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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2023

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 at May 9, 2023 was 24,531,474.

PROCESSA PHARMACEUTICALS, INC.
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Item 1: Financial Statements

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

	March 31, 2023	December 31, 2022
ASSETS		
Current Assets		
Cash and cash equivalents	$ 10,741,602	$ 6,503,595
Prepaid expenses and other	1,477,519	1,883,134
Total Current Assets	12,219,121	8,386,729
Property and Equipment, net	-	-
Other Assets		
Operating lease right-of-use assets, net of accumulated amortization	207,787	227,587
Security deposit	5,535	5,535
Total Other Assets	213,322	233,122
Total Assets	$ 12,432,443	$ 8,619,851
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Current maturities of operating lease liability	$ 81,166	$ 78,896
Accounts payable	316,709	327,548
Due to licensor	189,000	189,000
Due to related parties	-	51
Accrued expenses	1,573,961	403,061
Total Current Liabilities	2,160,836	998,556
Non-current Liabilities		
Non-current operating lease liability	129,358	150,554
Total Liabilities	2,290,194	1,149,110
Commitments and Contingencies	-	-
Stockholders' Equity		
Common stock, par value $0.0001, 50,000,000 shares authorized: 24,631,474 issued and 24,531,474 outstanding at March 31, 2023 and 16,135,400 issued and 16,035,400 outstanding at December 31, 2022	2,463	1,614
Additional paid-in capital	78,709,420	72,016,688
Treasury stock at cost — 100,000 shares at March 31, 2023 and December 31, 2022	(300,000)	(300,000)
Accumulated deficit	(68,269,634)	(64,247,561)
Total Stockholders' Equity	10,142,249	7,470,741
Total Liabilities and Stockholders' Equity	$ 12,432,443	$ 8,619,851

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 March 31,	
	2023	2022
Operating Expenses		
Research and development expenses	$ 1,627,480	$ 2,043,984
General and administrative expenses	2,478,055	1,184,730
Operating Loss	(4,105,535)	(3,228,714)
Other Income (Expense), net	83,462	1,583
Net Operating Loss Before Income Tax Benefit	(4,022,073)	(3,227,131)
Income Tax Benefit	-	-
Net Loss	$ (4,022,073)	$ (3,227,131)
Net Loss Per Common Share - Basic and Diluted	$ (0.18)	$ (0.20)
Weighted Average Common Shares Used to Compute Net Loss Per Common Shares - Basic and Diluted	22,770,789	15,831,118

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

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

	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 purchase agreement	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

	Common Stock		Additional Paid-In	Treasury Stock		Accumulated	
	Shares	Amount	Capital	Shares	Amount	Deficit	Total
Balance at January 1, 2023	16,135,400	$ 1,614	$ 72,016,688	(100,000)	$ (300,000)	$ (64,247,561)	$ 7,470,741
Stock-based compensation	63,882	6	341,498	-	-	-	341,504
Shares issued in connection with capital raises, net of transaction costs	8,432,192	843	6,351,234	-	-	-	6,352,077
Net loss	-	-	-	-	-	(4,022,073)	(4,022,073)
Balance, March 31, 2023	24,631,474	$ 2,463	$ 78,709,420	(100,000)	$ (300,000)	$ (68,269,634)	$ 10,142,249

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

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

	Three Months Ended March 31,	
	2023	2022
Cash Flows From Operating Activities		
Net loss	$ (4,022,073)	$ (3,227,131)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash lease expense for right-of-use assets	19,800	22,559
Amortization of issuance costs	-	3,113
Amortization of intangible asset	-	197,124
Stock-based compensation	341,504	828,897
Recording of warrant to be issued to purchase 3,160,130 shares of common stock in connection with a consulting agreement	1,310,875	-
Net changes in operating assets and liabilities:		
Prepaid expenses and other	405,615	216,717
Operating lease liability	(18,926)	(23,195)
Accounts payable	(10,839)	97,187
Due (from) to related parties	(51)	(1,772)
Other receivables	-	70,274
Accrued expenses	(139,975)	13,301
Net cash used in operating activities	(2,114,070)	(1,802,926)
Cash Flows From Financing Activities		
Net proceeds from common stock issued	6,352,077	-
Acquisition of treasury stock	-	(300,000)
Net cash provided by (used in) financing activities	6,352,077	(300,000)
Net Increase (Decrease) in Cash	4,238,007	(2,102,926)
Cash and Cash Equivalents – Beginning of Period	6,503,595	16,497,581
Cash and Cash Equivalents – End of Period	$ 10,741,602	$ 14,394,655
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

Organization

We are a clinical-stage biopharmaceutical company focused on incorporating our Regulatory Science Approach into the development of our Next Generation Chemotherapy (NGC) drugs to improve the safety and efficacy of cancer treatment. Our NGC drugs are modifications of existing FDA-approved oncology drugs resulting in an alteration of the metabolism and/or distribution while maintaining the well-known and established existing mechanisms of killing the cancer cells. By modifying the NGC drugs in this manner, we believe our three NGC treatments will provide improved safety-efficacy profiles when compared to their currently marketed counterparts.

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, 2022, as filed with the SEC. The results of operations for the interim periods shown in this report are not necessarily indicative of the results that may be expected for any other interim period or for the full year.

