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, 2024

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 10, 2024 was 2,858,007.

PROCESSA PHARMACEUTICALS, INC.
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Part I: Financial Information
Item 1: Financial Statements

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

	March 31, 2024	December 31, 2023
ASSETS		
Current Assets		
Cash and cash equivalents	$ 8,920,363	$ 4,706,197
Due from related parties	22,295	-
Prepaid expenses and other	857,635	926,300
Total Current Assets	9,800,293	5,632,497
Property and Equipment, net	2,415	2,554
Other Assets		
Lease right-of-use assets, net of accumulated amortization	136,489	146,057
Security deposit	5,535	5,535
Total Other Assets	142,024	151,592
Total Assets	$ 9,944,732	$ 5,786,643
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Current maturities of lease liabilities	$ 89,680	$ 83,649
Accounts payable	455,368	311,617
Due to licensor	-	189,000
Due to related parties	-	39
Accrued expenses	465,618	146,274
Total Current Liabilities	1,010,666	730,579
Non-current Liabilities		
Non-current lease liabilities	50,700	66,905
Total Liabilities	1,061,366	797,484
Commitments and Contingencies	-	-
Stockholders' Equity		
Common stock, par value $0.0001, 100,000,000 shares authorized: 2,860,981 issued and 2,855,981 outstanding at March 31, 2024 and 1,291,000 issued and 1,286,000 outstanding at December 31, 2023	286	129
Additional paid-in capital	87,278,542	80,658,111
Treasury stock at cost — 5,000 shares at March 31, 2024 and December 31, 2023	(300,000)	(300,000)
Accumulated deficit	(78,095,462)	(75,369,081)
Total Stockholders' Equity	8,883,366	4,989,159
Total Liabilities and Stockholders' Equity	$ 9,944,732	$ 5,786,643

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,	
	2024	2023
Operating Expenses		
Research and development expenses	$ 1,539,070	$ 1,627,480
General and administrative expenses	1,270,528	2,478,055
Operating Loss	(2,809,598)	(4,105,535)
Other Income (Expense), net	83,217	83,462
Net Loss	$ (2,726,381)	$ (4,022,073)
Net Loss Per Common Share - Basic and Diluted	$ (1.11)	$ (3.53)
Weighted Average Common Shares Used to Compute Net Loss Per Common Shares - Basic and Diluted	2,466,523	1,138,573

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, 2023	806,774	$ 80	$ 72,018,222	(5,000)	$ (300,000)	$ (64,247,561)	$ 7,470,741
Stock-based compensation	3,195	1	341,503	-	-	-	341,504
Shares issued in connection with capital raises, net of transaction costs	421,611	42	6,352,035	-	-	-	6,352,077
Net loss	-	-	-	-	-	(4,022,073)	(4,022,073)
Balance, March 31, 2023	1,231,580	$ 123	$ 78,711,760	(5,000)	$ (300,000)	$ (68,269,634)	$ 10,142,249

	Common Stock		Additional Paid-In	Treasury Stock		Accumulated	
	Shares	Amount	Capital	Shares	Amount	Deficit	Total
Balance at January 1, 2024	1,291,000	$ 129	$ 80,658,111	(5,000)	$ (300,000)	$ (75,369,081)	$ 4,989,159
Stock-based compensation	13,176	1	167,642	-	-	-	167,643
Shares issued in connection with capital raise, net of transaction costs	1,555,555	156	6,282,274	-	-	-	6,282,430
Shares issued in connection with license agreement	5,000	1	188,999	-	-	-	189,000
Settlement of stock award	-	-	(8,561)	-	-	-	(8,561)
Shares withheld to pay income taxes on stock-based compensation	(3,750)	(1)	(9,923)	-	-	-	(9,924)
Net loss	-	-	-	-	-	(2,726,381)	(2,726,381)
Balance, March 31, 2024	2,860,981	$ 286	$ 87,278,542	(5,000)	$ (300,000)	$ (78,095,462)	$ 8,883,366

