drugs is provided below:

- 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 completed a Phase 2A trial for PCS499 in patients with ulcerative and non-ulcerative necrobiosis lipoidica (NL) in late 2020, and in May 2021 we enrolled the first patient in our Phase 2B trial for the treatment of ulcerative NL. We expect to complete our interim analysis of the Phase 2B trial in mid-2022; complete the trial in the second half of 2022; and, depending on the results, begin a pivotal Phase 3 trial in 2023.

- PCS12852 is a highly specific and potent 5HT4 agonist which has already been evaluated in clinical studies in South Korea for gastric emptying and gastrointestinal motility. In October 2021, the FDA cleared our IND application to proceed with a Phase 2A trial for the treatment of gastroparesis. We anticipate beginning to enroll patients in the first half of 2022, with expected completion in the first half of 2023.

- PCS3117, which we licensed in June 2021, is a cytosine analog, similar to gemcitabine (Gemzar®) but different enough in chemical structure that some patients are more likely to respond to PCS3117 than gemcitabine. We are developing potential biomarkers to predict which patients are more likely to respond to PCS3117 than gemcitabine and other chemotherapy agents to provide a more targeted, precision medicine approach to the treatment of pancreatic and/or non-small cell lung cancer. Over the next 6-12 months, we will be developing and refining these biomarker assays for use in our clinical trials, which should be completed in the first half of 2022. We anticipate validating our approach and confirming our hypothesis in a planned Phase 2B study expected to start in the second half of 2022 and, depending on the results, conducting a Phase 3 pivotal trial in 2023-2024.

- PCS6422 is an orally administered irreversible enzyme inhibitor administered in combination with capecitabine. When combining capecitabine with PCS6422 (the "Next Generation Capecitabine"), capecitabine becomes a more potent cancer chemotherapy agent than current FDA approved capecitabine. On August 2, 2021, we enrolled the first patient in our Phase 1B dose-escalation maximum tolerated dose trial in patients with advanced refractory gastrointestinal (GI) tract tumors and our interim analysis of Cohorts 1 and 2 found no dose-limiting toxicities (DLTs), no drug related adverse events greater than Grade 1, and no hand-foot syndrome. In addition, the interim analysis revealed when PCS6422 inhibits DPD enzyme activity, 5-FU metabolism is significantly decreased (< 10% metabolized to F-BAL compared to typically 80%) and the potency of capecitabine is significantly increased (at least 50 x greater 5-FU potency based on systemic exposure per mg of capecitabine administered). The single dose of PCS6422, however, does not sustain the DPD inhibition throughout 7 days of capecitabine dosing which is needed to maintain the improved potency of capecitabine. Therefore, we are modifying the existing protocol to obtain more data on DPD inhibition and de novo formation. We anticipate that this additional data will allow us to select PCS6422 dosage regimens that will maintain DPD inhibition for each patient treated with this Next Generation Capecitabine (i.e., combination of PCS6422 and capecitabine). After interacting with the FDA and making protocol modifications, we expect to restart the Phase 1B study in the middle of the first half of 2022 while defining the Next Generation Capecitabine regimen (i.e., the PCS6422 regimens and the corresponding capecitabine regimens) by the end of 2022. Although we are making modifications to the existing Phase 1B protocol, we expect that our overall timeline has not changed with a Phase 2B or 3 trial starting in 2023-2024 and NDA submission in 2027-2028.

- Our only nonclinical drug candidate is PCS11T, an analog of SN38 (SN38 being the active metabolite of irinotecan) and a next generation irinotecan drug for multiple types of cancers. PCS11T is presently in the IND pre-clinical toxicology stage. We hope to submit an IND in the first half of 2023, followed by a Phase 1B maximum tolerated dose trial.

Impact of COVID-19

The COVID-19 pandemic has created uncertainties in the expected timelines for clinical stage biopharmaceutical companies such as ours, including possible delays in clinical trials and disruptions in the supply chain for raw materials used in clinical trial work. Such delays could materially impact our business in future periods. Furthermore, the spread

of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the economic impact brought by, and the duration of, COVID-19 is difficult to assess or predict, the COVID-19 pandemic and its resulting variants could result in further disruption of global financial markets, reducing our ability to access capital, which could negatively affect our liquidity. Policymakers around the globe have responded with fiscal policy actions to support the healthcare industries and economies as a whole. Whether this support continues is uncertain. Accordingly, the extent to which the COVID-19 global pandemic impacts our business, results of operations and financial condition will depend on future developments, which are highly uncertain and are difficult to predict. These developments include, but are not limited to, the duration and spread of the outbreak, its resulting variants, its severity, the actions to contain the virus or address its impact, U.S. and foreign government actions to respond to the reduction in global economic activity, and how quickly and to what extent normal economic and operating conditions can resume. For more information on the risks associated with COVID-19, refer to Part I, Item 1A, "Risk Factors" in our Annual Report on Form 10-K.

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 U.S. 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, 2020, 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

We have incurred losses since inception, devoting substantially all of our efforts toward research and development, and have an accumulated deficit of approximately $93.6 million at September 30, 2021. During the nine months ended September 30, 2021, we generated a net loss of approximately $8.2 million and we expect to continue to generate operating losses and negative cash flow from operations for the foreseeable future. However, we believe our cash balance at September 30, 2021 is adequate to fund our budgeted operations into the middle of 2023. Our ability to execute our longer-term operating plans, including unplanned future clinical trials for our portfolio of drugs depend on our ability to obtain additional funding from the sale of equity and/or debt securities, a strategic transaction or other funding transactions. We plan to continue to actively pursue financing alternatives, but there can be no assurance that we will obtain the necessary funding in the future when necessary.

We had no revenue during the nine months ended September 30, 2021 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 we incur and pay these expenses.

Use of Estimates

In preparing our condensed consolidated financial statements and related disclosures in conformity with U.S. GAAP and pursuant to the rules and regulations of the SEC, we make estimates and judgments that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Estimates are used for, but not limited to preclinical and clinical trial expenses, stock-based compensation, intangible assets, future milestone payments and income taxes. These estimates and assumptions are continuously evaluated and are based on management's experience and knowledge of the relevant facts and circumstances. While we believe the estimates to be reasonable, actual results could differ materially from those estimates and could impact future results of operations and cash flows.

Intangible Assets

Intangible assets acquired individually or with a group of other assets from others (other than in a business combination) are recognized at cost, including transaction costs, and allocated to the individual assets acquired based on relative fair values and no goodwill is recognized. Cost is measured based on cash consideration paid. If consideration given is in the form of non-cash assets, liabilities incurred, or equity interests issued, measurement of cost is based on either the fair value of the consideration given or the fair value of the assets (or net assets) acquired, whichever is more clearly evident and more reliably measurable. Costs of internally developing, maintaining or restoring intangible assets that are not specifically identifiable, have indeterminate lives or are inherent in a continuing business are expensed as incurred.

Intangible assets purchased from others for use in research and development activities and that have alternative future uses (in research and development projects or otherwise) are capitalized in accordance with ASC Topic 350, *Intangibles – Goodwill and Other.* Those that have no alternative future uses (in research and development projects or otherwise) and therefore no separate economic value are considered research and development costs and are expensed as incurred. Amortization of intangibles used in research and development activities is a research and development cost.

