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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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 (State or other jurisdiction of incorporation or organization)	**45-1539785** (IRS Employer Identification No.)

7380 Coca Cola Drive, Suite 106,
Hanover, Maryland 21076
(443) 776-3133

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See definition of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☐

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

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

The number of outstanding shares of the registrant's common stock as of November 1, 2023 was 24,631,474.

PROCESSA PHARMACEUTICALS, INC.
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ITEM 1: FINANCIAL STATEMENTS

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

	September 30, 2023	December 31, 2022
ASSETS		
Current Assets		
Cash and cash equivalents	$ 6,860,672	$ 6,503,595
Prepaid expenses and other	1,046,790	1,883,134
Total Current Assets	7,907,462	8,386,729
Property and Equipment, net	2,694	-
Other Assets		
Operating lease right-of-use assets, net	167,035	227,587
Security deposit	5,535	5,535
Total Other Assets	172,570	233,122
Total Assets	$ 8,082,726	$ 8,619,851
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Current maturities of operating lease liability	$ 82,744	$ 78,896
Accounts payable	346,299	327,548
Due to licensor	189,000	189,000
Due to related parties	5,791	51
Accrued expenses	202,236	403,061
Total Current Liabilities	826,070	998,556
Non-current Liabilities		
Non-current operating lease liability	88,777	150,554
Total Liabilities	914,847	1,149,110
Commitments and Contingencies	-	-
Stockholders' Equity		
Common stock, par value $0.0001, 100,000,000 shares authorized: 24,731,474 issued and 24,631,474 outstanding at September 30, 2023, and 16,135,400 issued and 16,035,400 outstanding at December 31, 2022	2,473	1,614
Additional paid-in capital	80,429,556	72,016,688
Treasury stock at cost — 100,000 shares at September 30, 2023 and December 31, 2022	(300,000)	(300,000)
Accumulated deficit	(72,964,150)	(64,247,561)
Total Stockholders' Equity	7,167,879	7,470,741
Total Liabilities and Stockholders' Equity	$ 8,082,726	$ 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating Expenses				
Research and development	$ 1,151,740	$ 3,136,838	$ 4,478,793	$ 8,319,907
General and administrative	1,015,872	2,920,280	4,508,818	6,137,674
Operating Loss	(2,167,612)	(6,057,118)	(8,987,611)	(14,457,581)
Other Income (Expense)				
Interest income, net	85,661	36,708	271,022	45,672
Net Loss	$ (2,081,951)	$ (6,020,410)	$ (8,716,589)	$ (14,411,909)
Net Loss per Common Share - Basic and Diluted	$ (0.08)	$ (0.37)	$ (0.34)	$ (0.90)
Weighted Average Common Shares Used to Compute Net Loss Applicable to Common Shares - Basic and Diluted	27,002,908	16,200,222	25,585,222	15,991,653

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

Processa Pharmaceuticals, Inc.
Condensed Consolidated Statements of Changes in Stockholders' Equity
Three and Nine Months Ended September 30, 2022 and 2023
(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
Stock-based compensation	(18,208)	(1)	2,009,370	-	-	-	2,009,369
Net loss	-	-	-	-	-	(5,164,368)	(5,164,368)
Balance, June 30, 2022	15,919,317	1,592	65,595,106	(100,000)	(300,000)	(45,214,831)	20,081,867
Stock-based compensation	86,888	9	3,213,806	-	-	-	3,213,815
Shares withheld to pay income taxes on stock-based compensation	(11,118)	(1)	(35,246)	-	-	-	(35,247)
Net loss	-	-	-	-	-	(6,020,410)	(6,020,410)
Balance, September 30, 2022	15,995,087	$ 1,600	$ 68,773,666	(100,000)	$ (300,000)	$ (51,235,241)	$ 17,240,025

	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
Stock-based compensation	-	-	319,123	-	-	-	319,123
Warrant granted in connection with a consulting agreement	-	-	1,310,875			-	1,310,875
Net loss	-	-	-	-	-	(2,612,565)	(2,612,565)
Balance, June 30, 2023	24,631,474	2,463	80,339,418	(100,000)	(300,000)	(70,882,199)	9,159,682
Stock-based compensation, net of forfeitures	100,000	10	142,884	-	-	-	142,894
Settlement of stock award	-	-	(52,746)	-	-	-	(52,746)
Net loss	-	-	-	-	-	(2,081,951)	(2,081,951)
Balance, September 30, 2023	24,731,474	$ 2,473	$ 80,429,556	(100,000)	$ (300,000)	$ (72,964,150)	$ 7,167,879

