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 June 30, 2022

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 August 4, 2022 was 15,856,205.

PROCESSA PHARMACEUTICALS, INC.
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ITEM 1: FINANCIAL STATEMENTS

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

	June 30, 2022	December 31, 2021
ASSETS		
Current Assets		
Cash and cash equivalents	$ 12,064,142	$ 16,497,581
Due from tax agencies	-	70,274
Prepaid expenses and other	1,896,633	1,759,296
Total Current Assets	13,960,775	18,327,151
Property and Equipment, net	-	-
Other Assets		
Operating lease right-of-use assets, net of accumulated amortization	28,890	74,181
Intangible assets, net of accumulated amortization	7,662,390	8,056,638
Security deposit	5,535	5,535
Total Other Assets	7,696,815	8,136,354
Total Assets	$ 21,657,590	$ 26,463,505
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Current maturities of operating lease liability	$ 26,552	$ 71,078
Accounts payable	648,104	218,905
Due to licensor	589,000	400,000
Due to related parties	-	1,772
Accrued expenses	307,412	279,265
Total Current Liabilities	1,571,068	971,020
Non-current Liabilities		
Non-current operating lease liability	4,655	7,385
Total Liabilities	1,575,723	978,405
Commitments and Contingencies	-	-
Stockholders' Equity		
Common stock, par value $0.0001, 50,000,000 shares authorized: 15,919,317 issued and 15,819,317 outstanding at June 30, 2022, and 15,710,246 issued and outstanding at December 31, 2021	1,592	1,571
Additional paid-in capital	65,595,106	62,306,861
Treasury stock at cost — 100,000 shares at June 30, 2022	(300,000)	-
Accumulated deficit	(45,214,831)	(36,823,332)
Total Stockholders' Equity	20,081,867	25,485,100
Total Liabilities and Stockholders' Equity	$ 21,657,590	$ 26,463,505

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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating Expenses				
Research and development expenses	$ 3,137,292	$ 1,614,954	$ 5,181,912	$ 3,086,401
Acquisition of in-process research and development	-	515,630	-	515,630
General and administrative expenses	2,034,456	1,329,213	3,218,550	2,051,073
Operating Loss	(5,171,748)	(3,459,797)	(8,400,462)	(5,653,104)
Other Income (Expense)				
Forgiveness of PPP loan and related accrued interest	-	163,771	-	163,771
Interest expense	-	-	-	(362)
Interest income	7,380	1,814	8,963	6,755
Net Operating Loss Before Income Tax Benefit	(5,164,368)	(3,294,212)	(8,391,499)	(5,482,940)
Income Tax Benefit	-	137,169	-	226,417
Net Loss	$ (5,164,368)	$ (3,157,043)	$ (8,391,499)	$ (5,256,523)
Net Loss per Common Share - Basic and Diluted	$ (0.32)	$ (0.20)	$ (0.53)	$ (0.35)
Weighted Average Common Shares Used to Compute Net Loss Applicable to Common Shares - Basic and Diluted	15,940,510	15,406,363	15,886,116	14,997,303

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

Processa Pharmaceuticals, Inc.
Condensed Consolidated Statement of Changes in Stockholders' Equity
Three and Six Months Ended June 30, 2021 and 2022
(Unaudited)

	Common Stock		Additional Paid-In	Treasury Stock		Accumulated	
	Shares	Amount	Capital	Shares	Amount	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

	Common Stock		Additional Paid-In	Treasury Stock			Accumulated
	Shares	Amount	Capital	Shares	Amount	Deficit	Total
Balance at January 1, 2022	15,710,246	$ 1,571	$ 62,306,861	-	$ -	$ (36,823,332)	$ 25,485,100
Stock-based compensation	103,670	10	828,887	-	-	-	828,897
Acquisition of treasury stock	-	-	-	(100,000)	(300,000)	-	(300,000)
Shares issued in connection with the Purchase Agreement with Lincoln Park	123,609	12	449,988	-	-	-	450,000
Net loss	-	-	-	-	-	(3,227,131)	(3,227,131)
Balance, March 31, 2022	15,937,525	1,593	63,585,736	(100,000)	(300,000)	(40,050,463)	23,236,866
Stock-based compensation	(18,208)	(1)	2,009,370	-	-	-	2,009,369
Net loss	-	-	-	-	-	(5,164,368)	(5,164,368)
Balance, June 30, 2022	15,919,317	$ 1,592	$ 65,595,106	(100,000)	$ (300,000)	$ (45,214,831)	$ 20,081,867

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

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

	Six Months Ended June 30,	
	2022	2021
Cash Flows From Operating Activities		
Net loss	$ (8,391,499)	$ (5,256,523)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	-	484
Non-cash lease expense for right-of-use assets	45,291	41,322
Non-cash milestone expense in connection with license agreement	189,000	-
Non-cash acquisition of in-process research and development	-	300,000
Amortization of issuance costs	40,613	-
Amortization of intangible asset	394,248	397,664
Deferred income tax benefit	-	(226,417)
Stock-based compensation	2,838,266	1,173,622
Forgiveness of PPP loan and related accrued interest	-	(163,771)
Net changes in operating assets and liabilities:		
Prepaid expenses and other	272,050	(876,899)
Operating lease liability	(47,256)	(42,320)
Accrued interest	-	362
Accounts payable	429,199	(32,816)
Due (from) to related parties	(1,772)	96,614
Other receivables	70,274	6,750
Accrued expenses	28,147	144,434
Net cash used in operating activities	(4,133,439)	(4,437,494)
Cash Flows From Financing Activities		
Net proceeds from private placement	-	9,875,550
Acquisition of treasury stock	(300,000)	-
Other	-	(23,085)
Net cash (used in) provided by financing activities	(300,000)	9,852,465
Net Increase (Decrease) in Cash	(4,433,439)	5,414,971
Cash and Cash Equivalents – Beginning of Period	16,497,581	15,416,224
Cash and Cash Equivalents – End of Period	$ 12,064,142	$ 20,831,195
Non-Cash Financing Activities		
Issuance of 123,609 shares of common stock in connection with the Purchase Agreement with Lincoln Park	$ 450,000	$ -

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

Note 1 – Organization and Summary of Significant Accounting Policies

Business Activities and Organization

We are a clinical-stage biopharmaceutical company focused on the development of drug products that are intended to provide treatment for patients who have a high unmet medical need condition that affects 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, PCS6422 and PCS3117) 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 drug 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 and complete enrollment of the Phase 2B trial during the first half of 2023; and, depending on the results, begin a pivotal Phase 3 trial in 2023. We have experienced delays in the enrollment of patients for this trial due in part to COVID-19 and the rare nature of this disease. We have initiated a number of recruitment programs to increase the enrollment of patients in this study and continue to evaluate additional options to meet our enrollment goals.