Liquidity

We have incurred losses since inception, devoting substantially all of our efforts toward research and development, and have an accumulated deficit of $68.3 million at March 31, 2023. During the three months ended March 31, 2023, we generated a net loss of $4.0 million and 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. Our ability to execute our longer-term operating plans, including 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 three months ended March 31, 2023 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 other operating expenses. Cash used to fund operating expenses is impacted by the timing of when we incur and pay these expenses.

During the three months ended March 31, 2023, we raised gross proceeds of $7.0 million (net proceeds of $6.4 million) from the sale of 8,432,192 shares of our common stock, as described in Note 2. We plan to use the net proceeds from these financings to prepare for future clinical trials; and on research and development expenses, working capital and other general corporate purposes.

Use of Estimates

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

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. At March 31, 2023 and December 31, 2022, we recorded a valuation allowance equal to the full recorded amount of our net deferred tax assets 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, no current income tax benefit or expense is expected for 2023 and the foreseeable future since the deferred tax liability has been offset completely at December 31, 2021 and we expect to generate 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 March 31, 2023, 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 consolidated financial position or results of operations.

Note 2 – Stockholders' Equity

Preferred Stock

There were no issued or outstanding shares of preferred stock at either March 31, 2023 or December 31, 2022.

Common Stock

During the three months ended March 31, 2023, we issued 8,432,192 shares of our common stock through several fundraising efforts.

ATM Offering

On August 20, 2021, we entered into the Sales Agreement with Oppenheimer & Co. Inc. (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 three months ended March 31, 2023, we sold 569,648 shares at an average price of $1.22 per share for aggregate gross proceeds of $693,000 (net proceeds of $672,000) prior to deducting sales commissions. On February 5, 2023, in connection with our Registered Direct Offering, we suspended the Sales Agreement with the Sales Agent, but we expect to reinstate it during 2023.

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, subject to the terms and conditions in the Purchase Agreement with Lincoln Park, including that the closing sale price of the common stock on the purchase date is not below a threshold price of $1.00. Any proceeds that we receive under the Purchase Agreement are expected to be used for working capital and general corporate purposes. During the three months ended March 31, 2023, we sold 50,000 shares at an average price of $1.08 per share for aggregate gross proceeds of $54,000 under the Purchase Agreement with Lincoln Park.

Registered Direct Offering

On February 14, 2023, we closed a registered direct offering (the "Offering") for the sale of 7,812,544 shares of common stock at a purchase price of $0.80 per share for gross proceeds of $6.3 million (net proceeds of $5.6 million). The Purchase Agreement provides that, subject to certain exceptions, until the earlier of (i) 90 days after the closing of the Offering or (ii) the trading day following the date that our common stock's closing price exceeds $2.00 for a period of 10 consecutive trading days, neither we nor our subsidiary will issue or enter into any agreement to issue or announce the issuance or proposed issuance of any shares of common stock or common stock equivalents.

We paid the Placement Agent a cash fee of 8.0% of the gross proceeds from the Offering, excluding proceeds received from our insiders, and reimbursed the Placement Agent for legal fees of $60,000. The engagement agreement with the Placement Agent requires us to indemnify the Placement Agent and certain of its affiliates against certain customary liabilities. On February 14, 2023, we amended our consulting agreement with Spartan originally entered into on August 24, 2022, extending the term of the consulting agreement until February 10, 2024. As compensation for services under the agreement, on April 17, 2023, we granted Spartan a warrant to purchase 3,160,130 shares of our common stock with an exercise price of $1.02. The warrant will expire three years from the date of issuance and contains both call and cashless exercise provisions.

Note 3 - 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 provides for the aggregate issuance of 6,000,000 shares of our common stock. At March 31, 2023, we have 1,394,122 shares available for future grants.

Stock Compensation Expense

We recorded stock-based compensation expense for the three month ended March 31, 2023 and 2022 as follows:

	2023	2022
Research and development	$ 99,621	$ 191,875
General and administrative	241,883	637,022
Total	$ 341,504	$ 828,897

At March 31, 2023, we recorded an expense and related accrued liability of $1.3 million related to the warrant we issued to Spartan, which is not included in the table above. 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

During the three months ended March 31, 2023, stock options to purchase 36,885 shares of common stock expired and there were no exercises or grants of stock options. At March 31, 2023, we had outstanding and exercisable options for the purchase of 141,611 shares with a weighted average exercise price of $18.22, a weighted average remaining contractual life of 2.9 years. At March 31, 2023, we did not have any unrecognized stock-based compensation expense related to our granted stock options.

Restricted Stock Awards

Activity with respect to our Restricted Stock Awards (RSAs) during the three months ended March 31, 2023 was as follows:

	Number of shares	Weighted-average grant-date fair value per share
Outstanding at January 1, 2023	61,888	$ 4.72
Granted	90,000	1.10
Cancelled	(26,118)	1.72
Outstanding and unvested at March 31, 2023	125,770	$ 2.75

On January 1, 2023, we granted RSAs totaling 90,000 shares of common stock to three directors for their service for the six month period ending June 30, 2023 in order to align their compensation plan with their service period and change the annual service period to begin and end on the date of respective Annual Meetings rather than the calendar year. Our directors are compensated through a combination of cash and equity. On March 8, 2023, the directors increased the cash component and decreased the equity component of their compensation by equal amounts on a retroactive basis, to the beginning of their respective service periods. Accordingly, we cancelled RSAs representing 26,118 shares of common stock.