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,	
	2024	2023
Cash Flows From Operating Activities		
Net loss	$ (2,726,381)	$ (4,022,073)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	139	-
Non-cash lease expense for right-of-use assets	21,372	19,800
Stock-based compensation	167,643	341,504
Recording of warrant to be issued to purchase 158,007 shares of common stock in connection with a consulting agreement	-	1,310,875
Net changes in operating assets and liabilities:		
Prepaid expenses and other	68,665	405,615
Operating lease liability	(21,083)	(18,926)
Accounts payable	143,751	(10,839)
Due (from) related parties	(22,334)	(51)
Accrued expenses	319,344	(139,975)
Net cash used in operating activities	(2,048,884)	(2,114,070)
Cash Flows From Financing Activities		
Net proceeds from issuance of stock	6,282,430	6,352,077
Shares withheld to pay taxes on stock-based compensation	(9,924)	-
Settlement of stock award	(8,561)	-
Payment of finance lease obligation	(895)	-
Net cash provided by financing activities	6,263,050	6,352,077
Net Increase in Cash	4,214,166	4,238,007
Cash and Cash Equivalents – Beginning of Period	4,706,197	6,503,595
Cash and Cash Equivalents – End of Period	$ 8,920,363	$ 10,741,602
Non-Cash Financing Activities		
Issuance of 5,000 shares of common stock in connection with a licensing agreement which had previously been recorded as a due to licensor	$ 189,000	$ -
Right-of-use asset	$ 11,804	$ -
Financing lease liability	(11,804)	-
Net	$ -	$ -

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.

On January 22, 2024, we filed a Certificate of Amendment to our Certificate of Incorporation, as amended with the Secretary of State of Delaware that effected a 1-for-20 reverse stock split of our common stock, par value $0.0001 per share (the "Reverse Stock Split"). Pursuant to the Certificate of Amendment, our issued common stock decreased from 24,706,474 shares to 1,291,000 shares and our outstanding common stock decreased from 24,606,474 to 1,286,000. The Reverse Stock Split did not affect our authorized common stock of 100,000,000 shares or our common stock par value. All shares of common stock, including common stock underlying warrants, stock options, restricted stock awards and restricted stock units, as well as exercise prices and per share information in these condensed consolidated financial statements give retroactive effect to the Reverse Stock Split.

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, 2023, 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

Our condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. We have incurred losses since inception, are currently devoting substantially all of our efforts toward research and development of our NGC drug product candidates, including conducting clinical trials and providing general and administrative support for these operations, and have an accumulated deficit of $78.1 million at March 31, 2024. During the three months ended March 31, 2024, we generated a net loss of $2.7 million and used $2.0 million in net cash for operating activities from continuing operations. To date, none of our drug candidates have been approved for sale, and therefore we have not generated any product revenue and do not expect positive cash flow from operations in the foreseeable future.

We have financed our operations primarily through public equity issuances, including an offering we closed on January 30, 2024 where we sold 476,000 shares of our common stock, pre-funded warrants to purchase up to 1,079,555 shares of our common stock, and warrants for the purchase of up to 1,555,555 shares of our common stock for net proceeds of $6.3 million, after deducting placement agent fees and offering-related expenses. Simultaneously with the closing of the sale, the pre-funded warrants were exercised in exchange for 1,079,555 shares of our common stock. We will continue to be dependent upon equity and/or debt financing until we are able to generate positive cash flows from its operations.

At March 31, 2024, we had cash and cash equivalents totaling $8.9 million which, based on our current business plans, we believe these funds will satisfy our capital needs into early 2025, including the beginning of our Phase 2 trial of NGC-Cap in breast cancer. Our ability to execute our longer-term operating plans, including future preclinical studies and 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 raise additional funds in the future through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements, but will only do so if the terms are acceptable to us. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of, or suspend our current or planned future clinical trial plans, or research and development programs. This may also cause us to not meet obligations contained in certain of our license agreements and put these assets at risk. To the extent that we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. There can be no assurance that future funding will be available when needed.

Absent additional funding, we believe that our cash and cash equivalents will not be sufficient to fund our operations for a period of one year or more after the date that these condensed consolidated financial statements are available to be issued based on the timing and amount of our projected net loss from continuing operations and cash to be used in operating activities during that period of time. As a result, substantial doubt exists about our ability to continue as a going concern within one year after the date that these condensed consolidated financial statements are available to be issued. The accompanying condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of recorded assets, or the amounts and classification of liabilities that might be different should we be unable to continue as a going concern based on the outcome of these uncertainties described above.

Use of Estimates

In preparing our condensed consolidated financial statements and related disclosures in conformity with 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, 2024 and December 31, 2023, 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 2024 and the foreseeable future since 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, 2024, 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 – Stockholders' Equity

Preferred Stock

There were no issued or outstanding shares of preferred stock at either March 31, 2024 or December 31, 2023.

Common Stock

During the three months ended March 31, 2024, we issued the following shares of common stock.

- On January 22, 2024, we issued 6,203 shares of common stock to five of our executive officers and one employee, net of 2,373 shares of common stock withheld for income taxes owed upon the distribution of the shares.

- On January 25, 2024, we issued 5,000 shares of common stock to Elion Oncology, Inc. ("Elion") in satisfaction of the third milestone event under a license agreement.