- 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 enrolled our first patient on April 5, 2022, anticipate completing enrollment in the second half of 2022 with top-line results by the end of 2022, and should complete our final analysis in the first half of 2023.

- 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. 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 the DPD enzyme, 5-FU metabolism can be significantly decreased (<10% metabolized to F-Bal compared to typically 80%) and the potency of capecitabine significantly increased compared to the present regimens of capecitabine (at least 50 times greater 5-FU potency based on systemic exposure per mg of capecitabine administered). The single dose of PCS6422, however, did not sustain the DPD inhibition throughout 7 days of capecitabine dosing which was needed to maintain the improved potency of capecitabine. Therefore, in an effort to define 6422 regimens that will maintain DPD inhibition throughout capecitabine dosing, we modified the protocol for the Phase 1B trial to not only determine the MTD of capecitabine, but to also further evaluate the timeline of DPD inhibition and de novo formation. We began enrolling patients in the amended Phase 1B trial in April 2022 and expect to complete enrollment while defining the Next Generation Capecitabine regimen (i.e., the PCS6422 regimens and the corresponding capecitabine regimens) by the end of 2022. 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.

- PCS3117 is a cytosine analog that is similar to gemcitabine (Gemzar®), but different enough in chemical structure that some patients are more likely to respond to PCS3117 than gemcitabine. We continue to evaluate the potential use of PCS3117 in patients with pancreatic cancer and to evaluate ways to identify patients who are more likely to respond to PCS3117 than gemcitabine. We anticipate initiating a Phase 2B trial or adaptive designed Phase 3 trial in 2023 subject to meeting with FDA and obtaining additional funding.

- 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. The manufacturing process and sites for drug substance and drug product are presently being evaluated. In addition, we are defining the potential paths to approval, which include defining the targeted patient population and the type of cancer. We hope to submit an IND in the first half of 2024, followed by a Phase 1B maximum tolerated dose trial.

Impact of COVID-19

The COVID-19 pandemic continues to create uncertainties in expected timelines by causing delays in clinical trials and disruptions in the supply chain for raw materials used in clinical trial work. We have experienced delays in the enrollment of patients in our PCS499 Phase 2B trial due to COVID-19. Some potential patients have died from COVID-19 prior to screening and others continue to be reluctant to travel to our testing sites for fear of contracting COVID-19. Delays in enrollment lengthen the time of studies and increase their costs, which 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 we are hopeful the infection rate of COVID-19 will continue to decline, we cannot predict the future impact COVID-19 will have on our current and future clinical trials. Continued delays could materially impact our business in future periods and further extend our timelines. For more information on the risks associated with COVID-19, refer to Part I, Item 1A, "Risk Factors" included in our Annual Report on Form 10-K for the year ended December 31, 2021.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and with the instructions of the Securities and Exchange Commission ("SEC") on Form 10-Q and Article 8 of Regulation S-X.

Accordingly, they do not include all the information and disclosures required by U.S. GAAP for complete financial statements. All material intercompany accounts and transactions have been eliminated in consolidation. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments necessary, which are of a normal and recurring nature, for the fair presentation of our 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, 2021, 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 moving the drugs in our pipeline through the regulatory process and other research and development activities, and have an accumulated deficit of approximately $45.2 million as of June 30, 2022. During the six months ended June 30, 2022, we generated a net loss of approximately $8.4 million, of which $3.5 million represented non-cash expenditures. Net cash used in our operating activities during the six months ended June 30, 2022 was approximately $4.1 million. We expect to continue to generate operating losses and negative cash flow from operations for the foreseeable future. Based on our current plans, we believe our current cash balances are adequate for at least the next twelve months without considering amounts available from the Purchase Agreement with Lincoln Park (see below and Note 3) or potential sales under our ATM Offering (see below). 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 six months ended June 30, 2022 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.

On August 20, 2021, we entered into an equity distribution agreement (the "Sales Agreement") with Oppenheimer & Co. Inc. 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 from the ATM Offering over time as a source for working capital and general corporate purposes. The shares under the ATM Offering will be sold and issued pursuant to our S-3 shelf registration statement (Registration No. 333-257588) filed on July 30, 2021.

On March 23, 2022, we entered into a Purchase Agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park") under which we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $15,000,000 of our shares of common stock, par value $0.0001 per share, subject to the terms and conditions in the Purchase Agreement, during the term of the Purchase Agreement. See Note 3 for additional details concerning the Purchase Agreement.

Use of Estimates

In preparing our condensed consolidated financial statements and related disclosures in conformity with GAAP and pursuant to the rules and regulations of the SEC, we make estimates and judgments that affect the amounts reported in the 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.

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 basis of assets and liabilities for financial reporting purposes and amounts recognized for income tax purposes. As of June 30, 2022 and December 31, 2021, we recorded a valuation allowance equal to the full recorded amount of our net deferred tax assets related to deferred start-up costs, 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.

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 recognized the tax benefit from our projected ordinary tax loss, which was used to offset the deferred tax liabilities related to the intangible asset and resulted in the recognition of a deferred tax benefit shown in the condensed consolidated statements of operations for six months ended June 30, 2021 and the remainder of 2021. No current income tax benefit or expense was recorded or is expected for 2022 or in the foreseeable future since the deferred tax liability has been offset completely as of December 31, 2021 and we expect to generate future taxable net operating losses.

Concentration of Credit Risk

Financial instruments that potentially subject us to significant concentration of credit risk consist primarily of our cash and cash equivalents. We utilize only well-established banks and financial institutions with high credit ratings. Balances on deposit are insured by the Federal Deposit Insurance Corporation (FDIC) up to specified limits. Total cash held by our banks at June 30, 2022 exceeded FDIC limits.

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 condensed consolidated financial position or results of operations.