At March 31, 2023, the total unrecognized stock-based compensation expense related to the outstanding and unvested RSAs was $163,100, which is expected to be recognized over a weighted average period of 0.5 years.

Restricted Stock Units

Activity with respect to our Restricted Stock Units (“RSUs”) during the three months ended March 31, 2023 was as follows:

	Number of shares	Weighted-average grant-date fair value per share
Outstanding at January 1, 2023	2,713,977	$ 3.69
Granted	966,503	1.10
Outstanding at March 31, 2023	3,680,480	3.01
Vested and unissued	2,585,247	3.50
Unvested at March 31, 2023	1,095,233	$ 1.86

At March 31, 2023, unrecognized stock-based compensation expense of $1.2 million for RSUs is expected to be fully recognized over a weighted average period of 2.1 years. The unrecognized expense excludes $322,000 of expense related to certain RSUs with a performance milestone that is not probable of occurring at this time.

Holders of our vested RSUs have our promise to issue shares of our common stock upon meeting the distribution restrictions contained in their Restricted Stock Unit Award Agreement. The distribution restrictions are different (longer) than the vesting schedule, imposing an additional restriction on the holder. Unlike RSAs, while certain 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

During the three months ended March 31, 2023, we agreed to grant a warrant to purchase a total of 3,160,130 shares of our common stock as compensation for services provided under an amended consulting agreement with Spartan, the placement agent for the Offering. The warrant was issued and exercisable on April 17, 2023 with an exercise price of $1.02 and expiration date of April 17, 2026. The warrant contains both call and cashless exercise provisions. We recorded $1,310,875 as a general and administrative expense and related accrued liability representing the fair value of this warrant on February 14, 2023, the date we amended the consulting agreement, since there were no contingent conditions on that date through April 17, 2023.

At March 31, 2023, we had outstanding stock purchase warrants, including the warrant issued on April 17, 2023, for the purchase of 3,366,480 shares with a weighted average exercise price of $1.61 and a weighted average remaining contractual life of 2.8 years. Stock purchase warrants for the purchase of 206,350 shares were exercisable at March 31, 2023 and the remaining outstanding stock purchase warrants will be exercisable in the second quarter of 2023.

At March 31, 2023, we did not have any unrecognized stock-based compensation expense related to our granted stock purchase warrants.

Note 4 – 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 months ended March 31, 2023 and 2022 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 months ended March 31, 2023 and 2022 was as follows:

	Three months ended March 31,	
	2023	**2022**
Basic and diluted net loss per share:		
Net loss available to common stockholders	$ (4,022,073)	$ (3,227,131)
Weighted average number of common shares-basic and diluted	22,770,789	15,831,118
Basic and diluted net loss per share	$ (0.18)	$ (0.20)

Our diluted net loss per share for the three months ended March 31, 2023 and 2022 excluded 4,729,094 (including the committed warrant to purchase 3,160,130 shares of common stock) and 795,342 of potentially dilutive common shares, respectively, related to outstanding stock options, 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 5 – 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% in determining the present value of the lease payments based on the information available at the lease commencement date.

Lease costs included in our condensed consolidated statements of operations totaled $22,461 and $21,918 for the three months ended March 31, 2023 and 2022, respectively. The weighted average remaining lease terms and discount rate for our operating leases were as follows at March 31, 2023:

Remaining lease term (years) for our facility lease	2.5
Remaining lease term (years) for our equipment lease	1.0
Weighted average remaining lease term (years) for our facility and equipment leases	2.5
Weighted average discount rate for our facility and equipment leases	8.0%

Annual lease liabilities for all operating leases were as follows at March 31, 2023:

2023	$ 70,600
2024	92,356
2025	70,040
Total lease payments	232,996
Less: Interest	(22,472)
Present value of lease liabilities	210,524
Less: current maturities	(81,166)
Non-current lease liability	$ 129,358

Note 6 – 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 $30,205 and $31,262 of reimbursements during the three months ended March 31, 2023 and March 31, 2022, respectively. No amounts were due from CorLyst at March 31, 2023 or 2022. Our CEO is also the CEO of CorLyst, and CorLyst is a shareholder.

Note 7 – Commitments and Contingencies

Purchase Obligations

We enter into contracts in the normal course of business with contract research organizations (CROs) and subcontractors to further develop our products. The contracts are cancelable, with varying provisions regarding termination. If we terminated a cancelable contract with a specific vendor, we would only be obligated for products or services that we received at the effective date of the termination and any applicable cancellation fees. At March 31, 2023, we are contractually obligated to pay up to $3.0 million of future services under the agreements with the CROs. Our actual contractual obligations will also vary depending on the progress and results of the remaining 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 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 licensors by the anticipated patents that we own or license and the cost to us of maintaining, enforcing and defending those patents; our and our licensors' ability to protect non-patented intellectual property rights; our exposure to and ability to defend third-party claims and challenges to our and our licensors' 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, 2022, which is available on the SEC's website at www.sec.gov. All forward-looking statements are qualified in their entirety by this cautionary statement, and the Company undertakes no obligation to revise or update this Quarterly Report on Form 10-Q to reflect events or circumstances after the date hereof.