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

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

Impairment of Long-Lived Assets and Intangibles Other Than Goodwill

We account for the impairment of long-lived assets in accordance with ASC 360, *Property, Plant and Equipment* and ASC 350, *Intangibles – Goodwill and Other,* which require that long-lived assets and certain identifiable intangibles be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to its expected future undiscounted net cash flows generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amounts of the assets exceed the fair value of the assets based on the present value of the expected future cash flows associated with the use of the asset. Assets to be

disposed of are reported at the lower of the carrying amount or fair value less costs to sell. Based on management's evaluation, there was no impairment loss recorded during the nine months ended September 30, 2021 or 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 over the requisite service period based on the estimated grant-date fair value of the awards. Stock-based awards with graded-vesting schedules are recognized on a straight-line basis over the requisite service period for each separately vesting portion of the award. We value restricted stock awards (RSAs) and restricted stock units (RSUs) based on the closing share price on the date of grant. We estimate the fair value of stock option and warrant 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 condensed consolidated statements of operations based upon the underlying individual's or consultant's role.

Stock-based compensation during the nine months ended September 30, 2021 consisted of the following:

Employee and Director stock-based compensation	$	1,815,094
Stock-based compensation paid to consultants for services rendered and to be rendered		549,962
		2,365,056
Total amount originally included in prepaid expenses		(410,908)
Less amortization of prepaid expenses		303,715
Total stock-based compensation for the nine months ended September 30, 2021	$	2,257,863

At September 30, 2021, $107,193 of stock-based compensation related to consultants for services is included in our prepaid expense and is being amortized over the contract period of one year as services are expected to be provided.

Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted average common shares outstanding and vested RSUs. Diluted net loss per share is computed by dividing net loss by the diluted weighted average common shares outstanding. Since we experienced a net loss for both periods presented, basic and diluted net loss per share are the same. As such, diluted loss per share for the nine months ended September 30, 2021 and 2020 excludes the impact of potentially dilutive common shares related to outstanding stock options, unvested restricted stock awards (RSAs), unvested restricted stock units (RSUs) and purchase warrants and, in 2020, the conversion of our 2019 Senior Notes and related party line of credit (LOC) since those shares would have an anti-dilutive effect on loss per share.

Our diluted net loss per share for the nine months ended September 30, 2021 and 2020 excluded 844,394 and 1,257,109, respectively, of potentially dilutive common shares, respectively, related to outstanding stock options, unvested RSAs, unvested RSUs and purchase warrants and, in 2020, the conversion of our Senior Notes and related party LOC since those shares would have had an anti-dilutive effect on loss per share during the periods then ended.

Recent Accounting Pronouncements

From time to time, the Financial Accounting Standards Board ("FASB") or other standard setting bodies issue new accounting pronouncements. Updates to the FASB Accounting Standards Codification are communicated through issuance of an Accounting Standards Update ("ASU"). We have implemented all new accounting pronouncements that are in effect and that may impact our 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 – License Agreement with Ocuphire Pharma, Inc.

On June 16, 2021, we executed a License Agreement with Ocuphire Pharma, Inc. ("Ocuphire Agreement") under which we received a license to research, develop and commercialize PCS3117 (formerly RX-3117) globally, excluding the Republic of Singapore, China, Hong Kong, Macau and Taiwan.

As consideration for the Ocuphire Agreement, we issued 44,689 shares of our common stock to Ocuphire, a cash payment of $200,000 and assumed $66,583 in certain liabilities. Additional consideration includes future development and regulatory milestones payments to Ocuphire upon our achievement of certain defined clinical milestones such as dosing a patient in pivotal trials and receiving marketing authorization by a regulatory authority in the United States or another country. In addition, we are required to pay Ocuphire one-time sales milestone payments based on the achievement during a calendar year of the highest annual Net Sales for products made and pay royalties based on annual Net Sales, as defined in the Ocuphire Agreement.

We are required to use commercially reasonable efforts, at our sole cost and expense 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) first patient administered drug in a Clinical Trial of a Product prior to June 16, 2024; and (ii) first patient administered drug in a Pivotal Clinical Trial of a Product or first patient administered drug in a Clinical Trial for a Second Indication of a Product prior to June 16, 2026. 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 120-day opportunity to cure such breach.

Note 3 – Property and Equipment

Property and equipment at September 30, 2021 and December 31, 2020 consisted of the following:

		September 30, 2021		December 31, 2020
Software	$	19,740	$	19,740
Office equipment		9,327		9,327
Total Cost		29,067		29,067
Less: accumulated depreciation		29,067		28,583
Property and equipment, net	$	-	$	484

Note 4 – Intangible Assets

Intangible assets at September 30, 2021 and December 31, 2020 consisted of the following:

	September 30, 2021	December 31, 2020
Gross intangible assets	$ 11,059,429	$ 11,059,429
Less: accumulated amortization	(2,805,668)	(2,212,303)
Total intangible assets, net	$ 8,253,761	$ 8,847,126

Amortization expense was $195,700 and $198,832 for the three months ended September 30, 2021 and 2020, and $593,365 and $596,496 for the nine months ended September 30, 2021 and 2020 and is included within research and development expense in the accompanying condensed consolidated statements of operations. As of September 30, 2021, our estimated amortization expense for the 2021 will be approximately $790,000 and approximately $788,000 per year for annual periods thereafter.

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 5 – 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, 2021 and December 31, 2020, we recorded a valuation allowance equal to the full recorded amount of our net deferred tax assets related to deferred start-up costs, purchased in-process research and development expenditures, federal orphan drug tax credit and certain other minor temporary differences since it is more-likely-than-not that such benefits will not be realized. The valuation allowance is reviewed quarterly and is maintained until sufficient positive evidence exists to support its reversal.

A deferred tax liability was recorded on March 19, 2018 when Processa received CoNCERT's license and "Know-How" in exchange for Processa stock that had been issued in the Internal Revenue Code Section 351 Transaction. The Section 351 Transaction treats the acquisition of the license and Know-How for stock as a tax-free exchange. As a result, under ASC 740-10-25-51 *Income Taxes*, Processa recorded a deferred tax liability of $3,037,147 for the acquired temporary difference between intangible assets (see Note 4) for the financial reporting basis of $11,038,929 and the tax basis of $1,782. The deferred tax liability will be reduced for the effect of non-deductibility of the amortization of the intangible asset and may be offset by the deferred tax assets resulting from net operating tax losses.

Under ACS 740-270 *Income Taxes – Interim Reporting*, we are required to project our annual federal and state effective income tax rate and apply it to the year-to-date ordinary operating tax basis loss before income taxes. Based on the projection, we expect to recognize the tax benefit from our projected ordinary tax loss, which can be used to offset the deferred tax liabilities related to the intangible assets and resulted in the recognition of a deferred tax benefit shown in the condensed consolidated statements of operations for three and nine months ended September 30, 2021 and 2020. No current income tax expense is expected for the foreseeable future as we expect to generate taxable net operating losses.

Note 6 – Stock-based Compensation

We recorded $2,257,863 and $357,039 of stock-based compensation expense for the nine months ended September 30, 2021 and 2020, respectively. During the nine months ended September 30, 2021, we awarded the following equity instruments:

Award Type	Number of Shares Awarded	Number of Shares Vested
Restricted stock awards – employee	37,500	-
Restricted stock units – employees	351,661	100,731
Restricted stock units – consultants	17,800	13,800
Stock options – consultant	30,000	15,000
Warrants – consultants	150,000	112,500

We valued the RSAs and RSUs based on the closing share price on the date of grant. The fair values of the stock options and warrants granted were estimated using the Black-Scholes option pricing model at the date of grant. The RSUs, stock options and warrants issued to consultants were for services to be provided in 2021 and 2022. Of the awards granted to consultants, 12,500 RSUs and 100,000 warrants vested upon grant but represent services that will be provided in 2021. As such, at September 30, 2021, we recognized $107,193 related to these awards as a prepaid expense for the portion of services the consultant has yet to provide.