Note 2 – Intangible Assets

Intangible assets at June 30, 2022 and December 31, 2021 consisted of the following:

	June 30, 2022	December 31, 2021
Gross intangible assets	$ 11,059,429	$ 11,059,429
Less: accumulated amortization	(3,397,039)	(3,002,791)
Total intangible assets, net	$ 7,662,390	$ 8,056,638

Gross intangible assets consist primarily of costs we capitalized when we acquired the license rights to PCS499 in 2018. Amortization expense was $394,248 and $397,664 for the six months ended June 30, 2022 and 2021, respectively, and is included within research and development expense in the accompanying condensed consolidated statements of operations. As of June 30, 2022, our estimated amortization expense for the year ended December 31, 2022 and for annual periods thereafter until the asset is fully amortized is approximately $788,000.

Note 3 – Stockholders' Equity

Preferred Stock

There were no issued or outstanding shares of preferred stock at either June 30, 2022 or December 31, 2021.

Common Stock

Increase in Our Authorized Number of Shares

On January 1, 2022, we amended our Certificate of Incorporation to increase the number of authorized shares of our common stock from 30,000,000 to 50,000,000. We believe 50,000,000 authorized shares of common stock better aligns our capital structure with our future needs.

ATM Offering

On August 20, 2021, we entered into the Sales Agreement with the Sales Agent under which we may issue and sell up to $30.0 million of our common stock from time to time under the ATM Offering. We expect to use net proceeds from the ATM Offering over time as a source for working capital and general corporate purposes. We did not sell any shares during the six months ended June 30, 2022.

Lincoln Park Capital Fund, LLC Purchase Agreement

On March 23, 2022, we entered into the Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park has committed to purchase up to $15.0 million of shares (the "Purchase Shares") of our common stock, $0.0001 par value per share, subject to the terms and conditions in the Purchase Agreement. We issued 123,609 shares of common stock (valued at $450,000) to Lincoln Park as a commitment fee in connection with entering into the Purchase Agreement and agreed to reimburse Lincoln Park $25,000 for fees incurred in connection with the Purchase Agreement. Concurrent with entering into the Purchase Agreement, we also entered into a registration rights agreement with Lincoln Park (the "Registration Rights Agreement"), pursuant to which we agreed to take certain actions relating to the registration under the Securities Act of 1933, as amended, of the offer and sale of the shares of common stock available for issuance under the Purchase Agreement.

Beginning on March 23, 2022, we have the right to present Lincoln Park with a purchase notice (a "Regular Purchase Notice"), directing Lincoln Park to purchase up to 25,000 Purchase Shares (the "Regular Purchase Amount") provided that the closing sale price of the common stock on the purchase date is not below a threshold price set forth in the Purchase Agreement (a "Regular Purchase"). The Regular Purchase Amount may be increased to up to 75,000 shares if the closing sale price of our common stock on the applicable purchase date equals or exceeds certain higher threshold prices set forth in the Purchase Agreement. We and Lincoln Park may mutually agree to increase the Regular Purchase Amount with respect to any Regular Purchase under the Purchase Agreement, provided that Lincoln Park's maximum committed purchase obligation under any single Regular Purchase shall not exceed $1,250,000. The above-referenced share amount limitations and closing sale price thresholds are subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction as provided in the Purchase Agreement. The purchase price per share for each Regular Purchase will be based on prevailing market prices of the common stock immediately preceding the time of sale as computed in accordance with the terms set forth in the Purchase Agreement. There are no upper limits on the price per share that Lincoln Park must pay for shares of common stock under the Purchase Agreement. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement.

The aggregate number of shares that we can issue to Lincoln Park under the Purchase Agreement may not exceed 3,142,430 shares (subject to proportional adjustments for stock splits, reverse stock splits and similar events as described above), which is equal to 19.99% of the outstanding shares of common stock immediately prior to the execution of the Purchase Agreement (the "Exchange Cap"), unless (i) stockholder approval is obtained to issue shares of common stock in excess of the Exchange Cap, in which case the Exchange Cap will no longer apply, or (ii) the average price of all sales of Purchase Shares to Lincoln Park under the Purchase Agreement equals or exceeds the lower of (i) the Nasdaq official closing price immediately preceding the execution of the Purchase Agreement or (ii) the arithmetic average of the five Nasdaq official closing prices for the common stock immediately preceding the execution of the Purchase Agreement, plus an incremental amount to take into account the issuance of the commitment shares to Lincoln Park under the Purchase Agreement, such that the transactions contemplated by the Purchase Agreement are exempt from the Exchange Cap limitation under applicable Nasdaq rules. In all instances, we may not sell shares of our common stock to Lincoln Park under the Purchase Agreement if it would result in Lincoln Park beneficially owning more than 9.99% of the outstanding shares of common stock.

We may terminate the Purchase Agreement at any time, at our sole discretion, without any cost or penalty, by giving one business day notice to Lincoln Park to terminate the Purchase Agreement. Lincoln Park has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of the common stock.

There are no limitations on use of proceeds, financial or business covenants, restrictions on future financings (other than restrictions on our ability to enter into variable rate transactions described in the Purchase Agreement), rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. We may deliver Purchase Notices under the Purchase Agreement, subject to market conditions, and in light of our capital needs from time to time and under the limitations contained in the Purchase Agreement. Any proceeds that we receive under the Purchase Agreement are expected to be used for working capital and general corporate purposes.

Repurchase of Shares from Aposense, Ltd.

On March 29, 2022, we purchased 100,000 shares of our common stock from Aposense Ltd. for $300,000 in a private transaction and are holding these shares as treasury stock until they are reissued or retired at the discretion of our Board of Directors.

Note 4 - Stock-based Compensation

On June 19, 2019, our stockholders approved, and we adopted the Processa Pharmaceuticals Inc. 2019 Omnibus Equity Incentive Plan (the "2019 Plan"). The 2019 Plan allows us, under the direction of our Board of Directors or a committee thereof, to make grants of stock options, restricted and unrestricted stock and other stock-based awards to employees, including our executive officers, consultants and directors. The 2019 Plan originally provided for the aggregate issuance of 3,000,000 shares of our common stock, with 627,086 shares available for future grants at June 30, 2022.

On July 11, 2022, our shareholders approved an increase in the aggregate number of shares of our common stock available for issuance under our 2019 plan by 3,000,000 shares to 6,000,000 shares in total.

Stock Compensation Expense

We recorded stock-based compensation expense for the three and six month periods ended June 30, 2022 and 2021 as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Research and development	$ 685,624	$ 191,594	$ 877,500	$ 245,385
General and administrative	1,323,745	673,729	1,960,766	928,237
Total	$ 2,009,369	$ 865,323	$ 2,838,266	$ 1,173,622

No tax benefits were attributed to the stock-based compensation expense because a valuation allowance was maintained for all net deferred tax assets relating to this expense.