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

Overview

We are a clinical-stage biopharmaceutical company focused on utilizing our Regulatory Science Approach, including the principles associated with FDA's Project Optimus Oncology initiative and the related FDA Draft Guidance, in the development of Next Generation Chemotherapy (NGC) oncology drug products. Our mission is to provide better treatment options than those that presently exist by extending a patient's survival and/or improving a patient's quality of life. This is achieved by improving upon FDA-approved, widely used oncology drugs or the cancer-killing metabolites of these drugs by altering how they are metabolized and/or distributed in the body, including how they are distributed to the actual cancer cells.

Regulatory science was conceived in the early 1990s when the founders of Processa and other faculty at the University of Maryland worked with the FDA to develop multiple FDA Guidance documents. Over the last 30 years, two of our founders, Dr. David Young and Dr. Sian Bigora, have expanded the original regulatory science concept to include other factors, such as the principles of Project Optimus, which can affect the risk-benefit analyses that FDA conducts for every FDA drug approval. In fact, the principles of FDA's Project Optimus have been used by Drs. Young and Bigora to identify and justify an "optimal" dosage regimen for a number of non-oncology FDA-approved drugs. Our Regulatory Science Approach and our past experience with the principles of Project Optimus differentiates us from other biotechnology companies by focusing us not only on the clinical science, but also on the equally important regulatory process. We believe utilizing our Regulatory Science Approach provides us with three distinct advantages:

- greater efficiencies (e.g., the right trial design and trial readouts);
- greater possibility of drug approval by the FDA or other regulatory authorities; and
- improvement over existing therapy with greater acceptance by patients/prescribers.

In January 2023, we announced our strategic prioritization to advance our pipeline of Next Generation Chemotherapy proprietary small molecule oncology drugs. By changing either the metabolism, distribution and/or elimination of already FDA-approved cancer drugs or their active metabolites while maintaining the mechanism of how the drug kills cancer cells, we believe our NGC treatments will provide improved safety-efficacy profiles when compared to their currently marketed counterparts - capecitabine, gemcitabine, and irinotecan. All future studies of these drugs are subject to availability of capital to conduct the trials.

The three NGC treatments in our pipeline are as follows:

- NGC-Capecitabine is a combination of PCS6422 and capecitabine. NGC-Capecitabine alters the metabolism of capecitabine without having any clinically meaningful biological effect itself. In clinical trials, NGC-Capecitabine has a safety profile different than capecitabine when administered alone. Side effects, such as Hand-Foot Syndrome (HFS) and cardiotoxicity that typically occur in up to 50-70% of patients treated with capecitabine and caused by specific capecitabine metabolites that are not formed to the same extent with NGC-Capecitabine, do not appear to be side effects associated with NGC-Capecitabine. These types of toxicities frequently result in decreased doses, interrupted doses or discontinuation of treatment with capecitabine. In addition, NGC-Capecitabine has been found to be 50 times more potent than capecitabine based on the systemic exposure of the capecitabine metabolite 5-FU, which is metabolized to the cancer-killing metabolites. Like capecitabine, NGC-Capecitabine could be used to treat patients with various cancers, such as metastatic colorectal, gastrointestinal, breast, and pancreatic. We estimate at least 200,000 patients in the United States were diagnosed in 2022 with metastatic colorectal, gastrointestinal, breast, and pancreatic cancers.

- NGC-Gemcitabine, also identified as PCS3117, is an oral analog of gemcitabine that is converted to its active metabolite by a different enzyme system than gemcitabine resulting in a positive response in gemcitabine patients as well as some gemcitabine treatment-resistant patients. Like gemcitabine, NGC-Gemcitabine could be used to treat patients with various cancers such as pancreatic, lung, ovarian, and breast. We estimate at least 275,000 patients in the United States were diagnosed in 2022 with pancreatic, lung, ovarian, and breast cancer. We plan to meet with the FDA in 2023 to discuss potential study designs including implementation of the Project Optimus initiative as part of the design, and then submit the Phase 2B protocol to the Investigational New Drug (IND Application) in the second half of 2023.

- NGC-Irinotecan, also identified as PCS11T, is a prodrug of the active metabolite of irinotecan (SN-38). The chemical structure of NGC-Irinotecan influences the uptake of the drug into cancer cells, resulting in more NGC-Irinotecan entering cancer cells than normal cells in mice. These levels were significantly greater than those seen with irinotecan, resulting in lower doses of NGC-Irinotecan having greater efficacy than irinotecan and improved safety in animal models. Like irinotecan, NGC-Irinotecan could be used to treat patients with various cancers such as lung, colorectal, gastrointestinal, and pancreatic cancer. We estimate at least 200,000 patients in the United States were diagnosed in 2022 with lung, colorectal, gastrointestinal, and pancreatic cancer. We plan to conduct IND-enabling and toxicology studies in 2023 and 2024.

Due primarily to the inability to identify and enroll patients since the beginning of our rare disease Phase 2 trial for PCS499 in ulcerative Necrobiosis Lipoidica (uNL), we decided to cease further enrollment in the PCS499 trial in February 2023. In addition, we have completed our Phase 2A trial for PCS12852 in gastroparesis patients with positive results. We did not experience any safety concerns during the conduct of either the PCS12852 or PCS499 trial. We are currently evaluating options to monetize PCS12852 and PCS499.