- On January 30, 2024, we sold, pursuant to securities purchase agreements (the "Purchase Agreement"), 476,000 shares of common stock, pre-funded warrants to purchase up to 1,079,555 shares of common stock in lieu of shares of common stock (the "Pre-Funded Warrants"), and warrants to purchase up to 1,555,555 shares of our common stock (the "Common Warrants') pursuant to a public offering (the "Offering"). The Common Warrants have an exercise price of $4.50, are immediately exercisable and will remain exercisable until the date that is five years after their original issuance. The Shares were offered at a combined public offering price of $4.50 per share and accompanying Common Warrant and $4.4999 per Pre-Funded Warrant and accompanying Common Warrant. The Pre-Funded Warrants had an exercise price of $0.0001 and were exercised in full simultaneously with the closing of the Offering in exchange for 1,079,555 shares of our common stock. Gross proceeds in connection with the Offering were $7.0 million. We received $6.3 million in net proceeds from the Offering, after deducting the fees of the placement agent and other offering-related expenses. We also issued to the placement agent warrants to purchase 62,222 shares of common stock, exercisable at $5.625 per share that expire on February 1, 2027.

- On February 5, 2024, we issued 1,250 shares of common stock to a consultant in accordance with their consulting agreement.

- On March 5, 2024, we issued 3,223 shares of common stock to a former employee, net of 1,377 shares of common stock withheld for income and FICA taxes owed upon the distribution of the shares.

During the three months ended March 31, 2023, we issued 421,611 shares of our common stock through several fundraising efforts described below:

- *ATM Offering* – On February 5, 2023, in connection with our Registered Direct Offering discussed below, we terminated our ATM and suspended the Sales Agreement with Oppenheimer & Co. Inc., but we may reinstate it in the future. During the three months ended March 31, 2023, we sold 28,483 shares at an average price of $24.40 per share for aggregate gross proceeds of $693,000 (net proceeds of $672,000) prior to deducting sales commissions.

- *Lincoln Park Capital Fund, LLC Purchase Agreement* – During the three months ended March 31, 2023, we sold 2,500 shares at an average price of $21.60 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 "Registered Direct Offering") for the sale of 390,628 shares of common stock at a purchase price of $16.00 per share for gross proceeds of $6.3 million (net proceeds of $5.6 million).

  We paid the placement agent, Spartan Capital Securities, LLC, ("Spartan") a cash fee of 8.0% of the gross proceeds from the Registered Direct Offering, excluding proceeds received from our insiders, and reimbursed Spartan for legal fees of $60,000. The engagement agreement with Spartan required us to indemnify Spartan and certain of its affiliates against certain customary liabilities. On February 14, 2023, we amended the 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 warrants to purchase 158,007 shares of our common stock with an exercise price of $20.40. The warrants expire on April 17, 2026 and contain 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 300,000 shares of our common stock. At March 31, 2024, we have 35,508 shares available for future grants.

Stock Compensation Expense

We recorded stock-based compensation expense for the three month ended March 31, 2024 and 2023 as follows:

	2024	2023
Research and development	$ 31,121	$ 99,621
General and administrative	136,522	241,883
Total	$ 167,643	$ 341,504

Stock Options

No stock options to purchase shares of common stock were forfeited or expired during the three months ended March 31, 2024. At March 31, 2024, we had outstanding and exercisable options for the purchase of 6,992 shares with a weighted average exercise price of $364.72 and a weighted average remaining contractual life of 1.9 years. At March 31, 2024, we did not have any unrecognized stock-based compensation expense related to our granted stock options.

Restricted Stock Awards

During the three months ended March 31, 2024, we vested 1,250 Restricted Stock Awards ("RSAs") with a weighted average grant-date fair value of $9.26 per share. We had no RSAs outstanding at March 31, 2024.

Restricted Stock Units

Activity with respect to our Restricted Stock Units ("RSUs") during the three months ended March 31, 2024 was as follows:

	Number of shares	Weighted-average grant-date fair value per share
Outstanding at January 1, 2024	222,722	$ 45.82
Granted	-	-
Forfeited	(7,290)	63.91
Issued	(9,426)	102.68
Outstanding at March 31, 2024	206,006	42.58
Vested and unissued	124,529	59.75
Unvested at March 31, 2024	81,477	$ 16.33

On January 1, 2024, we granted RSUs for the future issuance of no more than 39,202 shares of our common stock, contingent upon receiving shareholder approval to increase the number of shares available under our 2019 Omnibus Incentive Plan ("Incentive Plan") at our annual shareholder meeting in June 2024. The number of shares to be issued under the RSUs will be based on the greater of: (i) $30.00 per share or (ii) the closing price per share on the day we receive shareholder approval to increase the number of shares available under the Incentive Plan.