Stock Options

No stock options were granted, cancelled or forfeited during the six months ended June 30, 2022. At June 30, 2022, we had outstanding options for the purchase of 178,496 shares with a weighted average exercise price of $17.07 and a weighted average remaining contractual life of 3.1 years. Options exercisable at June 30, 2022 for the purchase of 176,315 shares of our common stock had a weighted average exercise price $17.02 and a weighted average remaining contractual life of 3.0 years. We had, as of June 30, 2022, total unrecognized stock-based compensation expense for these stock options of approximately $37,000, which is expected to be fully recognized by the end of the third quarter of 2022.

Restricted Stock Awards

On January 4, 2022, we granted and issued Restricted Stock Awards ("RSAs") for 9,766 shares of our common stock to a consultant for services to be provided in 2022. These RSAs had a fair market value of $50,000 on the date of grant and were expensed as stock-based compensation during the six months ended June 30, 2022. Effective January 1, 2022, we also granted 72,832 RSAs to our directors for their 2022 service which had a fair market value of $252,000 on the date of grant and will cliff vest on December 31, 2022. Additionally, on March 31, 2022, we issued 17,572 RSAs to our directors in satisfaction of the $120,000 of directors' fees we had accrued at December 31, 2021. On May 31, 2022, a director did not seek reelection and forfeited the 18,208 RSAs related to their 2022 service. We did not cancel any RSAs during the six months ended June 30, 2022.

At June 30, 2022, we had unvested RSAs for 145,733 shares with a weighted average grant date fair value of $6.13. Unvested RSAs representing 120,733 shares are expected to vest at various dates in 2022, 12,500 shares are expected to vest in 2023, and the remainder are expected to vest in 2024. As of June 30, 2022, the total unrecognized stock-based compensation expense related to the outstanding RSAs was approximately $310,000 which is expected to be recognized over a weighted average period of approximately 0.8 years.

Restricted Stock Units

Activity with respect to our Restricted Stock Units ("RSUs") during the six months ended June 30, 2022 was as follows:

	Number of shares	Weighted-average grant-date fair value per share
Outstanding at January 1, 2022	439,593	
Awarded	1,363,917	$ 3.01
Forfeited	(22,088)	7.81
Issued	(3,500)	6.65
Outstanding at June 30, 2022	1,777,922	4.12
Vested and unissued	(440,374)	4.97
Unvested at June 30, 2022	1,337,548	$ 3.83

As of June 30, 2022, unrecognized stock-based compensation expense of approximately $4.0 million for RSUs is expected to be fully recognized over a weighted average period of 0.8 years. The unrecognized expense excludes approximately $349,000 of expense related to certain RSUs with a performance milestone that is not probable of occurring at this time.

During the six months ended June 30, 2022, we granted RSUs related to the future issuance of 243,131 shares of our common stock pursuant to agreements with our Executive team and certain other employees where a portion of their base compensation is paid in RSUs. The value of an RSU award is based on the average share price of the month services were provided. These RSUs are vested but must meet distribution requirements before any shares of common stock are issued. Effective July 1, 2022, we established a $5.00 per share floor for the computation of the number of shares our Executive team members could earn under this program.

Included in RSUs awarded during the six months ended June 30, 2022 are RSUs awarded on April 1, 2022 for 1,979,818 shares of our common stock, of which RSUs related to the future issuance of 879,819 shares were subject to shareholder approval, which was received on July 11, 2022. These RSUs vest on January 1, 2023 and are subject to distribution requirements before any shares of common stock are issued. The RSUs that were not subject to shareholder approval had a fair value on April 1, 2022 of $3.3 million while the RSUs that were approved by the shareholders on July 11, 2022 have a fair value, as of the approval date, of $2.9 million. The $3.3 million is being recognized ratably over the period April 1, 2022 through December 31, 2022, while the $2.9 million will be recognized ratably over the remainder of 2022 beginning in the third quarter of 2022.

Holders of our vested RSUs will be issued shares of our common stock upon the satisfaction of the distribution restrictions contained in their Restricted Stock Unit Award Agreement. The distribution restrictions are typically different (longer) than the vesting schedule, imposing an additional restriction on the holder. Unlike RSAs, while employees may hold fully vested RSUs, the individual does not hold any shares or have any rights of a shareholder until the distribution restrictions are met. Upon distribution to the employee, each RSU converts into one share of our common stock. The RSUs contain dividend equivalent rights.

Warrants

No stock purchase warrants were granted, cancelled or forfeited during the six months ended June 30, 2022. At June 30, 2022, we had outstanding and vested stock purchase warrants for the purchase of 303,725 shares with a weighted average exercise price of $10.66 and a weighted average remaining contractual life of 1.3 years.

Effective May 3, 2022, we extended the expiration date of a warrant held by a consultant by one year in connection with the extension of their service agreement. No other terms of the warrant, including the exercise price of $7.18, were changed. We will recognize expense of approximately $33,000 related to this warrant modification over a one-year period beginning May 2022.

Note 5 – Net Loss per Share of Common Stock

Net Loss Per Share

Basic net loss per share is computed by dividing our net loss available to common shareholders by the weighted average number of shares of common stock outstanding (which excludes unvested RSAs and includes vested RSUs) during the period. Diluted loss per share is computed by dividing our net loss available to common shareholders by the diluted weighted average number of shares of common stock (which includes the potentially dilutive effect of stock options, unvested RSAs, unvested RSUs and warrants) during the period. Since we experienced a net loss for both periods presented, basic and diluted net loss per share are the same. As such, diluted loss per share for the three and six month periods ended June 30, 2022 and 2021 excludes the impact of potentially dilutive common shares since those shares would have an anti-dilutive effect on net loss per share.

The computation of net loss per share for the three and six month periods ended June 30, 2022 and 2021 was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Basic and diluted net loss per share:				
Net loss available to common stockholders	$ (5,164,368)	$ (3,157,043)	$ (8,391,499)	$ (5,256,523)
Weighted average number of common shares-basic and diluted	15,940,510	15,406,363	15,886,116	14,997,303
Basic and diluted net loss per share	$ (0.32)	$ (0.20)	$ (0.53)	$ (0.35)

Our diluted net loss per share for the three and six month periods ended June 30, 2022 and 2021 excluded 1,965,502 and 709,954 of potentially dilutive common shares, respectively, related to outstanding stock options, stock purchase warrants and unvested restricted stock since those shares would have had an anti-dilutive effect on net loss per share during the periods then ended.