Our shift in prioritization to NGC oncology drugs does not change our mission. We continue to be focused on drug products that improve the survival and/or quality of life for patients by improving the safety and/or efficacy of the drug in a targeted patient population, while providing a more efficient and probable path to FDA approval, and differentiating our drugs from those on the market or are currently being developed.

Historically, much of oncology drug development has searched for novel or different ways to treat cancer. Our de-risked approach is to modify and improve three different and well-known, currently approved, and successfully used chemotherapy treatments so that the human body metabolizes and/or distributes these NGC treatments differently than their presently approved counterpart drugs while maintaining the cancer-killing mechanism of action. FDA's newly issued Project Optimus Oncology initiative and draft guidance on determining the optimal dose for oncology drugs recommends that the dose-response (both safety and efficacy) relationships be evaluated for all oncology drugs. Our Regulatory Science Approach, developed over the last 30 years, is very well aligned with the principles of Project Optimus and draft guidance where the objective is to identify the optimal dosage regimen, rather than the old approach of identifying the maximum tolerated dose (MTD) and adjust dosing accordingly. To date, we have data that suggests our NGC treatments are likely to have a better safety-efficacy profile than the current widely used marketed counterpart drugs, not only potentially making the development and approval process more efficient, but also clearly differentiating our NGC treatments from the existing treatment. We believe our NGC treatments have the potential to extend the survival and/or quality of life for more patients diagnosed with cancer while decreasing the number of patients who are required to dose-adjust or discontinue treatment because of side effects or lack of response.

Our Strategy

Our strategy is to develop our pipeline of Next Generation Chemotherapy (NGC) proprietary small molecule oncology drugs using our Regulatory Science approach, encompassing the principles of the FDA's recent Project Optimus initiative and draft guidance on determining the optimal dosage regimen of oncology drugs.

By changing either the metabolism, distribution, and/or elimination of already FDA-approved cancer drugs or their active metabolites while maintaining the mechanism of how the drug kills cancer cells, we believe our three NGC treatments will provide improved safety-efficacy profiles when compared to their currently marketed counterparts - capecitabine, gemcitabine, and irinotecan. By combining these modified approved cancer treatments with our Regulatory Science Approach and our experience using the principles of FDA's Project Optimus initiative, we will be able to increase the probability of FDA approval, improve the safety-efficacy profile over their existing counterparts which is important to patients and prescribers, and more efficiently develop each drug.

Our pipeline of NGCs (i) already has data demonstrating the desired pharmacological activity in humans or appropriate animal models and is able to provide improved safety and/or efficacy by some modification in the formation and/or distribution of the active moieties associated with the drug and (ii) targets cancers for which a single positive pivotal trial demonstrating efficacy might provide enough evidence that the clinical benefits of the drug and its approval outweighs the risks associated with the drug.

Our Drug Pipeline

Our pipeline currently consists of NGC-Capecitabine, NGC-Gemcitabine and NGC-Irinotecan (also identified as PCS6422, PCS3117 and PCS11T, respectively) and two non-oncology drugs (PCS12852 and PCS499). A timeline and summary of each drug is provided below.

Next Generation Chemotherapy Improving Safety and Efficacy							
Drug	Primary and Secondary Indications	Development Stage					Anticipated Milestones
		Preclin	Phase 1	Phase 2	Phase 3	IND	
Next Generation Capecitabine (PCS6422)	Colorectal, Breast, Gastric, Pancreatic, & Other Solid Tumor Cancers		→				☑ Colorectal and breast cancer Proof of Concept trials with lower dosing of PCS6422 ☑ FDA discussion – Project Optimus & Phase 2 design ■ Complete Phase 1B trial ☐ Initiate Phase 2 start-up tasks ☐ Phase 2 interim analysis ☐ Complete enrollment
Next Generation Gemcitabine (PCS3117)	Pancreatic, Gall Bladder, Non-Small Cell Lung, & Other Solid Tumor Cancers			→			☑ Treatment naïve and treatment refractory Proof of Concept pancreatic cancer trials ■ Re-analysis of pancreatic cancer data using Proj. Opt. ☐ Initiate Phase 2 start-up tasks ☐ Phase 2 interim analysis ☐ Complete enrollment
Next Generation Irinotecan (PCS11T)	Lung, Colorectal, Pancreatic, Gastric, Cervical & Other Cancers	→					☑ Cancer animal study determining dose-response relationship ■ Re-analysis of animal dose-response results using Proj. Opt. ☐ Initiate IND enabling studies ☐ Complete IND enabling studies

Candidates for Out-Licensing, Partnering, or Other Monetizing Event							
Drug	Primary and Secondary Indications	Development Stage					Anticipated Milestones
		Preclin	Phase 1	Phase 2	Phase 3	IND	
PCS12852	Moderate/Severe Gastroparesis & Other GI Motility Conditions			→			☑ Complete Phase 2 trial ■ Out-licensing, partnering, or other opportunities for further development
PCS499	Ulcerative Necrobiosis Lipoidica (uNL), Other			→			☑ Discontinue Phase 2B trial ■ Out-licensing, partnering, or other opportunities for further development

Key:

☑ Milestone completed
■ Milestone in progress
☐ Anticipated milestones in 2023-2024

Next Generation Chemotherapy Pipeline

- Next Generation Capecitabine (NGC-Capecitabine), also identified as PCS6422, is a combination of PCS6422 and the FDA-approved cancer drug capecitabine. PCS6422 is an orally administered irreversible inhibitor of the enzyme dihydropyrimidine dehydrogenase (DPD). DPD metabolizes 5-Fluorouracil (5-FU), the major metabolite of capecitabine and widely used itself as an intravenous chemotherapeutic agent in many types of cancer, to multiple metabolites classified as catabolites. These catabolites do not have any cancer-killing properties but frequently cause dose-limiting side effects that may require dose adjustments or discontinuation of therapy.