At March 31, 2024, unrecognized stock-based compensation expense of $723,000 for RSUs (which excludes the above grant on January 1, 2024) is expected to be fully recognized over a weighted average period of 1.4 years. The unrecognized expense excludes $420,000 of expense related to certain grants of RSUs with performance milestones that are not probable of occurring at this time.

Holders of our vested RSUs will be issued 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, 2024, other than warrants to purchase 1,617,777 shares of common stock as part of our public offering (see Note 2), we did not grant any warrants to purchase shares of our common stock and warrants to purchase 5,000 shares of common stock expired. We also repurchased a warrant issued to a consultant in 2023 for the purchase of 15,000 shares of our common stock in exchange for a payment of $10,000.

At March 31, 2024, we had outstanding stock purchase warrants for the purchase of 1,778,284 shares with a weighted average exercise price of $6.17 and a weighted average remaining contractual life of 4.5 years. All the outstanding stock purchase warrants are exercisable at March 31, 2024. We did not have any unrecognized stock-based compensation expense related to our granted stock purchase warrants at March 31, 2024.

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, 2024 and 2023 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, 2024 and 2023 was as follows:

	Three months ended March 31,	
	2024	**2023**
Basic and diluted net loss per share:		
Net loss available to common stockholders	$ (2,726,381)	$ (4,022,073)
Weighted average number of common shares-basic and diluted	2,466,523	1,138,573
Basic and diluted net loss per share	$ (1.11)	$ (3.53)

	2024	**2023**
Weighted-average number of common shares outstanding – basic and diluted	2,331,867	1,010,410
Weighted-average number of vested RSUs– basic and diluted	134,657	128,164
Weighted-average number of common shares-basic and diluted	2,466,523	1,138,573

Our diluted net loss per share for the three months ended March 31, 2024 and 2023 excluded 1,866,753 and 236,496 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 – 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 a financing 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 for each of the three month periods ending March 31, 2024 and 2023. The weighted average remaining lease terms and discount rate for our operating leases were as follows at March 31, 2024:

Remaining lease term (years) for our facility lease	1.5
Remaining lease term (years) for our equipment lease	1.8
Weighted average discount rate for our facility and equipment leases	8.0%

Annual lease liabilities for the operating lease were as follows at March 31, 2024:

2024	$	68,247
2025		70,040
Total lease payments		138,287
Less: Interest		(8,816)
Present value of lease liabilities		129,471
Less: current maturities		(84,878)
Non-current lease liability	$	44,593

Annual lease liabilities for the financing lease were as follows at March 31, 2024:

2024	$	4,849
2025		6,820
2026		488
Total lease payments		12,157
Less: Interest		(1,248)
Present value of lease liabilities		10,909
Less: current maturities		(4,802)
Non-current lease liability	$	6,107

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 $23,000 and $30,000 of reimbursements during the three months ended March 31, 2024 and March 31, 2023, respectively. At March 31, 2024, $22,295 were due from CorLyst and no amounts were due at March 31, 2023. Our President, Research and Development is 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, 2024, we are contractually obligated to pay up to $984,000 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; 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, 2023, 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.

Our regulatory science approach 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 Guidances. Regulatory science is the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products. Over the last 30 years, two of our founders, Dr. David Young and Dr. Sian Bigora, have expanded the original regulatory science concept by including the pre-clinical and clinical studies to justify the benefit-risk assessment required for FDA approval when designing the development programs of new drug products.

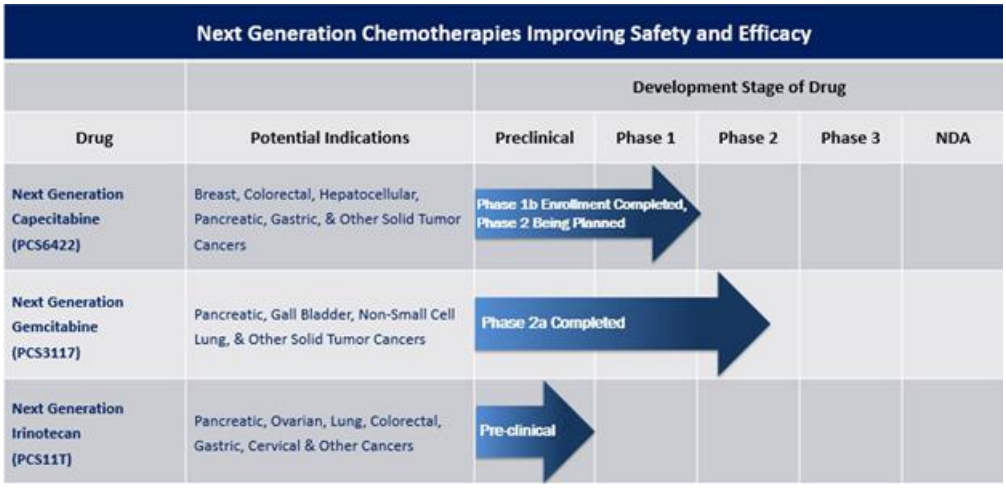
Our regulatory science approach defines the scientific information that the FDA requires to determine if the benefit outweighs the risk of a drug in a specific population of patients and at a specific dosage regimen for a specific drug product. The studies are designed to obtain the necessary scientific information to support the regulatory decision.