On August 5, 2020, we issued 324,360 RSAs under the 2019 Omnibus Incentive Plan to our employees and directors, of which 214,078 shares of common stock vested on October 6, 2020 when we successfully completed our underwritten public offering and up-listed to the Nasdaq Capital Market and 55,142 shares of common stock vested on August 5, 2021. The remaining 53,610 shares of common stock vest on August 5, 2022, the second year anniversary of the grant date. Between the fourth quarter of 2020 and September 30, 2021, 29,847 shares have been forfeited to pay for federal, state and local income taxes or upon employment termination.

On July 1, 2021, we granted 198,930 RSUs under the 2019 Omnibus Incentive Plan to our employees. Of the RSUs awarded, 79,572 RSUs contain a service condition that requires continued employment over a two-year period. Half (or 39,786) of the RSUs vest on July 1, 2022 and the remaining half vest on July 1, 2023. 119,358 RSUs vest upon meeting the following performance criteria: (i) 39,786 RSUs vest upon the completion of the interim analysis of Cohorts 1 and 2 for our PCS6422 Phase 1B clinical trial; (ii) 39,786 RSUs vest upon the completion of the interim analysis of our PCS499 Phase 2B clinical trial; and (iii) 39,786 RSUs vest upon the next capital raise(s) totaling a cumulative amount of at least $30 million.

At September 30, 2021, we had the following awards outstanding related to stock-based compensation:

Award Type	Amount Outstanding	Amount Vested	Amount Unvested
Restricted stock awards	344,513	239,374	105,139
Restricted stock units	369,461	114,531	254,930
Stock Options	182,128	145,357	36,771
Warrants	150,000	112,500	37,500

The weighted average exercise price of stock options and warrants outstanding at September 30, 2021 was $17.06 and $10.66, respectively. At September 30, 2021, we had warrants for the purchase of 303,725 shares of our common stock outstanding which expire at various dates through February 16, 2023. Warrants for the purchase of 153,725 shares of our common stock were issued in connection with PIPE transactions and other fundraising efforts we had over the last three years.

Note 7 – Paycheck Protection Program Loan

In May 2020, we entered into a $162,459 Paycheck Protection Promissory Note (the "PPP Loan") with 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 term of the loan was two years with a maturity date of May 5, 2022, and it contained a favorable fixed annual interest rate of 1.00%. Payments of principal and interest on the PPP Loan were deferred for the first six months of the term of the PPP Loan until November 5, 2020. Principal and interest were 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, and on the maintenance of employee and compensation levels during a certain time period following the funding of the PPP Loan. We used the entire proceeds of our PPP Loan for payroll costs and applied for full forgiveness on January 18, 2021. In August 2021, we received notice of loan forgiveness from the Small Business Administration, which we recorded in the three months ended June 30, 2021.

Note 8 – Stockholders' Equity

During the nine months ended September 30, 2021, we granted 17,800 shares of our common stock and issued a combination of warrants and stock options for the purchase of 180,000 shares of common stock to consultants in accordance with consulting agreements for services that will be provided in 2021 and 2022. The total value of these issuances was $797,216. We are amortizing this amount over the related contract lives and at September 30, 2021, we included $107,193 as a prepaid expense, representing the portion of services yet to be provided. We also granted 37,500 RSAs to an employee in accordance with their employment agreement.

On February 24, 2021, we sold in a private placement 1,321,132 shares of our common stock to accredited and institutional investors for gross proceeds of $10.2 million. Net proceeds from the offering were $9.9 million. In connection with the placement, we issued warrants for the purchase of 79,268 shares of our common stock to our placement agent. These warrants are exercisable for cash at $9.30 per share and expire on February 24, 2023.

On June 16, 2021, we issued 44,689 shares of our common stock to Ocuphire Pharma, Inc. pursuant to the Ocuphire Agreement (see Note 2).

In August 2020, we issued 324,360 RSAs. Of these, 6,043 shares were forfeited during the nine months ended September 30, 2021 to pay for federal, state and local income taxes or upon employment termination. No similar forfeiture occurred during the nine months ended September 30, 2020.

On August 20, 2021, we entered into an equity distribution agreement (the "Sales Agreement") with Oppenheimer & Co. Inc. (the "Sales Agent") under which we may issue and sell in a registered "at-the-market" offering shares of our common stock having an aggregate offering price of up to $30.0 million from time to time through or to our Sales Agent (the "ATM Offering"). We expect to use net proceeds, if any, from the ATM Offering over time as a source for working capital and general corporate purposes. We are not obligated to make any sales of our common stock under the Sales Agreement and no assurance can be given that we will sell any shares under the Sales Agreement, or, if we do, as to the price or amount of shares that we will sell, or the dates on which any such sales will take place. We will pay the Sales Agent an aggregate of up to 3.0% of the gross proceeds of the sales price per share of common stock sold through the Sales Agent under the Sales Agreement. The shares under the ATM Offering will be sold and issued pursuant to our S-3 shelf registration statement. We sold no shares under the ATM Offering during August and September 2021.

There were no issued or outstanding shares of preferred stock at September 30, 2021 or December 31, 2020.

Note 9 – Net Loss per Share of Common Stock

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

The computation of net loss per share for the three and nine months ended September 30, 2021 and 2020 was as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Basic and diluted net loss per share:				
Net loss	$ (2,987,217)	$ (3,071,285)	$ (8,243,740)	$ (4,679,035)
Weighted average number of common shares-basic and diluted	15,531,442	5,594,370	15,177,306	5,542,026
Basic and diluted net loss per share	$ (0.19)	$ (0.55)	$ (0.54)	$ (0.84)

The following potentially dilutive securities were excluded from the computation of diluted net loss per share as their effect would have been anti-dilutive for the periods presented.

	Nine months ended September 30,	
	2021	2020
Stock options, unvested RSAs, unvested RSUs and purchase warrants	844,394	814,285
Senior convertible notes and convertible related party LOC, plus related accrued interest	-	442,824

Note 10 – Operating Leases

We lease our office space under an operating lease agreement. This lease does not have significant rent escalation, concessions, leasehold improvement incentives, or other build-out clauses. Further, the lease does not contain contingent rent provisions. We also lease office equipment under an operating lease. Our office space lease includes both lease (e.g., fixed payments including rent, taxes, and insurance costs) and non-lease components (e.g., common-area or other maintenance costs), which are accounted for as a single lease component as we have elected the practical expedient to group lease and non-lease components for all leases. Our leases do not provide an implicit rate and, as such, we have used our incremental borrowing rate of 8% in determining the present value of the lease payments based on the information available at the lease commencement date.

Lease costs included in our condensed consolidated statements of operations totaled $24,198 and $24,029 for the three months ended September 30, 2021 and 2020, respectively, and $70,029 and $72,230 for the nine months ended September 30, 2021 and 2020. The weighted average remaining lease terms and discount rate for our

operating leases were as follows at September 30, 2021:

Weighted average remaining lease term (years) for our facility and equipment leases	1.22
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, 2021:

2021	$	24,804
2022		75,969
2023		6,228
2024		1,557
Total lease payments		108,558
Less: Interest		(7,016)
Present value of lease liabilities		101,542
Less: current maturities		(92,769)
Non-current lease liability	$	8,773

Note 11 – Related Party Transactions

A shareholder, CorLyst, LLC, reimburses us for shared costs related to payroll, health care insurance and rent based on actual costs incurred, which are recognized as a reduction of our general and administrative operating expenses in our condensed consolidated statements of operations. No amounts were due from CorLyst at September 30, 2021 and December 31, 2020. At September 30, 2020, we had $700,000 outstanding under a convertible related party LOC. This LOC was converted into shares of our common stock on October 6, 2020.