  When combining capecitabine with PCS6422 in NGC-Capecitabine, PCS6422 significantly changes the metabolism and distribution of 5-FU. After formation from capecitabine, 5-FU is metabolized to anabolites (which kill both cancer cells and normal duplicating cells) and catabolites (which cause side effects and have no cancer killing properties). Due to this change in metabolism of capecitabine and the change in the overall metabolite profile of anabolites and catabolites, the side effect and efficacy profile of NGC-Capecitabine has been found to be different than the existing FDA-approved capecitabine. Since the potency of NGC-Capecitabine is also more potent than FDA-approved capecitabine based on the 5-FU systemic exposure per mg of capecitabine administered, the amount of capecitabine anabolites formed from 1 mg of capecitabine administered in NGC-Capecitabine will, therefore, be much greater than formed from the administration of 1 mg of existing 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 2A of the ongoing clinical trial found no dose-limiting toxicities (DLTs), no drug-related adverse events greater than Grade 1, and no adverse events associated with the catabolites of 5-FU such as HFS. In this Phase 1B trial, it was demonstrated that the irreversible inhibition of DPD by PCS6422 could alter the metabolism, distribution and elimination of 5-FU, making NGC-Capecitabine significantly more potent than capecitabine alone (50 times more potent) and potentially leading to higher levels of anabolites which can kill replicating cancer and normal cells. By administering NGC-Capecitabine to cancer patients, the balance between anabolites and catabolites changes depending on the dosage regimens of PCS6422 and capecitabine used, making the efficacy-safety profile of NGC-Capecitabine different than that of FDA-approved capecitabine and requiring further evaluation of the PCS6422 and capecitabine regimens to determine the optimal NGC-Capecitabine regimens for patients.

  In order for NGC-Capecitabine to provide a safer and more efficacious profile for cancer patients compared to existing chemotherapy, understanding how the different regimens of PCS6422 and capecitabine may affect the systemic and tumor exposure to the anabolites, as well as the systemic exposure to the catabolites, is required. This can be achieved by following the timeline of DPD irreversible inhibition and the formation of new DPD using the plasma concentrations of 5-FU and its catabolites.

  In an effort to better estimate the timeline of DPD inhibition and formation of new DPD, we modified the protocol for the Phase 1B trial and began enrolling patients in the amended Phase 1B trial in April 2022. On November 1, 2022, we announced that data from the Phase 1B trial identified multiple dosage regimens with potentially better safety and efficacy profiles than currently existing chemotherapy regimens. Since 5-FU exposure is dependent on both the PCS6422 regimen and the capecitabine regimen, safe regimens were identified as well as regimens that cause DLTs. One of the regimens in the Phase 1B trial did cause DLTs in two patients, one of whom died. The Phase 1B trial is continuing to enroll patients and is expected to complete enrollment in 2023. The next trial will be a Phase 2 trial to determine which regimens provide an improved efficacy-safety profile over present therapy using the principles of the FDA's Project Optimus initiative to help guide the design of the trial. This FDA initiative requires us to consider NGC regimens that are not at the maximum tolerated dose or exposure level.

  Discussions with the FDA in April 2023 have clarified that the major goal for the next Phase 2 trial will be to evaluate and understand the dose- and exposure-response relationship for anti-tumor activity, safety and tolerability. The specific dosage regimens for the trial will be defined following the determination of the MTD from our ongoing Phase 1B trial. As a result, we have begun trial preparation tasks and will collaborate with the FDA to further define the dosage regimens and final design prior to the trial. We will need to obtain additional funding before we can conduct this trial.

- NGC-Gemcitabine, also identified as PCS3117, is a cytidine analog similar to gemcitabine (Gemzar®), but different enough in chemical structure that some patients are more likely to respond to PCS3117 than gemcitabine. The difference in response occurs because NGC-Gemcitabine is metabolized to its active metabolite through a different enzyme system than gemcitabine. We continue to evaluate the potential use of NGC-Gemcitabine in patients with pancreatic cancer and to evaluate ways to identify patients who are more likely to respond to NGC-Gemcitabine than gemcitabine. We plan to meet with the FDA in 2023 to discuss potential trial designs including implementation of the Project Optimus initiative as part of the design and then submit the Phase 2B protocol to the IND.

- NGC-Irinotecan, also identified as PCS11T, is an analog of SN38 (SN38 is the active metabolite of irinotecan) and should have an improved safety/efficacy profile in every type of cancer that irinotecan is presently used. The manufacturing process and sites for drug substance and drug product are presently being evaluated and IND-enabling toxicology studies will then be initiated. In addition, we are defining the potential paths to approval, which include defining the targeted patient population and the type of cancer. We plan to conduct IND enabling and toxicology studies in 2023 and 2024, subject to available funding.