Recently, the FDA has taken steps to define some of the regulatory science required for the FDA approval of oncology products. Through the FDA's Project Optimus Oncology Initiative and the related Draft Guidance on determining the "optimal" dosage regimen for an oncology drug, the FDA has chosen to make the development of oncology drugs more science-based than in the past. Since the principles of the FDA's Project Optimus and the related Draft Guidance have been used by our regulatory science approach in a number of non-oncology drugs in the past, our 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
- greater ability to evaluate the benefit-risk of a drug compared to existing therapy, which allows prescribers to provide better treatment options for each patient.

Our strategic prioritization is to advance our pipeline of NGC proprietary small molecule oncology drugs. The NGC products are new chemical entities, but they work by changing 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.

Our Drug Pipeline



Our pipeline currently consists of NGC-Cap, NGC-Gem and NGC-Iri (also identified as PCS6422, PCS3117 and PCS11T, respectively) and two non-oncology drugs (PCS12852 and PCS499). The non-oncology drugs are not included in the pipeline chart above, as we are exploring our options for those drugs, which may include out-licensing or partnership opportunities. A summary of each drug is provided below.

Next Generation Chemotherapy Pipeline

- Next Generation Capecitabine (NGC-Cap) is a combination of PCS6422 and a lower dose of 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.

  Capecitabine, as presently prescribed and FDA-approved, forms the cancer drug 5-FU which is then further metabolized to anabolites (which kill both cancer cells and normal duplicating cells) and catabolites (which cause side effects and have no cancer killing properties). When capecitabine is given in combination with PCS6422 in NGC-Cap, PCS6422 significantly changes the metabolism of 5-FU, which results in a change in the distribution of 5-FU within the body. Due to this change in metabolism and the overall metabolite profile of anabolites and catabolites, the side effect and efficacy profile of NGC-Cap has been found to be different from capecitabine given without PCS6422. Since the potency of NGC-Cap is also greater 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-Cap 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. 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-Cap significantly (up to 50 times) more potent than capecitabine alone and potentially leading to higher levels of anabolites which can kill replicating cancer and normal cells. By administering NGC-Cap 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-Cap different than that of FDA-approved capecitabine and requiring further evaluation of the PCS6422 and capecitabine regimens to determine the optimal NGC-Cap regimens for patients.

  In order for NGC-Cap 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 dose-limiting toxicities ("DLTs"). One of the early regimens in the Phase 1B trial did cause DLTs in two patients, one of whom died. No other DLTs were noted in the study. The Phase 1B trial has completed enrollment, the recommended Phase 2 dosage regimens have been determined and the Phase 2 study is being initiated. The Phase 2 trial will determine which regimens may 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 March 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 and safety. The specific dosage regimens for the trial have been defined from our ongoing Phase 1B trial. Cohort 3 in the Phase 1B trial, which dosed patients with PCS6422 in combination with capecitabine at 150 mg BID (twice a day), completed with no dose-limiting toxicities. Enrollment in Cohort 4 was expanded to include three additional patients to further evaluate the safety at this dose. No DLTs were observed in this cohort, but the safety evaluation suggested that doing at the higher Cohort 5 (300 mg BID) would result in increased safety concerns and the Cohort 4 dose would be the maximum dose evaluated. The study is ongoing for patients who continue to receive clinical benefit from NGC-Cap.

  Following the FDA meeting on December 11, 2023, we have decided the next NGC-Cap trial would be a Phase 2 trial in breast cancer. This decision was supported through discussions with the FDA where we agreed with the FDA that the development of NGC-Cap in breast cancer would be a more efficient development program than metastatic colorectal cancer and improve the likelihood of FDA approval. The FDA has agreed that the data generated from past and existing studies could be used to directly support the Phase 2 trial in breast cancer. Capecitabine is already approved as both monotherapy and combination therapy in breast cancer, which contributes to the logic and efficiency of our current direction. In addition, the FDA's agreement that our present data would support a Phase 2 trial in breast cancer makes the expansion seamless. The objective for the Phase 2 trial will be to provide safety-efficacy data to preliminarily demonstrate the benefit of NGC-Cap over capecitabine. Based on this expansion to breast cancer, we expanded our Oncology Advisory Board to include key breast cancer oncologists. We have already determined the Phase 2 study design and plan to use the funding from our January 2024 public offering to begin enrolling patients in the third quarter of 2024.