Note 6 – 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. 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. We also lease office equipment under an operating lease. Our leases do not provide an implicit rate and, as such, we have used our incremental borrowing rate of 8% to determine 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 $24,137 and $21,801 for the three months ended June 30 and 2021, respectively, and $48,528 and $45,831 for the six months ended June 30, 2022 and 2021, respectively. The weighted average remaining lease terms and discount rate for our operating leases were as follows at June 30, 2022:

Remaining lease term (years) for our facility lease	0.3
Remaining lease term (years) for our equipment lease	1.8
Weighted average remaining lease term (years) for our facility and equipment leases	0.7
Weighted average discount rate for our facility and equipment leases	8.0%

Annual lease liabilities for all operating leases were as follows as of June 30, 2022:

2022	$	26,457
2023		6,420
2024		1,605
Total lease payments		34,482
Less: Interest		(3,275)
Present value of lease liabilities		31,207
Less: current maturities		(26,552)
Non-current lease liability	$	4,655

Note 7 – Related Party Transactions

CorLyst, LLC ("CorLyst") reimburses us for shared costs related to payroll, health insurance and rent based on actual costs incurred, which are recognized as a reduction of our general and administrative operating expenses being reimbursed in our condensed consolidated statement of operations. We recorded $63,689 and $61,549 of reimbursements during the six months ended June 30, 2022 and 2021, respectively. No amounts were due from CorLyst at June 30, 2022 or 2021. Our CEO is also the CEO of CorLyst, and CorLyst is a shareholder.

Note 8 – Elion License Agreement

On May 17, 2022, we amended the third Milestone Event of Section 6.4 of our License Agreement with Elion Oncology, Inc. changing the third Milestone Event from "1st Patient in Dose Confirmation Study" to (a) determination of the maximum tolerated dose (MTD) or (b) determination of the recommended Phase 2 Dose. Prior to this amendment, the third milestone was not considered probable since it was unknown when, or if a dose confirmation study was going to be conducted. As a result of the modification, we consider it probable that the MTD could be determined in connection with our current Phase 1B trial for PCS6422. We recorded an expense and related liability of $189,000 representing the value of the shares we anticipate issuing to Elion at the fair value on the date of modification. No other terms or conditions of the License Agreement were modified.

Note 9 – Commitments and Contingencies

Purchase Obligations

We enter into contracts in the normal course of business with contract research organizations and subcontractors to further develop our products. The contracts are cancellable, with varying provisions regarding termination. If 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. As of June 30, we are contractually obligated to pay up to approximately $5.5 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.

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

Forward Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" that reflect, when made, the Company's expectations or beliefs concerning future events that involve risks and uncertainties. Forward-looking statements frequently are identified by the words "believe," "anticipate," "expect," "estimate," "intend," "project," "will be," "will continue," "will likely result," or other similar words and phrases. Similarly, statements herein that describe the Company's objectives, plans or goals also are forward-looking statements. Actual results could differ materially from those projected, implied or anticipated by the Company's forward-looking statements. Some of the factors that could cause actual results to differ include: our limited operating history, limited cash and history of losses; our ability to achieve profitability; our ability to obtain adequate financing to fund our business operations in the future; the impact of the global pandemic caused by the novel coronavirus, COVID-19, including its impact on our ability to obtain financing or complete clinical trials; our ability to secure required FDA or other governmental approvals for our product candidates and the breadth of the indication sought; the impact of competitive or alternative products, technologies and pricing; whether we are successful in developing and commercializing our technology, including through licensing; the adequacy of protections afforded to us and/or our licensor by the anticipated patents that we own or license and the cost to us of maintaining, enforcing and defending those patents; our and our licensor's ability to protect non-patented intellectual property rights; our exposure to and ability to defend third-party claims and challenges to our and our licensor's anticipated patents and other intellectual property rights; and our ability to continue as a going concern. For a discussion of these and all other known risks and uncertainties that could cause actual results to differ from those contained in the forward-looking statements, see "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, 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

Our mission is to develop drug products that improve the survival and/or quality of life for patients with high unmet medical need conditions for which few or no treatment options currently exist. We are a clinical-stage development company, not a discovery company, that seeks to identify and develop drugs for patients who need better treatment options. 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 that 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 of 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 "benefit/risk" equation to identify a regulatory path with higher clinical benefit and/or lower clinical risk with shorter timelines to deliver better treatment options 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 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 timeframe 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. Throughout their careers, the combined scientific, development and regulatory experience of our team members have 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 do not guarantee that they will successfully develop and commercialize drugs in our current pipeline. In addition, the growth in revenues of companies in which our executive officers and directors served 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 Strategy

Our strategy is to obtain and develop drugs that will not only treat patients with unmet medical need conditions, but, with our regulatory science approach, have the potential to be more efficiently developed with a greater probability of development success than what typically occurs in the biotech-pharma industry, as well as a better return on investment given lower development costs, more efficient development, and high commercial value. Given the prior successes of our regulatory science approach, we have selected drugs for our portfolio which may have a greater chance for approval in a population of patients who desperately need better treatment options. We have applied rigorous standards to identify drugs for our portfolio, namely:

i. The drug must represent a treatment option to patients with a high unmet medical need condition by improving survival and/or quality of life for these patients,

ii. The drug or its metabolite or a drug with similar pharmacological properties must have demonstrated some evidence of efficacy in the target population, and

iii. The drug presents opportunities to be developed such that within 2-4 years, critical value-added clinical milestones can be achieved while advancing the drug closer to commercialization and adding to the potential for a high return on investment.

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

Recent Developments

On March 23, 2022, we entered into a purchase agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which Lincoln Park has committed to purchase up to $15.0 million of shares (the "Purchase Shares") of our common stock, $0.0001 par value per share ("Common Stock"), subject to the terms and conditions in the Purchase Agreement. We issued 123,609 shares of common stock (valued at $450,000) to Lincoln Park as a commitment fee in connection with entering into the Purchase Agreement and agreed to reimburse Lincoln Park $25,000 for fees incurred in connection with the Purchase Agreement. Concurrent with entering into the Purchase Agreement, we also entered into a registration rights agreement with Lincoln Park (the "Registration Rights Agreement"), pursuant to which we agreed to take certain actions relating to the registration under the Securities Act of 1933, as amended, of the offer and sale of the shares of common stock available for issuance under the Purchase Agreement. See Note 3 to the Condensed Consolidated Financial Statements for additional details concerning the Purchase Agreement. We put this facility in place to ensure that financing will not hinder the continued development of our pipeline should we run into unexpected circumstances in the future.