Note 12 – 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 and complete our clinical trials. The contracts are cancellable, with varying provisions regarding termination. If we terminated a cancellable contract with a specific vendor, 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 are contractually obligated to pay up to approximately $3.7 million of future services under the agreements with the CROs, but our actual contractual obligations will vary depending on the progress and results of the clinical trials.

Note 13 – Subsequent Events

On October 6, 2021, we issued 100,000 shares in accordance with our license agreement with Elion Oncology, Inc.

On November 3, 2021, our shareholders approved an amendment to our Fourth Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 30,000,000 shares to 50,000,000 shares.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operation

Forward Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" that reflect, when made, the Company's expectations or beliefs concerning future events that involve risks and uncertainties. Forward-looking statements frequently are identified by the words "believe," "anticipate," "expect," "estimate," "intend," "project," "will be," "will continue," "will likely result," or other similar words and phrases. Similarly, statements herein that describe the Company's objectives, plans or goals also are forward-looking statements. Actual results could differ materially from those projected, implied or anticipated by the Company's forward-looking statements. Some of the factors that could cause actual results to differ include: our limited operating history, limited cash and history of losses; our ability to achieve profitability; our ability to obtain adequate financing to fund our business operations in the future; 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; and 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. 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, 2020, 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 provide treatment for patients who have a high unmet medical need condition that effects survival or the patient's quality of life and for which few or no treatment options currently exist.

We are a development company, not a discovery company, that seeks to identify and develop drugs for patients who need better treatment options than presently exist for their medical condition. In order to increase the probability of development success, our pipeline only includes drugs which have previously demonstrated some efficacy in the targeted population or a drug with very similar pharmacological properties has been shown to be effective in the population.

Our screening criteria for identifying and selecting new candidates include:

- addressing an unmet or underserved clinical need,
- having demonstrated evidence of efficacy in humans, and
- leveraging our regulatory science approach to improve the probability for approval.

In many instances, these clinical candidates have significant pre-clinical and clinical data that we may leverage to high value inflection points while de-risking the programs and adding in optionality to potential future indications. Our regulatory science approach developed by our team over decades of work with regulatory authorities attempts to balance the "risk/benefit" equation to identify a regulatory path with lower risk and shorter timelines to deliver urgent or unmet medical needs to patients, physicians and

caregivers.

Our pipeline 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 a single positive pivotal study demonstrating efficacy might provide 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 successful development team with a track record of drug approvals and successful exits. Our team is experienced in developing drug products through all principal regulatory tiers from IND enabling studies to NDA submission. The combined scientific, development and regulatory experience of our team members 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 members in drug development and commercialization is an important indicator of our future success, the past successes of our team members in developing and commercializing pharmaceutical products does not guarantee that they will successfully develop and commercialize drugs in our current pipeline. 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 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.

Our Drug Pipeline

Our clinical pipeline (shown below) summarizes each drug, organized by the therapeutic area (i.e., non-oncology and oncology) and stage of development (i.e., Nonclinical to Phase 3).

We currently have five drugs: four in various stages of clinical development (PCS499, PCS12852, PCS3117 and PCS6422) and one in nonclinical development (PCS11T). We group our drugs into non-oncology (PCS499 and PCS12852) and oncology (PCS3117, PCS6422 and PCS11T). A summary of each of our five drugs is provided below:

- 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 completed a Phase 2A trial for PCS499 in patients with ulcerative and non-ulcerative necrobiosis lipoidica (NL) in late 2020, and in May 2021 we enrolled the first patient in our Phase 2B trial for the treatment of ulcerative NL. We expect to complete our interim analysis of the Phase 2B trial in mid-2022; complete the trial in the second half of 2022 (2H'22); and, depending on the results, begin a pivotal Phase 3 trial in 2023.

- PCS12852 is a highly specific and potent 5HT4 agonist which has already been evaluated in clinical studies in South Korea for gastric emptying and gastrointestinal motility. In October 2021, the FDA cleared our IND application to proceed with a Phase 2A trial for the treatment of gastroparesis. We anticipate beginning to enroll patients in the 1H'22, with expected completion in the first half of 2023 (1H'23).

- PCS3117, which we licensed in June 2021, is a cytosine analog, similar to gemcitabine (Gemzar®) but different enough in chemical structure that some patients are more likely to respond to PCS3117 than gemcitabine. We are developing potential biomarkers to predict which patients are more likely to respond to PCS3117 than gemcitabine and other chemotherapy agents to provide a more targeted, precision medicine approach to the treatment of pancreatic and/or non-small cell lung cancer. Over the next 6-12 months, we will be developing and refining these biomarker assays for use in our clinical trials, which should be completed in the 1H'22. We anticipate validating our approach and confirming our hypothesis in a planned Phase 2B study expected to start in the 2H'22 and, depending on the results, conducting a Phase 3 pivotal trial in 2023-2024.

- PCS6422 is an orally administered irreversible enzyme inhibitor administered in combination with capecitabine. When combining capecitabine with PCS6422 (the "Next Generation Capecitabine"), capecitabine becomes a more potent cancer chemotherapy agent than current FDA approved capecitabine. On August 2, 2021, we enrolled the first patient in our Phase 1B dose-escalation maximum tolerated dose trial in patients with advanced refractory gastrointestinal (GI) tract tumors and our interim analysis of Cohorts 1 and 2 found no dose-limiting toxicities (DLTs), no drug related adverse events greater than Grade 1, and no hand-foot syndrome. In addition, the interim analysis revealed when PCS6422 inhibits DPD enzyme activity, 5-FU metabolism is significantly decreased (< 10% metabolized to F-BAL compared to typically 80%) and the potency of capecitabine is significantly increased (at least 50 x greater 5-FU potency based on systemic exposure per mg of capecitabine administered). The single dose of PCS6422, however, does not sustain the DPD inhibition throughout 7 days of capecitabine dosing which is needed to maintain the improved potency of capecitabine. Therefore, we are modifying the existing protocol to obtain more data on DPD inhibition and de novo formation. We anticipate that this additional data will allow us to select PCS6422 dosage regimens that will maintain DPD inhibition for each patient treated with this Next Generation Capecitabine (i.e., combination of PCS6422 and capecitabine). After interacting with the FDA and making protocol modifications, we expect to restart the Phase 1B study in the middle of the first half of 2022 while defining the Next Generation Capecitabine regimen (i.e., the PCS6422 regimens and the corresponding capecitabine regimens) by the end of 2022. Although we are making modifications to the existing Phase 1B protocol, we expect that our overall timeline has not changed with a Phase 2B or 3 trial starting in 2023-2024 and NDA submission in 2027-2028.

- Our only nonclinical drug candidate is PCS11T, an analog of SN38 (SN38 being the active metabolite of irinotecan) and a next generation irinotecan drug for multiple types of cancers. PCS11T is presently in the IND pre-clinical toxicology stage. We hope to submit an IND in the 1H'23, followed by a Phase 1B maximum tolerated dose trial.

Drug	Disease Target	Preclinical	Phase 1	Phase 2	Phase 3	Planned Milestones
PCS499 Phase 2B	Ulcerative Necrobiosis Lipoidica					Interim Analysis in mid-2022; Final Analysis 2H'22; FPI Phase 3 SPA 2023
PCS12852 Phase 2A	Gastroparesis, Constipation Disorders					FPI Phase 2A 1H'22; Final Analysis 1H'23
PCS3117 Phase 2B	Pancreatic, Non-Small Cell Lung Cancer					Complete Biomarker Assay 1H'22; FPI Phase 2B 2H'22; FPI Phase 3 SPA 2023-2024
PCS6422 Phase 1B	Metastatic Colorectal, Breast Cancer					MTD Determined 2H'22; FPI Phase 2B/3 2023-2024
PCS11T Pre-IND	Small Cell Lung; Colorectal Cancer					Complete IND Enabling Studies; Phase 1B IND Submission 1H'23

Key
FPI – First Patient In (i.e. randomized)
IND – Investigational New Drug
MTD – Maximum Tolerated Dose
SPA – FDA Special Protocol Assessment

PCS499

PCS499, an oral tablet of a deuterated analog of one of the major metabolites of pentoxifylline (PTX or Trental®), 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 targeted Necrobiosis Lipoidica (NL) as our lead indication for PCS499. NL is a chronic, disfiguring condition affecting the skin and 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 65,000 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 make it extremely difficult to develop effective treatments for this condition. Because PCS499 and its metabolites appear to affect most of the biological pathways that contribute to the pathophysiology associated with NL, PCS499 may provide a novel treatment solution for NL.