  Our license agreement with Elion for NGC-Cap requires us to use commercially reasonable efforts, at our sole cost and expense, to research, develop and commercialize products in one or more countries, including meeting specific diligence milestones that include dosing a first patient with a product in a Phase 2 or 3 clinical trial on or before October 2, 2024. We are currently conducting pre-trial activities and planning to dose the first patient in our Phase 2 trial before the conclusion of the third quarter of 2024 and ahead of the required diligence milestone.

- NGC-Gem 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. In addition, we believe those patients inherently resistant or who acquire resistance to gemcitabine are likely not to be resistant to NGC-Gem. The difference in response occurs because NGC-Gem is metabolized to its active metabolite through a different enzyme system than gemcitabine. We continue to evaluate the potential use of NGC-Gem in patients with pancreatic and other potential cancers and to evaluate ways to identify patients who are more likely to respond to NGC-Gem than gemcitabine. We plan to meet with the FDA in 2024 to discuss potential trial designs including implementation of the Project Optimus initiative as part of the design. Similar to NGC-Cap, we will need to obtain additional funding before we can begin the Phase 2 trial for NGC-Gem.

  Our license agreement with Ocuphire Pharma, Inc. ("Ocuphire") for NGC-Gem requires us to use commercially reasonable efforts, at our sole cost and expense to oversee such commercialization efforts, to research, develop and commercialize products in one or more countries, including meeting specific diligence milestones that consist of: (i) dosing a patient in a clinical trial prior to June 16, 2024; and (ii) dosing a patient in a pivotal clinical trial or in a clinical trial for a second indication of the drug prior to June 16, 2026. We are currently in discussions with Ocuphire to extend these deadlines.

- NGC-Iri 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 2024, subject to available funding.

We are 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 approach is to take three current FDA-approved cancer drugs, e.g. capecitabine, gemcitabine and irinotecan, and modify and improve how the human body metabolizes and/or distributes these NGC treatments compared to their presently approved counterpart chemotherapy drugs while maintaining the cancer-killing mechanism of action; thus, our reason for calling our drugs Next Generation Chemotherapy (or NGC) treatments. Part of the development includes determining the optimal dosage regimen based on the dose-response relationship as described in the FDA's Project Optimus Initiative and Draft Optimal Dosage Regimen Oncology Guidance. To date, we have data that we believe 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.

Other Drugs in Our Pipeline

In 2023, we completed our Phase 2A trial for PCS12852 in gastroparesis patients with positive results. Additionally, in February 2023, due primarily to the inability to identify and enroll patients in our rare disease Phase 2 trial for PCS499 in ulcerative Necrobiosis Lipoidica (uNL), we decided to cease further enrollment in the PCS499 trial and terminated the trial. We did not experience any safety concerns during the conduct of either the PCS12852 or PCS499 trial. We continue to evaluate options to monetize these non-core drug assets, which may include out-licensing or partnering these assets with one or more third parties.

Recent Developments

Reverse Stock Split

On January 22, 2024, we effected a 1-for-20 reverse stock split, reducing the number of our common shares issued on that date from 24,706,474 shares to 1,291,000 shares. There is no corresponding reduction in the number of authorized shares of common stock and no change in the par value per share. All share and per share amounts and conversion and exercise prices presented herein have been adjusted retroactively to reflect this change.

Public Offering

On January 30, 2024, we raised gross proceeds of $7.0 million (net proceeds of $6.3 million) from the sale of 476,000 shares of our common stock, pre-funded warrants to purchase up to 1,079,555 shares of our common stock and warrants to purchase 1,555,555 shares of our common stock in a public offering, as described in Note 2. Simultaneously with the closing of the sale, the pre-funded warrants were exercised in exchange for 1,079,555 shares of our common stock. We plan to use the net proceeds from this financing for continued research and development for NCG-Cap, and working capital and general corporate purposes.

Results of Operations

Comparison of the three months ended March 31, 2024 and 2023

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

	Three months ended March 31,		
	2024	2023	Change
Operating Expenses			
Research and development expenses	$ 1,539,070	$ 1,627,480	$ (88,410)
General and administrative expenses	1,270,528	2,478,055	(1,207,527)
Operating Loss	(2,809,598)	(4,105,535)	
Other Income (Expense), net	83,217	83,462	(245)
Net Loss	$ (2,726,381)	$ (4,022,073)	

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, 2024, our research and development expenses decreased by $88,410 to $1,539,070 from $1,627,480 for the three months ended March 31, 2023. Costs for the three months ended March 31, 2024 and 2023 were as follows:

	Three months ended March 31,	
	2024	2023
Research and development salaries and benefits	$ 507,790	$ 518,803
Preclinical, clinical trial and other costs	1,031,280	1,108,677
Total	$ 1,539,070	$ 1,627,480

The decrease in research and development expenses was primarily due to a decrease in preclinical, clinical trial and other costs during the three months ended March 31, 2024 when compared to the same period in 2023. This decrease was attributable to having only one open clinical trial for NGC-Cap in 2024. During the same period in 2023, in addition to clinical trial costs for NGC-Cap, we also were incurring closing costs in our clinical trial for PCS12852 and PCS499.