Impact of COVID-19

The COVID-19 pandemic continues to create uncertainties in expected timelines by causing delays in clinical trials and disruptions in the supply chain for raw materials used in clinical trial work. We have experienced delays in the enrollment of patients in our PCS499 Phase 2B trial due to COVID-19. Some potential patients have died from COVID-19 prior to screening and others continue to be reluctant to travel to our testing sites for fear of contracting COVID-19. Delays in enrollment lengthen the time of studies and increase their costs, which 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 we are hopeful the infection rate of COVID-19 will continue to decline, we cannot predict the future impact COVID-19 will have on our current and future clinical trials. Continued delays could materially impact our business in future periods and further extend our timelines.

Our Drug Pipeline

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

Drug	Disease Target	Nonclin	Phase 1	Phase 2	Phase 3	Upcoming Milestones
PCS499 Phase 2B	Ulcerative Necrobiosis Lipoidica					2H'22 – Complete Interim Group Enrollment 1H'23 - Interim Analysis; Complete Enrollment
PCS12852 Phase 2A	Gastroparesis					2H'22 - Complete Enrollment; Top-Line Results 1H-2H'23 – Initiate Phase 2B study
PCS6422 (Next Generation Capecitabine) Phase 1B	Metastatic Colorectal, Other Cancers					2H'22 - Complete Enrollment & Preliminary Identification of Next Generation Capecitabine MTD 1H'23 -Define Possible Paths to FDA Approval
PCS3117 Phase 2B	Pancreatic, Other Cancers					2H'22 – 1H'23 -Define Possible Paths to FDA Approval
PCS11T Pre-IND	Small Cell Lung, Other Cancers					2H'22 – Select Manufacturing Sites; Define Possible Paths to FDA Approval

Key
FPI – First Patient In (i.e., randomized)
MTD – Maximum Tolerated Dose

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 ulcerative Necrobiosis Lipoidica (uNL) 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 has been reported to occur in up to 30% of NL patients, which can lead to more severe complications, such as deep tissue infections and osteonecrosis threatening the life of the limb.

The degeneration of tissue occurring at the NL lesion site may be caused by a number of pathophysiological changes, which makes 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 NL patient enrolled 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 ulcerated and non-ulcerated 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 AEs and were 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 uNL 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 non-ulcerated NL, 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 uNL 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 may be significantly less than 13% over 1-2 years and likely 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 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 uNL and better understand the potential response of uNL patients on drug and on placebo. We currently have selected six clinical trial sites in the United States and are evaluating additional sites to add to our study. We had four sites in Europe, but these sites were unable to recruit patients timely, largely due to COVID-19, so we decided to close them and concentrate our efforts on recruiting patients within the United States.

We began recruiting for the clinical trial in the first half of 2021. On May 19, 2021, we dosed our first patient in the randomized, placebo-controlled trial and are planning to complete an interim analysis of the data from this trial during the first half of 2023. 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, with the intent to define a Special Protocol Assessment for the Phase 3 study and to agree on the next steps to obtain approval.

We have experienced delays in the enrollment of patients in the PCS499 Phase 2B trial due to COVID-19. Many potential patients also have co-morbidities, such as diabetes, and have been unwilling to travel to the testing sites for fear of contracting COVID-19. Potential patients in this trial have died from COVID-19 prior to screening. We have initiated a number of programs to hopefully increase the enrollment rate in this study, including paying for travel to study sites and informing physicians who might be treating these patients that a trial is occurring.

PCS12852

On August 19, 2020, we in-licensed PCS12852 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. PCS12852 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.

Two clinical studies, both of 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 percentage 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 received guidance from the FDA in the first half of 2021 and in October 2021 we received notice of safe to proceed for PCS12852 evaluation in a Phase 2A randomized, placebo-controlled study in patients with gastroparesis. We enrolled our first patient on April 5, 2022, anticipate completing enrollment in the second half of 2022 with top-line results by the end of 2022, and should complete our final analysis 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 was designed to evaluate the change in gastric emptying in patients with gastroparesis from 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 documented serious side effects which limit dosing to no more than 12 weeks. Other 5-HT4 drugs have been used clinically but the side effects, mainly caused by binding to other receptors, has resulted in these drugs not being a viable option to treat patients with gastroparesis.

PCS6422 ("Next Generation Capecitabine" when administered with Capecitabine)

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 affects 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 a decrease in F-Bal, although the timeframe and magnitude for DPD inhibition have been shown to vary, ranging from 2-14 days depending on the de novo formation of DPD within a patient and the dosage regimen of PCS6422. With the inhibition of DPD, the level of the 5-FU anti-cancer metabolites could also be potentially higher within cancer and normal cells leading to an improved efficacy profile and/or increased side effects associated with these antimetabolites such as neutropenia. By combining capecitabine (an 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 Area Under the Plasma Concentration Curve (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 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. In addition, later preclinical work suggested that when PCS6422 was present in excess to 5-FU and at the same time, it diminished the antitumor activity of 5-FU, which we believe supports the rationale of dosing PCS6422 such that the exposure at the time of 5-FU or capecitabine administration is as low as possible, yet continues to inhibit DPD activity to less than 10% of normal activity.

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 PCS6422 and several doses of capecitabine 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. We began patient recruitment in the study during the second half of 2021 and enrolled our first patient on August 2, 2021.

The interim analysis of Cohorts 1 and 2 was conducted in the fourth quarter of 2021. DLTs, drug related adverse events of greater than Grade 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 the single dose administration of PCS6422 on Day 1. In February 2022, we submitted a modified Phase 1B trial protocol to the FDA 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, as well as the potential for using individualized/personalized treatment of patients with Next Generation Capecitabine.

We anticipate that this additional data will allow us to select PCS6422 dosage regimens that will maintain DPD inhibition throughout capecitabine dosing and allow more of the drug to be metabolized to active tumor killing metabolites instead of metabolites that only cause side effects for each patient treated with this Next Generation Capecitabine. After interacting with the FDA and making protocol modifications, we restarted the Phase 1B study in April 2022 and expect to complete enrollment while defining the Next Generation Capecitabine regimens by the end of 2022. 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.

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 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 evaluated.

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 evaluated, 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. 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, an evaluation of the cause of treatment resistance to PCS3117 was not undertaken.