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 initiated and completed 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.

The primary objective of the Phase 2A trial was to evaluate the safety and tolerability of PCS499 in patients with NL and to use the safety and efficacy data to design future clinical trials. Based on toxicology studies and healthy human volunteer studies, we 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 (SAEs) reported. All adverse events (AEs) reported in the study were mild in severity. As expected, gastrointestinal symptoms were the most frequent adverse events and reported in four patients, all of which resolved within 1-2 weeks of starting dosing.

Two of the twelve patients in the study presented with 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. The other ten patients, presenting with mild to moderate NL and no ulceration, had more limited improvement of the NL lesions during treatment. Historically, 13 - 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 ulcerated NL patients has not been evaluated independently, medical experts who treat NL patients suggest that the natural progression of an open ulcerated wound to complete closure would be significantly less than 13% over 1-2 years and probably close to 0% in patients with the larger ulcers.

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 have designed the next trial as a randomized, placebo-controlled Phase 2B study to evaluate the ability of PCS499 to completely close ulcers in patients with NL and better understand the potential response of NL patients on drug and on placebo. We have selected 10 clinical trial sites: six in the United States and four in Europe.

On May 19, 2021, we dosed our first patient in the randomized, placebo-controlled trial and are planning an interim analysis of the data from this trial in mid-2022. After obtaining the results from this Phase 2B study, we expect to have an end of Phase 2 meeting with the FDA to agree on the design of the Phase 3 study, to define a Special Protocol Assessment for the Phase 3 study and to agree on the next steps to obtain approval.

PCS12852

On August 19, 2020, we in-licensed PCS12852 (formerly known as YH12852) from Yuhan Corporation ("Yuhan"), pursuant to which we acquired an exclusive license to develop, manufacture and commercialize PCS12852 globally, excluding South Korea.

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 gastroparesis, chronic constipation, constipation-predominant irritable bowel syndrome, and functional dyspepsia. 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 receptors other than 5-HT4.

Two clinical studies, both which have demonstrated the effectiveness of PCS12852 on GI motility, have been previously conducted by Yuhan with PCS12852. In a Phase 1 trial (Protocol YH12852-101), the initial safety and tolerability of PCS12852 were evaluated after single and multiple oral doses in healthy subjects. PCS12852 was shown to increase GI motility in this study, increasing stool frequency with faster onset when compared to prucalopride, a less specific 5-HT4 agonist FDA-approved drug for the treatment of chronic idiopathic constipation. Based on an increase of ≥1 spontaneous bowel movement (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 SAEs occurred during the

study. The most frequently reported AEs were headache, nausea and diarrhea which were temporal, manageable and reversible within 24 hours. There were no clinically significant changes in platelet aggregation and ECG parameters including a change in QTc prolongation in the study. In a Phase 1/2A clinical trial (Protocol YH12852-102), the safety, tolerability, gastric emptying rate and pharmacokinetics of multiple doses of a PCS12852 immediate release (IR) formulation and a delayed release (DR) formulation were evaluated. 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 2mg prucalopride 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 increased the gastric emptying rate and increased GI motility.

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

We submitted an IND application in September 2021 based on guidance received from the FDA and were cleared in October 2021 to proceed with a Phase 2A randomized, placebo-controlled study for the treatment of gastroparesis. We anticipate beginning to enroll patients in the first half of 2022, with expected completion in the first half of 2023. The purpose of the Phase 2A trial is to evaluate the safety, efficacy and pharmacokinetics of two different dosing regimens for PCS12852. Data obtained from this study will be used to better design a future Phase 2/3 efficacy study. Since patients with gastroparesis have an abnormal pattern of upper GI motility in the absence of mechanical obstruction, the Phase 2A study will be designed to evaluate the change on gastric emptying in patients with gastroparesis on the two different dosing regimens of PCS12852 compared to placebo. The only FDA-approved drug to treat gastroparesis is metoclopramide, a dopamine D2 receptor antagonist that has serious side effects and can only be used as a short-term treatment. Other 5-HT4 drugs have been used clinically but the side effects, caused mainly by binding to other receptors, has resulted in these drugs not being a viable option to treat patients with gastroparesis. It should be noted that PCS12852 is a highly specific 5-HT4 agonist that has been shown in nonclinical studies to have a cardiovascular side effect only at concentrations greater than 1,000 times the maximum concentration seen in humans.

PCS3117

On June 16, 2021, we executed a License Agreement with Ocuphire Pharma, Inc. (“Ocuphire Agreement”) under which we received a license to research, develop and commercialize PCS3117 (formerly RX-3117) globally, excluding Republic of Singapore, China, Hong Kong, Macau and Taiwan.

PCS3117 is a novel, investigational, oral small molecule nucleoside compound. PCS3117 is an analog of the endogenous nucleoside, cytidine, and an analog of the cancer drug gemcitabine. Once intracellularly activated (phosphorylated) by the enzyme UCK2, it is incorporated into the DNA or RNA of cells and inhibits both DNA and RNA synthesis, which induces apoptotic cell death of tumor cells. PCS3117 has received orphan drug designation from the FDA and the European Commission for the treatment of patients with pancreatic cancer.

Gemcitabine is usually used as second line therapy for metastatic pancreatic cancer and non-small cell lung cancer, as well as used as second line therapy for other types of cancer. The difference between PCS3117 and gemcitabine is how they are activated to cancer killing nucleotides. PCS3117 also has additional pharmacological pathways which will result in cancer cell apoptosis. Since 45% - 85% of pancreatic cancer and non-small cell lung cancer patients are inherently resistant or acquire resistance to gemcitabine, the differences between PCS3117 and gemcitabine could potentially provide a therapeutic alternative to patients who do not or will not respond to gemcitabine.

Resistance to gemcitabine or PCS3117 is likely caused by:

- an increase in the cytidine deaminase (CDA) enzyme which breaks down gemcitabine and PCS3117,
- a deficiency in transportation of gemcitabine or PCS3117 across the cell membrane,
- down regulation of the activation enzyme (dCK for gemcitabine, UCK2 for PCS3117),
- a change in ribonucleotide reductase activity, and
- non-genetic influences that alter gene expression.

PCS3117 has shown broad spectrum anti-tumor activity against over 100 different human cancer cell lines and efficacy in 17 different mouse xenograft models. In preclinical trials, PCS3117 retained its anti-tumor activity in human cancer cell lines made resistant to the anti-tumor effects of gemcitabine. In August 2012, the completion of an exploratory Phase 1 clinical trial of PCS3117 in cancer patients to investigate the oral bioavailability, safety and tolerability of the compound was reported. In that study, oral administration of a 50 mg dose of PCS3117 indicated an oral bioavailability of 56% and a plasma half-life ($T_{1/2}$) of 14 hours. In addition, PCS3117 appeared to be well tolerated in all subjects throughout the dose range tested.