As we continue our Phase 1B clinical trial for NGC-Cap and begin our Phase 2 trial for NGC-Cap, we anticipate our research and development costs will increase. We will also continue incurring nominal costs for NGC-Gem as we prepare to meet with the FDA to discuss potential study designs and for NGC-Iri should we decide to conduct IND-enabling and toxicology studies.

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, 2024 decreased by $1,207,527 to $1,270,528 from $2,478,055 for the three months ended March 31, 2023. This decrease was due primarily as a result of a non-recurring expense that was incurred during 2023 in connection with the stock purchase warrant granted to Spartan, which had a fair value of $1,310,875, under the amended consulting agreement (see Note 2 to the condensed consolidated financial statements); and a decrease in employee stock-based compensation of $132,000 since our 2024 stock grant is contingent on receiving shareholder approval to increase the number of shares available for issuance under our Incentive Plan. The decreases were offset by an increase in professional fees by $48,000; a net $19,000 increase in various office expenses; and $162,000 increase in salaries and other payroll-related costs from increased salary rates, primarily paid to our executive officers. We also received $7,000 less in reimbursements from CorLyst during the three months ended March 31, 2024 when compared to the same period in 2023.

Other Income

Other income represents interest income of $83,217 and $83,462 for the three months ended March 31, 2024 and 2023, respectively.

Income Tax Benefit

We did not recognize any income tax benefit for the three months ended March 31, 2024 or 2023.

Cash Flows

The following table sets forth our sources and uses of cash and cash equivalents for the three months ended March 31, 2024 and 2023:

	Three months ended March 31,	
	2024	2023
Net cash (used in) provided by:		
Operating activities	$ (2,048,884)	$ (2,114,070)
Financing activities	6,263,050	6,352,077
Net increase in cash	$ 4,214,166	$ 4,238,077

Net cash used in operating activities

We used net cash in our operating activities of $2,048,884 and $2,144,070 during the three months ended March 31, 2024 and 2023, respectively. The decrease in cash used in operating activities during the first quarter of 2024 compared to the same period in 2023 of $65,184 was primarily related to decreased operating costs in the first quarter of 2024.

As we continue our development of NGC-Cap 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. As we begin our Phase 2 clinical trial for NGC-Cap in 2024, we anticipate our clinical trial costs will increase when compared to prior periods since our current activities are related primarily to the completion of our Phase 1b trial for NGC-Cap.

Net cash provided by financing activities

During the three months ended March 31, 2024, we sold 476,000 shares of common stock, pre-funded warrants to purchase up to 1,079,555 shares of common stock in lieu of shares of common stock, all of which were exercised into shares of our common stock, and warrants to purchase up to 1,555,555 shares of our common stock pursuant to a public offering for net proceeds of $6.3 million. We also used cash classified as financing activities of $9,924 to pay income taxes owed on stock-based compensation, $8,561 for the settlement of a stock award and $895 for payments owed under a financing lease obligation.

During the three months ended March 31, 2023, we raised net proceeds of $6.4 million from the sale of 421,611 shares of our common stock.

Liquidity

At March 31, 2024 we had cash and cash equivalents totaling $8.9 million which, based on our current business plans, we believe will satisfy our capital needs into early 2025. However, absent additional funding, our current cash and cash equivalents will not be sufficient to fund our planned operations for a period of one year or more after the date that these condensed consolidated financial statements were available to be issued based on the timing and amount of our projected net loss from continuing operations and the related amount of cash to be used in operating activities during that period of time. Our ability to execute our longer-term operating plans, including future preclinical studies and 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 have incurred losses since inception, currently devoting substantially all of our efforts toward research and development of our next generation chemotherapy drug product candidates, including conducting clinical trials and providing general and administrative support for these operations, and have an accumulated deficit of $78.1 million at March 31, 2024. During the three months ended March 31, 2024, we generated a net loss of $2.7 million and used $2.0 million in net cash for operating activities from continuing operations. To date, none of our drug candidates have been approved for sale, and therefore we have not generated any product revenue and do not expect positive cash flow from operations in the foreseeable future.