Non-Oncology Pipeline for Out-licensing or Partnership

- PCS12852 is a highly specific and potent 5HT4 agonist that has already been evaluated in clinical studies in South Korea for gastric emptying and gastrointestinal motility in healthy volunteers and volunteers with a history of constipation. 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 and completed enrollment of the trial on September 2, 2022. Results from this Phase 2A trial, which included 25 patients with moderate to severe gastroparesis, demonstrated improvements in gastric emptying in patients receiving 0.5 mg of PCS12852 as compared to placebo. The results indicated that for the patients in the PCS12852 group, the mean time for 50% of the gastric contents to empty (t50) compared to their baseline value (±SD) decreased by -31.90 min (±50.53) (compared to the change seen in the placebo group of only -9.36 min (±42.43). Significant gastric emptying differences were not observed between the placebo and the 0.1 mg dose. Adverse events associated with the administration of PCS12852 were generally mild to moderate as expected, limited in duration, and quickly resolved without any sequelae. There were no cardiovascular safety events or serious adverse events reported during the trial. Additionally, the 0.5 mg of PCS12852 showed a greater improvement than placebo in the gastroparesis symptomology scales (including both total scores in the scales, as well as sub-scores such as nausea, vomiting and abdominal pain) used in the trial. With the trial now complete, we have the data necessary to finalize the development plan for the treatment of diabetic gastroparesis patients. We plan to monetize PCS12852 by looking for licensing and/or partnering opportunities.

- PCS499 is an oral tablet of the deuterated analog of one of the major metabolites of pentoxifylline (PTX or Trental®). PCS499 is a drug that can be used to treat unmet medical need conditions caused by multiple pathophysiological changes. We completed a Phase 2A trial for PCS499 in patients with ulcerative and non-ulcerative necrobiosis lipoidica (uNL and NL, respectively) in late 2020, and in May 2021, we enrolled the first patient in our Phase 2B trial for the treatment of uNL. Although we initiated several recruitment programs to increase the enrollment of patients in this trial, we were only able to recruit four patients. We have experienced extremely slow enrollment in the trial given the extreme rarity of the condition (rarer than reported in the literature), the impact of COVID-19, and the reluctance of patients to be in a clinical trial. We will complete the Phase 2B uNL trial for those currently enrolled, but will halt further efforts to enroll new patients in the trial. There have been no safety concerns during the conduct of the trial. Although we believe that PCS499 can be effective in treating uNL, we received preliminary data in late February 2023 that indicated that the placebo response is likely much greater than the literature and clinical experts believe; thus, a much larger sample size would be required in a pivotal trial for an indication where it was extremely difficult to enroll even 10 patients. We are also evaluating other, less rare indications for PCS499. As with PCS12852, we plan to monetize PCS499 by looking for licensing and/or partnership opportunities.

Recent Developments

During the three months ended March 31, 2023, we raised gross proceeds of $7.0 million (net proceeds of $6.4 million) from the sale of 8,432,192 shares of our common stock through the following transactions:

- In January 2023, we sold 50,000 shares at an average price of $1.08 per share for an aggregate gross proceeds of $54,000 through the Purchase Agreement we entered into with Lincoln Park Capital in March 2022, under which we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $15.0 million of our shares of common stock, subject to the terms and conditions in the Purchase Agreement.

- On February 3, 2023, we sold 569,648 shares at an average price of $1.22 per share for an aggregate gross proceeds of $693,000 (net proceeds of $672,000) prior to deducting sales commissions, pursuant to our 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.

- On February 14, 2023, we closed a registered direct offering for the sale of 7,812,544 shares of our common stock at a purchase price of $0.80 per share to accredited investors for gross proceeds of $6.3 million. Net proceeds from the offering were $5.6 million.

Termination of PCS499 Trial

Due to enrollment difficulties that we have experienced since the beginning of our rare disease trial for PCS499 in uNL, we decided to cease further enrollment in the PCS499 trial in February 2023. There were no safety concerns noted during the trial.

Results of Operations

Comparison of the three months ended March 31, 2023 and 2022

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

	Three months ended March 31,		
	2023	2022	Change
Operating Expenses			
Research and development expenses	$ 1,627,480	$ 2,043,984	$ (416,504)
General and administrative expenses	2,478,055	1,184,730	1,293,325
Operating Loss	(4,105,535)	(3,228,714)	
Other Income (Expense), net	83,462	1,583	81,879
Net Operating Loss Before Income Tax Benefit	(4,022,073)	(3,227,131)	(794,942)
Income Tax Benefit	-	-	-
Net Loss	$ (4,022,073)	$ (3,227,131)	

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) program and testing related expenses including external consulting and professional fees related to the product testing and our development activities and (ii) internal research and development staff salaries and other payroll costs including stock-based compensation, payroll taxes and employee benefits.