Final results from a Phase 1B clinical trial of PCS3117 were presented in June 2016 showing evidence of single agent activity. Patients in the study had generally received four or more cancer therapies prior to enrollment. In this study, 12 patients experienced stable disease persisting for up to 276 days and three patients showed evidence of tumor burden reduction. A maximum tolerated dose of 700 mg was identified in the study. At the doses tested, PCS3117 appeared to be well tolerated with a predictable pharmacokinetic profile following oral administration.

In March 2016, a multi-center Phase 2A clinical trial of PCS3117 in patients with relapsed or refractory pancreatic cancer was initiated to further evaluate safety and efficacy. The study was designed as a two-stage study with 10 patients in stage 1 and an additional 40 patients in stage 2. According to pre-set criteria, if greater than 20% of the patients had an increase in progression free survival of more than four months, or an objective clinical response rate and reduction in tumor size, additional pancreatic cancer patients would be enrolled into stage 2. Secondary endpoints included time to disease progression, overall response rate and duration of response, as well as pharmacokinetic assessments and safety parameters. In January 2018, the final data from this trial showed evidence of tumor shrinkage in some patients with metastatic pancreatic cancer that was resistant to gemcitabine and who had failed on multiple prior treatments was presented. In this study, 31% of patients experienced progression free survival for two months or more and five patients, or 12%, had disease stabilization for greater than four months. Although the pre-set criteria of 20% of the patients having an increase in progression free survival for four months was not met, some of the gemcitabine refractory patients did respond to PCS3117. However, an evaluation of why patients were resistant to PCS3117 was not undertaken within the study.

In November 2017, a Phase 2A trial of PCS3117 in combination with ABRAXANE in patients newly diagnosed with metastatic pancreatic cancer was initiated. The multicenter, single-arm, open-label study was designed to evaluate PCS3117 in combination with ABRAXANE in first line metastatic pancreatic cancer patients. In February 2019, the target enrollment of 40 evaluable patients in this trial was reached. As of July 24, 2019, an overall response rate of 23% had been observed in 40 patients that had at least one scan on treatment. Preliminary and unaudited data indicated that the median progression free survival for patients in the study was approximately 5.6 months. The most commonly reported related adverse events were nausea, diarrhea, fatigue, alopecia, decreased appetite, rash, vomiting and anemia. Again, evaluation of the cause of treatment resistance to PCS3117 was not undertaken.

In order to identify patients who would more likely respond to PCS3117 than gemcitabine, we will be refining existing assays and developing new assays of biological molecules (i.e., biomarkers) over the next 6-12 months that could help to identify which patients with pancreatic cancer or non-small cell lung cancer are more likely to respond to or activate PCS3117 over gemcitabine.

PCS6422

On August 23, 2020, we in-licensed PCS6422 from Elion Oncology, Inc. (“Elion”), pursuant to which we acquired an exclusive license to develop, manufacture and

commercialize PCS6422 globally.

PCS6422 is an oral, potent, selective and irreversible inhibitor of dihydropyrimidine dehydrogenase (DPD), the enzyme that rapidly metabolizes a common chemotherapy drug known as 5-FU, into inactive metabolites, such as α-fluoro-β-alanine (F-Bal). F-Bal is a metabolite that has no anti-cancer activity but causes unwanted side effects, which notably leads to dose interruptions and significantly affect a patient's quality of life. 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 activities of daily living, 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 will significantly reduce 5-FU side effects related to F-Bal. One dose of PCS6422 irreversibly inhibits existing DPD and all formation of F-Bal must then come from the de novo formation of new DPD. Thus, we believe inhibition of DPD will result in an improved safety profile given the decrease in F-Bal and potentially higher 5-FU intra-tumoral anti-cancer metabolites that could improve efficacy. By combining capecitabine (oral pro-drug form of 5-FU) with PCS6422, the change in 5-FU metabolism should result in an increase in the systemic exposure of 5-FU based on the 5-FU AUC per mg of capecitabine dosed. This results in needing less capecitabine to kill cancer cells and treat each patient, making the combination of PCS6422 and capecitabine (the "Next Generation Capecitabine") more potent than current FDA approved capecitabine.

Fluoropyrimidines (e.g., 5-FU, capecitabine) remain 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®, the brand name of capecitabine, is an oral pro-drug of 5-FU and 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 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 dramatically increased the antitumor potency of capecitabine without 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.

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 if the reversible inhibitor is not present, 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 large amounts of 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 is 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, even after PCS6422 has been completely eliminated out of the body. We believe this can optimize the potential cytotoxic effect of the 5-FU nucleotide metabolites and minimize the catabolism of 5-FU to F-Bal.

Prior to Elion's involvement, two multicenter Phase 3 studies were conducted in patients with colorectal cancer with PCS6422 administered in 10-fold excess to 5-FU and administered with the 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 proposed dosing PCS6422 several hours before 5-FU to allow PCS6422 to be cleared before the administration of 5-FU.

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. On May 17, 2020, an IND for the Phase 1B study was granted safe to proceed by the FDA. This Phase 1B study was designed to evaluate: i) the safety and tolerability of escalating doses of capecitabine with a fixed single dose of PCS6422 in advanced GI tumor patients; ii) the pharmacokinetics of PCS6422, capecitabine, 5-FU and selected metabolites; iii) the activity of DPD over time after PCS6422 administration; and iv) the maximum tolerated dose in up to 30 patients over multiple cycles. On August 2, 2021, we enrolled the first patient in the study.

The interim analysis of Cohorts 1 and 2 was recently conducted. DLTs, drug related adverse events of greater than 1 and hand-foot syndrome were not observed in these patients. Also, this Next Generation Capecitabine effectively inhibited DPD enzyme activity 24-48 hours after PCS6422 administration with < 10% of 5-FU metabolized to F-Bal as compared to ~80% with the FDA approved capecitabine. Additionally, 5-FU potency based on the 5-FU AUC systemic exposure per mg of capecitabine dosed was 50 times greater with Next Generation Capecitabine. The interim analysis showed, however, that the improved metabolic profile and increased potency was not sustained at Day 7 after PCS6422 single dose administration. We plan to modify the Phase 1B trial to not only determine the MTD of capecitabine but also to further evaluate the timeline of DPD inhibition and de novo formation as a function of PCS6422 dosing.

We anticipate that this additional data will allow us to select PCS6422 dosage regimens that will maintain DPD inhibition throughout capecitabine dosing for each patient treated with this Next Generation Capecitabine. After interacting with the FDA and making protocol modifications, we expect to restart the Phase 1B study in the middle of the first half of 2022 while defining the Next Generation Capecitabine regimens by the end of 2022. Although we are making modifications to the existing Phase 1B protocol, we expect that our overall timeline has not changed with a Phase 2B or 3 trial starting in 2023-2024 and NDA submission in 2027-2028.

PCS11T

On May 24, 2020, we in-licensed PCS11T (formerly known as ATT-11T) from Aposense, Ltd. ("Aposense"), pursuant to which we were granted Aposense's patent rights and Know-How to develop and commercialize their next generation irinotecan cancer drug, PCS11T.

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 AEs. 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 required toxicological studies required to file the IND and initiate the Phase 1B study in oncology patients with solid tumors in 2023.