We have financed our operations primarily through public equity issuances, including an offering we closed on January 30, 2024 in which we sold 476,000 shares of our common stock, pre-funded warrants to purchase up to 1,079,555 shares of our common stock, and warrants for the purchase of up to 1,555,555 shares of our common stock for net proceeds of $6.3 million, after deducting placement agent fees and offering-related expenses. Following closing of the sale, the pre-funded warrants were exercised in exchange for 1,079,555 shares of our common stock. We will continue to be dependent upon equity and/or debt financing until we are able to generate positive cash flows from its operations.

We plan to raise additional funds in the future through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements, but will only do so if the terms are acceptable to us. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of, or suspend our current or planned future clinical trial plans, or research and development programs. This may also cause us to not meet obligations contained in certain of our license agreements and put these assets at risk. To the extent that we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. There can be no assurance that future funding will be available when needed.

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, 2023.

Off Balance Sheet Arrangements

At March 31, 2024, 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 those included in 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, 2024, 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, 2024 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, 2024 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

As of the date of this report, to our knowledge, there are no legal proceedings or regulatory actions material to us to which we are a party, or have been a party to, or of which any of our property is or was the subject matter of, and no such proceedings or actions are known by us to be contemplated, except as provided below:

On May 7, 2024, the Company received notification from Elion purporting to terminate the license agreement by and between the Company and Elion as a result of the Company's alleged breach thereof. The Company believes that Elion's claims are without merit and disputes that the license agreement has been validly terminated.

On May 10, 2024, the Company filed a complaint for declaratory judgment and other claims against Elion in New York State Court. The Company intends to enforce its rights under the license agreement and will pursue such other remedies as it determines are appropriate.

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, 2023, other than the addition of the following risk factor:

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

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

On May 7, 2024, the Company received notification from Elion purporting to terminate the license agreement by and between us and Elion as a result of the Company's alleged breach thereof. The Company believes that Elion's claims are without merit and disputes that the license agreement has been validly terminated.

On May 10, 2024, the Company filed a complaint for declaratory judgment and other claims against Elion in New York State Court. The Company intends to enforce its rights under the license agreement and will pursue such other remedies as it determines are appropriate.

If we are unsuccessful or are unable to enforce our rights under the license agreement, our business and results of operations may be adversely affected.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

a) As previously reported, on August 23, 2020, we entered into a condition precedent License Agreement with Elion (and as subsequently amended, the "Elion License Agreement"), pursuant to which we acquired an exclusive license to develop, manufacture and commercialize PCS6422 globally. The terms of the Elion License Agreement require us to use commercially reasonable efforts, at our sole cost and expense, to research, develop and commercialize products in one or more countries, including meeting specific diligence milestones that include dosing a first patient with a product in a Phase 2 or 3 clinical trial on or before October 2, 2024. We are currently conducting pre-trial activities and planning to dose the first patient in our Phase 2 trial before the conclusion of the third quarter of 2024 and ahead of the required diligence milestone.

The foregoing summary of the Elion License Agreement is qualified in its entirety by reference to the full text of the Elion License Agreement, which was filed as Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on August 27, 2020, and is incorporated by reference herein.

On May 7, 2024, the Company received notification from Elion purporting to terminate the Elion License Agreement as a result of the Company's alleged breach of the Elion License Agreement. The Company believes that Elion's claims are without merit and disputes that the Elion License Agreement has been validly terminated.

On May 10, 2024, the Company filed a complaint for declaratory judgment and other claims against Elion in New York State Court. The Company intends to enforce its rights under the license agreement and will pursue such other remedies as it determines are appropriate.

b) None.

c) During the three months ended March 31, 2024, none of our directors or officers adopted or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

SEC Ref. No.	Title of Document
4.1	Form of Common Warrant (incorporated by reference to Exhibit 4.1 to Exhibit 8-K Filed on January 30, 2024)
4.2	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.3 to Form 8-K filed on January 30, 2024)
10.1	Form of Securities Purchase Agreement, dated January 26, 2024, by and between Processa Pharmaceuticals, Inc. and each of the Purchasers (as defined therein) (incorporated by reference to Exhibit 10.1 to Form 8-K filed January 30, 2024)
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/ George Ng*

George Ng
Chief Executive Officer
(Principal Executive Officer)
Dated: May 10, 2024

By: */s/ James Stanker*

James Stanker
Chief Financial Officer
(Principal Financial and Accounting Officer)
Dated: May 10, 2024

Exhibit 31.1

CERTIFICATION

I, George Ng, 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, 2024;

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/ George Ng*
George Ng
Chief Executive Officer
(Principal Executive Officer)
Date: May 10, 2024

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, 2024;

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 10, 2024

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, 2024 (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/ George Ng*
George Ng
Chief Executive Officer
(Principal Executive Officer)
Date: May 10, 2024

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, 2024 (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 10, 2024