We are currently defining the potential paths to approval, which include an evaluation of which population of pancreatic cancer patients to target, FDA acceptable primary endpoints for the population, and other ways (e.g., biomarkers) to identify patients likely to respond to PCS3117 over gemcitabine.

PCS11T

On May 24, 2020, we in-licensed PCS11T 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. Therefore, there is 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 acetylcholine 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 evaluating the manufacturing process and sites for drug substance and drug product. In addition, we are defining the potential paths to approval, which include defining the targeted patient population and type of cancer. We hope to submit an IND in the first half of 2024, followed by a Phase 1B trial in oncology patients with solid tumors.

Results of Operations

Comparison of the three and six months ended June 30, 2022 and 2021

The following table summarizes our operations during the periods indicated:

	Three Months Ended June 30,			Six Months Ended June 30,		
	2022	2021	Change	2022	2021	Change
Operating Expenses						
Research and development expenses	$ 3,137,292	$ 1,614,954	$ 1,522,338	$ 5,181,912	$ 3,086,401	$ 2,095,511
Acquisition of in-process research and development	-	515,630	(515,630)	-	515,630	(515,630)
General and administrative expenses	2,034,456	1,329,213	705,243	3,218,550	2,051,073	1,167,477
Operating Loss	(5,171,748)	(3,459,797)		(8,400,462)	(5,653,104)	
Other Income (Expense)						
Forgiveness of PPP loan and related accrued interest	-	163,771	(163,771)	-	163,771	(163,771)
Interest expense	-	-	-	-	(362)	362
Interest income	7,380	1,814	5,566	8,963	6,755	2,208
Net Operating Loss Before Income Tax Benefit	(5,164,368)	(3,294,212)	(1,870,156)	(8,391,499)	(5,482,940)	(2,908,559)
Income Tax Benefit	-	137,169	(137,169)	-	226,417	(226,417)
Net Loss	$ (5,164,368)	$ (3,157,043)		$ (8,391,499)	$ (5,256,523)	

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) amortization of the exclusive PCS499 license intangible asset used in research and development activities, (ii) internal research and development staff related salaries and other payroll costs including stock-based compensation, payroll taxes and employee benefits, and (iii) program and testing related expenses including 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.

Our research and development expenses increased during both the three and six month periods ended June 30, 2022 when compared to the same periods in 2021 as shown below.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Amortization of intangible assets	$ 197,124	$ 198,832	$ 394,248	$ 397,664
Research and development salaries and benefits	1,037,768	453,721	1,565,020	702,390
Preclinical, clinical trial and other costs	1,902,400	962,401	3,222,644	1,986,347
Total	$ 3,137,292	$ 1,614,954	$ 5,181,912	$ 3,086,401

Our research and development expenses increased during both the three and six month periods ended June 30, 2022 when compared to the same periods in 2021. The majority of our increase in research and development expenses was due to increases in preclinical, clinical trial and other costs. These increases result from activity in our three active clinical trials. Expenses include costs we paid contract research organizations, regulatory filing and maintenance fees, drug product testing and stability, consulting, and other clinical fees. Additionally, on May 17, 2022, we amended the third Milestone Event of our License Agreement with Elion changing the third Milestone Event as described in Note 8 to our condensed consolidated financial statements. As a result, we recorded research and development expense and a related liability of $189,000 representing the value of the shares we anticipate issuing to Elion at the fair value on the date of modification. During the same period in 2021, we were beginning our Phase 2B clinical trial for PCS499 and Phase 1B clinical trial for PCS6422 and conducting pre-IND tasks for PCS12852.

During the three and six months ended June 30, 2022, when compared to the same period in 2021, we also experienced increases in payroll and related costs of approximately $88,000 and $228,000, respectively and increases in stock-based compensation of approximately $494,000 and $632,000, respectively, as a result of expanding our development team, and increasing salary rates and stock-based compensation.

We anticipate our research and development costs to increase in the future as we continue our clinical trials, including the cost of having drug product manufactured, and continue evaluating the remaining drugs in our portfolio and expanding our development team.

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, conduct our Phase 1B clinical trial for PCS6422 in gastrointestinal tumors and conduct our Phase 2 trial for PCS12852 in gastroparesis.

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. At June 30, 2022, we recorded $1.1 million in prepaid expenses for advanced payments made to our CROs related to our three current clinical trials.

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

General and Administrative Expenses.

Our general and administrative expenses for the three months ended June 30, 2022 increased by approximately $705,000 to $2.0 million from $1.3 million for the three months ended June 30, 2021. The majority of the increase was due to an increase in employee stock-based compensation of approximately $702,000 and in payroll and other related costs of $58,300. We also experienced increases in insurance, office, tax, and other expenses of approximately $36,000, which were offset by a decrease of approximately $89,000 in professional fees, and other miscellaneous expenses. Reimbursements from CorLyst totaled approximately $32,000 for rent and other costs during the three months ended June 30, 2022, approximately $1,600 more than reimbursements for the same period in 2021.

During the six month period ended June 30, 2022, our general and administrative expenses increased by approximately $1.2 million to $3.2 million from $2.0 million for the six months ended June 30, 2021. The majority of the increase was due to an increase in employee stock-based compensation of approximately $983,000 and in payroll and other related costs of approximately $68,000. We also experienced net increases in other expenses including insurance, office, and tax of approximately $118,000. Reimbursements from CorLyst totaled approximately $64,000 for rent and other costs during the six months ended June 30, 2022, approximately $2,000 more than reimbursements for the same period in 2021.

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 approximately $7,400 and $166,000 for the three months ended June 30, 2022 and 2021, respectively, and approximately $9,000 and $170,000 for the six months ended June 30, 2022 and 2021, respectively. During the three and six months ended June 30, 2021, we recognized $163,771 as other income for the principal amount and 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.

Income Tax Benefit.

We did not recognize any income tax benefit for the three or six months ended June 30, 2022 compared to the $137,169 and $226,417 income tax benefit we recognized for the three and six months ended June 30, 2021, 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*, we 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 has been reduced for the effect of the non-deductibility of the amortization of the intangible asset and has been offset by the deferred tax assets resulting from net operating tax losses that was fully amortized at December 31, 2021. This offset resulted in the recognition of a deferred tax benefit shown in the consolidated statements of operations in 2021 and prior periods.