Impact of COVID-19

The COVID-19 pandemic has created uncertainties in the expected timelines for clinical stage biopharmaceutical companies such as ours, including possible delays in clinical trials and disruptions in the supply chain for raw materials used in clinical trial work. Such delays could materially impact our business in future periods. Furthermore, the spread

of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the economic impact brought by, and the duration of, COVID-19 is difficult to assess or predict, the COVID-19 pandemic and its resulting variants could result in further disruption of global financial markets, reducing our ability to access capital, which could negatively affect our liquidity. Policymakers around the globe have responded with fiscal policy actions to support the healthcare industries and economies as a whole. Whether this support continues is uncertain. Accordingly, the extent to which the COVID-19 global pandemic impacts our business, results of operations and financial condition will depend on future developments, which are highly uncertain and are difficult to predict. These developments include, but are not limited to, the duration and spread of the outbreak, its resulting variants, its severity, the actions to contain the virus or address its impact, U.S. and foreign government actions to respond to the reduction in global economic activity, and how quickly and to what extent normal economic and operating conditions can resume. For more information on the risks associated with COVID-19, refer to Part I, Item 1A, "Risk Factors" in our Annual Report on Form 10-K.

Results of Operations

Comparison of the three and nine months ended September 30, 2021 and 2020

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2021	2020	Change	2021	2020	Change
Operating Expenses						
Research and development expenses	$ 1,722,364	$ 532,587	$ 1,189,777	$ 4,806,845	$ 1,461,416	$ 3,345,429
Acquisition of in-process research and development	50,953	2,000,000	(1,949,047)	566,583	2,000,000	(1,433,417)
General and administrative expenses	1,338,113	422,958	915,155	3,391,105	1,282,239	2,108,866
Operating Loss	(3,111,430)	(2,955,545)		(8,764,533)	(4,743,655)	
Other Income (Expense)						
Forgiveness of PPP loan and related accrued interest	-	-	-	163,771	-	163,771
Interest expense	-	(186,209)	186,209	(362)	(222,660)	222,298
Interest income	1,771	12	1,759	8,525	859	7,666
Net Operating Loss Before Income Tax Benefit	(3,109,659)	(3,141,742)	32,083	(8,592,599)	(4,965,456)	(3,627,143)
Income Tax Benefit	122,442	70,457	51,985	348,859	286,421	62,438
Net Loss	$ (2,987,217)	$ (3,071,285)		$ (8,243,740)	$ (4,679,035)	

Revenues.

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

Research and Development Expenses.

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

During the three months ended September 30, 2021 and 2020, we incurred total research and development expenses of $1,722,364 and $532,587, respectively. Research and development expenses were $4,806,845 and $1,461,416 for the nine months ended September 30, 2021 and 2020, respectively. Expenses for the three and nine months ended September 30, 2021 and 2020 were as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Amortization of intangible assets	$ 195,700	$ 198,832	$ 593,365	$ 596,496
Research and development salaries and benefits	546,415	156,195	1,246,887	411,020
Preclinical, clinical trial and other costs	980,249	177,560	2,966,593	453,900
Total	$ 1,722,364	$ 532,587	$ 4,806,845	$ 1,461,416

Overall, during the three months ended September 30, 2021, our research and development expenses increased by $1,189,777 when compared to the same period in 2020. The increase was primarily due to an increase in preclinical, clinical trial and other costs of $802,689, which was attributable to expenses we incurred as we commenced our Phase 2B clinical trial for PCS499, Phase 1B clinical trial for PCS6422 and for pre-IND costs for PCS12852. Expenses include payments to contract research organizations, regulatory filing and maintenance fees, drug product testing and stability, consulting, and other clinical fees. During the same period in 2020, we were completing the patient portion of our Phase 2A clinical trial for PCS499 and incurring regulatory filing and consulting fees as we prepared for our meeting with the FDA. Additionally, during the three months ended September 30, 2021, we experienced increases in payroll and related costs of $390,220 from increased employee salary rates, hiring additional personnel and stock-based compensation, when compared to the same period in 2020.

During the nine months ended September 30, 2021, our research and development costs increased by $3,345,429 when compared to the same period in 2020. The increase was primarily due to a $2,512,693 increase in expenses related to the clinical and pre-clinical trial costs mentioned above. Payroll and related costs increased by $835,867 during the nine months ended September 30, 2021 when compared to the same period in 2020 for the reasons mentioned above.

We anticipate our research and development costs to continue to increase significantly as we: (i) continue clinical trials for PCS499 and PCS6422 and begin the clinical trial for PCS12852, including the cost of having drug product manufactured; (ii) complete a biomarker assay for PCS3117; and (iii) obtain IND enabling data for PCS11T.

The funding necessary to bring a drug candidate to market is subject to numerous uncertainties. Once a drug candidate is identified, the further development of that drug candidate may 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. Some 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 conduct the Phase 2B trial to evaluate the ability of PCS499 to completely close ulcers in patients with NL and to continue with an amended Phase 1B clinical trial for PCS6422. On May 19, 2021, we dosed the first patient in our PCS499 randomized, placebo-controlled trial and on August 2, 2021, we dosed the first patient in our PCS6422 trial and we are delaying enrolling additional patients until we interact with the FDA and modify the protocol to provide us with data on the timeline of DPD inhibition and de novo formation. We expect that the PCS6422 Phase 1B trial will be restarted in the middle of the first half of 2022.

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

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

Acquisition of In-Process Research and Development.

In connection with the Ocuphire Agreement, we recorded $50,953 and $566,583 of acquired in-process research and development expense during the three and nine months ended September 30, 2021, respectively. The total acquisition cost includes the issuance of 44,689 shares (with a fair value of $300,000) of our common stock we issued to Ocuphire, a cash payment of $200,000 and $66,583 in expenses we agreed to pay on behalf of Ocuphire. We believe the in-process research and development asset acquired has no alternative future use. During the same periods in 2020, we recorded $2.0 million of acquired in-process research and development expense in connection with our license agreement with Yuhan Corporation.

General and Administrative Expenses.

Our general and administrative expenses for the three months ended September 30, 2021 increased by $915,155 to $1,338,113 when compared to $422,958 for the same period in 2020. The majority of the increase was due to increased professional and other consulting fees of $341,282 and increased payroll and related costs of $531,503 (which includes a $458,777 increase in employee stock-based compensation) from increased salary rates. We also experienced an increase in our insurance, office and other miscellaneous expenses totaling $80,310. These increases were offset by reductions in other office, tax and depreciation expenses totaling $33,407. Reimbursements from CorLyst totaled $30,870 for rent and other costs during the three months ended September 30, 2021 were $4,533 more than reimbursements received for the same period in 2020.

For the nine months ended September 30, 2021, general and administrative expenses increased by $2,108,866 to $3,391,105 when compared to $1,282,239 for the same period in 2020. The increase was attributable to a $972,495 increase in professional fees, a $1,191,032 increase in payroll and related costs (which includes a $977,550 increase in stock-based compensation), as well as an increase of $182,924 in insurance, office, and other miscellaneous expenses. These increases were offset by reductions of $222,145 in travel, depreciation and equipment expenses, and Delaware franchise taxes. Reimbursements from CorLyst totaled $92,419 during the nine months ended September 30, 2021 were approximately $15,440 more than reimbursements received for the same period in 2020.

We expect the general and administrative expenses to continue to increase as we add staff to support our growing research and development activities and the administration required to operate as a public company.

Other Income and (Expense)

Net other income and (expense) was $1,771 and ($186,197) for the three months ended September 30, 2021 and 2020, respectively, and $171,934 and ($221,801) for the nine months ended September 30, 2021 and 2020, respectively. During the nine months ended September 30, 2021, we recognized $163,771 as other income for the principal amount and related accrued interest related to the forgiveness of our PPP loan. Interest income represents interest earned on money market funds. Interest expense in 2021 was related to our Paycheck Protection Program loan while interest expense in 2020 was related to our $805,000 8% Senior Notes sold in 2019 and 2020 borrowings on a related party LOC. Included in interest expense is the amortization of debt issuance costs totaling $157,129 for the nine months ended September 30, 2020.

Income Tax Benefit.