During the three months ended March 31, 2023, our research and development expenses decreased by $416,504 to $1,627,480 from $2,043,984 for the three months ended March 31, 2022. Costs for the three months ended March 31, 2023 and 2022 were as follows:

	Three months ended March 31,	
	2023	2022
Amortization of intangible assets	$ -	$ 197,124
Research and development salaries and benefits	518,803	526,616
Preclinical, clinical trial and other costs	1,108,677	1,320,244
Total	$ 1,627,480	$ 2,043,984

The decrease in research and development expenses, excluding amortization, was primarily due to a decrease in preclinical, clinical trial and other costs during the three months ended March 31, 2023 when compared to the same period in 2022. This decrease was attributable to the completion of our clinical trial for PCS12852 and the early termination of our clinical trial for PCS499. We also did not have any amortization expense, as we fully impaired our intangible asset at December 31, 2022. During the same period in 2022, we had three active clinical trials and amortization expense for our intangible asset.

Until we begin our next clinical trial, we anticipate our research and development costs to remain consistent as we close out and receive final reports related to our clinical trials for PCS499 and PCS12852. We will, however, continue incurring costs in our clinical trial for NGC-Capecitabine, including the cost of having drug product manufactured and other tasks necessary for the Phase 2 clinical trial, as well as costs necessary to submit the Phase 2B protocol for NGC-Gemcitabine.

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.

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

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

General and Administrative Expenses

Our general and administrative expenses for the three months ended March 31, 2023 increased by $1,293,325 to $2,478,055 from $1,184,730 for the three months ended March 31, 2022. This increase is primarily attributable to the fair value of $1,310,875 related to the stock purchase warrant granted to Spartan under the amended consulting agreement (see Note 2 to the condensed consolidated financial statements), which was primarily offset by a decrease in taxes.

Other Income

Other income represents interest income of $83,462 and $1,583 for the three months ended March 31, 2023 and 2022, respectively.

Income Tax Benefit

We did not recognize any income tax benefit for the three months ended March 31, 2023 or 2022.

Cash Flows

The following table sets forth our sources and uses of cash and cash equivalents for the three months ended March 31, 2023 and 2022:

	Three months ended March 31,	
	2023	2022
Net cash (used in) provided by:		
Operating activities	$ (2,114,070)	$ (1,802,926)
Financing activities	6,352,077	(300,000)
Net increase (decrease) in cash	$ 4,238,077	$ (2,102,926)

Net cash used in operating activities

We used net cash in our operating activities of $2,144,070 and $1,802,926 during the three months ended March 31, 2023 and 2022, respectively. The increase in cash used in operating activities during the first quarter of 2023 compared to the same period in 2022 was primarily related to increased cash compensation to our executive team and directors.

As we continue our clinical trial for NGC-Capecitabine and evaluate the other NGC 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. These amounts will begin to decrease when compared to prior periods due to our current cash balances unless we raise enough funds to conduct future clinical trials.

Net cash (used in) provided by financing activities

During the three months ended March 31, 2023, we raised net proceeds of $6.4 million from the sale of 8,432,192 shares of our common stock. We used net cash in financing activities during the three months ended March 31, 2022 of $300,000 to purchase 100,000 shares of our common stock from a licensee.

Liquidity

At March 31, 2023 we had $10.7 million in cash and cash equivalents.

We have incurred losses and net cash used in our operating activities during the three months ended March 31, 2023, which we expect to continue for the foreseeable future. We have no sales. We have incurred losses since our inception, devoting substantially all of our efforts toward research and development, and have an accumulated deficit of $68.3 million at March 31, 2023. During the three months ended March 31, 2023, we generated a net loss of $4.0 million, of which $1.7 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. Our ability to execute our longer-term operating plans, including 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 needed.

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 our current clinical trials and the cost of third-party manufacturing;
- 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 for our pre-clinical and clinical activities;
- 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 a Purchase Agreement with Lincoln Park Capital or a future at-the-market offering, but there can be no assurance that capital will continue to be available to us on acceptable terms, won't be limited, or be available 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 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, 2022.

Off Balance Sheet Arrangements

At March 31, 2023, we did not have any off-balance sheet arrangements.

Critical Accounting Policies and Use of Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities.

We believe that the estimates, assumptions and judgments involved in the accounting policies described in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of our most recent Annual Report on Form 10-K have the greatest potential impact on our financial statements, so we consider these to be our critical accounting policies. Actual results could differ from the estimates we use in applying our critical accounting policies. We are not currently aware of any reasonably likely events or circumstances that would result in materially different amounts being reported.

There have been no changes in our critical accounting policies from our most recent Annual Report on Form 10-K.

Recently Issued Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Item 3 is not applicable to us as a smaller reporting company and has been omitted.

Item 4. Controls and Procedures

At March 31, 2023, 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 at March 31, 2023 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 March 31, 2023 that have materially affected, or are reasonably likely to materially affect the Company's 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, 2022.

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

None.

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

None.

(c) Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

SEC Ref. No.	Title of Document
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: May 15, 2023

By: */s/ James Stanker*
James Stanker
Chief Financial Officer
(Principal Financial and Accounting Officer)
Dated: May 15, 2023

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 three months ended March 31, 2023;

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 at, 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, at 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: May 15, 2023

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 three months ended March 31, 2023;

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 at, 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, at 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: May 15, 2023

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 March 31, 2023 (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: May 15, 2023

Solely for the purposes of complying with 18 U.S.C. §1350, I, the undersigned Chief Financial Officer of Processa Pharmaceuticals, Inc. (the "Company"), hereby certify, to the best of my knowledge, that the quarterly report on Form 10-Q of the Company for the quarter ended March 31, 2023 (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: May 15, 2023