Cash Flows

The following table sets forth our sources and uses of cash and cash equivalents for the six months ended June 30, 2022 and 2021:

	Six months ended June 30,	
	2022	2021
Net cash (used in) provided by:		
Operating activities	$ (4,133,439)	$ (4,437,494)
Financing activities	(300,000)	9,852,465
Net increase (decrease) in cash	$ (4,433,439)	$ 5,414,971

Net cash used in operating activities

We used net cash in our operating activities of $4,133,439 and $4,437,494 during the six months ended June 30, 2022 and 2021, respectively. The decrease in cash used in operating activities during the six months ended June 30, 2022 compared to the same period in 2021 was primarily related to the impact of non-cash operating activities, the utilization of prepaid expenses by our CROs in clinical trials and the timing of payments made to our vendors.

At June 30, 2022, our prepaid expense and other balance consisted primarily of $1.1 million for advanced payments we made to our CROs that have not yet been applied to our clinical trials, representing a $200,000 reduction from the prepaid amount recorded at December 31, 2021 of $1.3 million. Our prepaid expense and other at June 30, 2022 also included the unamortized non-cash commitment fee we paid to Lincoln Park of $409,000 and the unamortized ATM offering related costs of $186,000. The remainder of the change in prepaid expenses and other was the result of several other operating activities, none of which, individually or in the aggregate were considered significant by management.

Our net loss for the six months ended June 30, 2022 of $8.4 million was $3.1 million greater than the comparable period in 2021.

As we continue our three clinical trials and evaluate 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 as the drugs in our pipeline continue to advance and if new or additional clinical trials begin.

Net cash (used in) provided by financing activities

We used net cash in financing activities during the six months ended June 30, 2022 of $300,000 to purchase 100,000 shares of our common stock from a licensee. During the six months ended June 30, 2021, we closed a private offering raising net proceeds of $9,875,550.

Liquidity

At June 30, 2022, we had $12.0 million in cash and cash equivalents.

On March 23, 2022, we entered into the Purchase Agreement with Lincoln Park under which we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $15,000,000 of our shares of common stock, par value $0.0001 per share, subject to the terms and conditions in the Purchase Agreement, during the term of the Purchase Agreement as more fully described in Note 3 to the Consolidated Financial Statements. In addition, on August 20, 2021, we entered into the Sales Agreement with the Sales Agent under which we may issue and sell up to $30.0 million from time to time under the ATM Offering. We expect to use net proceeds from the ATM Offering over time as a source for working capital and general corporate purposes. During the year ended December 31, 2021, we sold 21,597 shares of our common stock under the ATM Offering at an average price of approximately $8.33 per share for aggregate gross proceeds of approximately $180,000 prior to deducting sales commissions. We did not sell any shares during the six months ended June 30, 2022.

We have incurred losses and net cash used in our operating activities during the six months ended June 30, 2022, which we expect to continue for the foreseeable future. We do not currently nor 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 $45.2 million at June 30, 2022. During the six months ended June 30, 2022, we generated a net loss of approximately $8.4 million, of which $3.5 million are non-cash expenses. Based on our current plans, we believe our current cash balance is adequate for at least the next twelve months without considering amounts available from the Purchase Agreement with Lincoln Park or potential sales under our ATM Offering. 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 will need to raise additional capital to fully implement our business plan if the costs of our 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. 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 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 PCS3117 and PCS11T, as well as 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 currently 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 and the Purchase Agreement with Lincoln Park, 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, 2021.

Off Balance Sheet Arrangements

At June 30, 2022, 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 since 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

As of June 30, 2022, management, with the participation of the Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on the evaluation of its disclosure controls and procedures, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2022 to provide reasonable assurance that information required to be disclosed in our reports under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our 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 their objectives, and management necessarily applies its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2022 that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

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, 2021.

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

(a) Recent Sale of Unregistered Securities

There were no sales of unregistered securities during the three months ended June 30, 2022.

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

None.

(c) Issuer Purchases of Equity Securities

During the six months ended June 30, 2022, we purchased 100,000 shares of our common stock from Aposense Ltd. for $300,000 in a private transaction and are holding these shares as treasury stock until they are reissued or retired at the discretion of our Board of Directors.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

On July 25, 2022, we changed our transfer agent from Equiniti Trust Ltd. to Continental Stock Transfer and Trust Company.

Item 6. Exhibits

SEC Ref. No.	Title of Document
31.1*	Rule 153-14(a) Certification by Principal Executive Officer
31.2*	Rule 153-14(a) Certification by Principal Financial Officer
32.1*++	Section 1350 Certification of Principal Executive Officer and Principal Financial Officer
99.1	XBRL Files
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

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

SIGNATURES

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

PROCESSA PHARMACEUTICALS, INC.

By: */s/ David Young*
David Young
Chief Executive Officer
(Principal Executive Officer)
Dated: August 11, 2022

By: */s/ James Stanker*
James Stanker
Chief Financial Officer
(Principal Financial and Accounting Officer)
Dated: August 11, 2022

Exhibit 31.1

CERTIFICATION

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

1. I have reviewed this quarterly report on Form 10-Q of PROCESSA PHARMACEUTICALS, INC. for the period ended June 30, 2022;

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.

By: */s/ David Young*
David Young
Chief Executive Officer
(Principal Executive Officer)
Date: August 11, 2022

Exhibit 31.2

CERTIFICATION

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

1. I have reviewed this quarterly report on Form 10-Q of PROCESSA PHARMACEUTICALS, INC. for the period ended June 30, 2022;

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.

By: */s/ James Stanker*
James Stanker
Chief Financial Officer
(Principal Financial and Accounting Officer)
Date: August 11, 2022

Exhibit 32.1

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

Solely for the purposes of complying with 18 U.S.C. §1350, I, the undersigned Chief Executive Officer of Processa Pharmaceuticals, Inc. (the "Company"), hereby certify, to the best of my knowledge, that the quarterly report on Form 10-Q of the Company for the quarter ended June 30, 2022 (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.

By: */s/ David Young*
David Young
Chief Executive Officer
(Principal Executive Officer)
Date: August 11, 2022

Solely for the purposes of complying with 18 U.S.C. §1350, I, the undersigned Chief Financial Officer of Processa Pharmaceuticals, Inc. (the "Company"), hereby certify, to the best of my knowledge, that the quarterly report on Form 10-Q of the Company for the quarter ended June 30, 2022 (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.

By: */s/ James Stanker*
James Stanker
Chief Financial Officer
(Principal Financial and Accounting Officer)
Date: August 11, 2022