An income tax benefit of $122,442 and $70,457 was recognized for the three months ended September 30, 2021 and 2020, respectively, and $348,859 and $286,421 for the nine months ended September 30, 2021 and 2020, 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.

Cash Flows

The following table sets forth our sources and uses of cash and cash equivalents for the nine months ended September 30, 2021 and 2020:

	Nine months ended September 30,	
	2021	2020
Net cash (used in) provided by:		
Operating activities	$ (5,990,321)	$ (867,839)
Financing activities	9,667,285	501,731
Net increase (decrease) in cash	$ 3,676,964	$ (366,108)

Net cash used in operating activities

We used net cash in our operating activities of $5,990,321 and $867,839 during the nine months ended September 30, 2021 and 2020, respectively. The increase in cash used in operating activities during the nine months ended September 30, 2021 compared to the comparable period in 2020 was primarily related to costs we incurred related to our Phase 2B clinical study for PCS499, Phase 1B clinical study for PCS6422, pre-clinical costs for PCS12852, as well as increased professional fees and salaries. Our prepaid

expenses increased by $951,895 during the nine months ended September 30, 2021, primarily due to deposits paid to our CROs for clinical trial related costs. Of this amount, $107,193 represents amounts paid to consultants using shares of our common stock and warrants and $180,285 are deferred offering costs which impact net cash provided by financing activities. As a result, the change in prepaid expenses impacting net cash used in operating activities is $664,417.

As we continue our clinical trials for PCS499 and PCS6422, begin a Phase 2A clinical trial for PCS12852, and continue to evaluate and develop the other drugs in our portfolio, we anticipate our research and development efforts and ongoing general and administrative costs will continue to generate negative cash flows from operating activities for the foreseeable future. We expect these amounts to increase in the future.

Net cash provided by financing activities

We received $9,875,550 in net proceeds from our February 2021 private placement transaction. During the nine months ended September 30, 2021, we also incurred $180,285 in expenses related to our ATM Offering. Net cash provided by financing activities during the nine months ended September 30, 2020 of $501,731 was from borrowings totaling $700,000 under a convertible related party LOC agreement and $162,459 we received from Bank of America pursuant to a promissory note under the Paycheck Protection Program, less transaction costs of $360,728 related to our 2020 underwritten public offering which occurred in October 2020.

Liquidity

On February 24, 2021, we closed a private placement for the sale of 1,321,132 shares of our common stock at a purchase price of $7.75 per share to accredited and institutional investors for gross proceeds of $10.2 million. Net proceeds from the offering were $9.9 million. We also completed an underwritten public offering in late 2020 where we raised net proceeds from the offering of approximately $17.1 million. As a result of these offerings, at September 30, 2021 we had $19.1 million in cash.

On August 20, 2021, we entered into an equity distribution agreement (the "Sales Agreement") with Oppenheimer & Co. Inc. (the "Sales Agent") under which we may issue and sell in a registered "at-the-market" offering shares of our common stock having an aggregate offering price of up to $30.0 million from time to time through or to our Sales Agent (the "ATM Offering"). We expect to use net proceeds, if any, from the ATM Offering over time as a source for working capital and general corporate purposes. We are not obligated to make any sales of our common stock under the Sales Agreement and no assurance can be given that we will sell any shares under the Sales Agreement, or, if we do, as to the price or amount of shares that we will sell, or the dates on which any such sales will take place. We will pay the Sales Agent an aggregate of up to 3.0% of the gross proceeds of the sales price per share of common stock sold through the Sales Agent under the Sales Agreement. The shares under the ATM Offering will be sold and issued pursuant to our S-3 shelf registration statement. We sold no shares under the ATM Offering during August and September 2021.

We have incurred losses and net cash used in our operating activities during the nine months ended September 30, 2021, which we expect to continue for the foreseeable future. We do not currently or have since our inception had any sales. We have incurred losses since our inception, devoting substantially all of our efforts toward research and development, and have an accumulated deficit of approximately $33.6 million at September 30, 2021. During the nine months ended September 30, 2021, we generated a net loss of approximately $8.2 million. However, we believe our cash balance at September 30, 2021 is adequate to fund our budgeted operations into the middle of 2023. Our ability to execute our longer-term operating plans, including unplanned future clinical trials for our portfolio of drugs depend on our ability to obtain additional funding from the sale of equity and/or debt securities, a strategic transaction or other funding transactions. We plan to continue to actively pursue financing alternatives, but there can be no assurance that we will obtain the necessary funding in the future when necessary.

Our estimate of future cash needs is based on assumptions that may prove to be wrong, and we could utilize our available cash 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 in the future 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. We also plan to complete a biomarker assay for PCS3117 and obtain IND enabling data for PCS11T. 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.

Our future capital requirements will depend on many factors, including:

- the cost of clinical trials for PCS499, PCS6422 and PCS12852, and the cost of third-party manufacturing;
- the cost of completing the biomarker assay and clinical trials for PCS3117;
- the delays in patient enrollment due to the COVID-19 pandemic;
- the initiation, progress, timing, costs and results of drug manufacturing, pre-clinical studies, and clinical trials of PCS11T and any other future product candidates;
- the number and characteristics of product candidates that we pursue;
- the outcome, timing, and costs of seeking regulatory approvals;
- the costs associated with hiring additional personnel and consultants as our pre-clinical and clinical activities increase;
- the emergence of competing therapies and other adverse market developments;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending, and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the extent to which we in-license or acquire other products and technologies; and
- the costs of operating as a public company.

Until such time as we can generate substantial product revenues to support our capital requirements, if ever, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, collaborations and licensing arrangements or other capital sources. We also have an effective S-3 shelf registration statement on file with the SEC, which provides us flexibility and optionality to raise capital, including pursuant to the ATM Offering, but there can be no assurance that capital will continue to be available to us on acceptable terms or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders.

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, 2020.

Off Balance Sheet Arrangements

At September 30, 2021, 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 2020 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 U.S. GAAP and SEC guidelines, their related controls and the operation thereof. These material weaknesses continue to be present at September 30, 2021.

Changes in Internal Control over Financial Reporting

During the nine months ended September 30, 2021, we implemented changes to our cash disbursements process in order to strengthen our internal controls. Changes include a central accounts payable email address for invoice intake and processing, and an electronic invoice approval process. We also began utilizing an electronic payment system called CashPro through Bank of America, N.A., which allows us to establish single and dual approval requirements based on dollar thresholds. We believe these additions have materially improved our internal control over financial reporting. We are continuing to take remediation actions to rectify our control deficiencies (including material weaknesses) through the adoption and implementation of written policies and procedures for transaction processing, accounting and financial reporting, as well as strengthening our supervisory review processes.

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

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

There have been no material changes to our risk factors as described in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2020.

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

None.

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
1.1	Equity Distribution Agreement, dated August 20, 2021, by and among Processa Pharmaceuticals, Inc. and Oppenheimer & Co. Inc (incorporated by reference to Form 8-K filed on August 20, 2021)
31.1*	Rule 153-14(a) Certification by Principal Executive Officer
31.2*	Rule 153-14(a) Certification by Principal Financial Officer
32.1*++	Section 1350 Certification of Principal Executive Officer and Principal Financial Officer
99.1	XBRL Files

* Filed herewith.

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

SIGNATURES

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

PROCESSA PHARMACEUTICALS, INC.

By: */s/ David Young*
David Young
Chief Executive Officer
(Principal Executive Officer)
Dated: November 11, 2021

By: */s/ James Stanker*
James Stanker
Chief Financial Officer
(Principal Financial and Accounting Officer)
Dated: November 11, 2021

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.;

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 11, 2021

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.;

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 11, 2021

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 period ended September 30, 2021 (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 11, 2021

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 period ended September 30, 2021 (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 11, 2021

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