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

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

	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Cash Flows From Operating Activities		
Net loss	$ (8,716,589)	$ (14,411,909)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	82	-
Lease expense for right-of-use assets	60,552	66,126
Milestone expense in connection with license agreement	-	189,000
Amortization of issuance costs	-	78,113
Amortization of intangible asset	-	591,372
Stock-based compensation	803,521	6,052,081
Warrants 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	836,344	299,074
Operating lease liability	(57,929)	(69,420)
Accounts payable	18,751	92,161
Due (from) to related parties	5,740	(1,772)
Other receivables	-	70,274
Accrued expenses	(200,825)	(62,858)
Net cash used in operating activities	(5,939,478)	(7,107,758)
Cash Flows From Investing Activities		
Purchase of property and equipment	(2,776)	-
Net cash used in investing activities	(2,776)	-
Cash Flows From Financing Activities		
Net proceeds from common stock issued	6,352,077	(35,247)
Settlement of stock award	(52,746)	-
Acquisition of treasury stock	-	(300,000)
Net cash provided by (used in) financing activities	6,299,331	(335,247)
Net Increase (Decrease) in Cash	357,077	(7,443,005)
Cash and Cash Equivalents – Beginning of Period	6,503,595	16,497,581
Cash and Cash Equivalents – End of Period	$ 6,860,672	$ 9,054,574
Non-Cash Financing Activities		
Issuance of 123,609 shares of common stock in connection with the Purchase Agreement with Lincoln Park	$ -	$ 450,000
Right-of-use asset obtained in exchange for operating lease liability	$ -	$ (238,924)
Operating lease liability	-	238,924
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.

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.

Going Concern and Management's Plans

We have incurred losses since inception, devoting substantially all of our efforts toward research and development, and have an accumulated deficit of $73.0 million at September 30, 2023. During the nine months ended September 30, 2023, we generated a net loss of $8.7 million and used $5.9 million in net cash for operating activities from continuing operations. We expect continued operating losses and negative cash flow from operations for the foreseeable future.

During the nine months ended September 30, 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 are using 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.

Our condensed consolidated financial statements have been prepared using U.S. GAAP and are based on the assumption that we will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. We face certain risks and uncertainties that are present in many emerging pharmaceutical companies regarding product development, limited working capital, recurring losses and negative cash flow from operations, future profitability, ability to obtain future capital, protection of patents, technologies and property rights, competition, rapid technological change, navigating the domestic and major foreign markets' regulatory and clinical environment, recruiting and retaining key personnel, dependence on third party manufacturing organizations, third party collaboration and licensing agreements, lack of sales and marketing activities. We currently have no customers or pharmaceutical products to sell or distribute. These risks and other factors raise substantial doubt about our ability to continue as a going concern.

At September 30, 2023, we had cash and cash equivalents totaling $6.9 million. Based on our current plans, we believe our current cash balances will enable us to complete our current clinical trial in NGC-Capecitabine (NGC-Cap, also known as PCS6422), prepare for a Phase 2 trial for NGC-Cap, and fund our administrative costs through the second quarter of 2024. Our ability to execute our longer-term operating plans, including future clinical trials for our NGC drugs, will 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, including out-licensing and/or entering into partnerships on any of our non-core assets, but there can be no assurance that we will obtain the necessary funding in the future when necessary.

We had no revenue during the nine months ended September 30, 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 for operating expenses. Cash used to fund operating expenses is impacted by the timing of when we incur and pay these expenses.

We are hoping to raise additional funds in late 2023 or early 2024, but will only do so if the terms are acceptable to us. Additional funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of, or suspend our current or planned future clinical trial plans, or research and development programs. This may also cause us to not meet diligence obligations contained in certain of our license agreements and put these assets at risk. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. To the extent that we raise additional capital through 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, making capital expenditures or declaring dividends.

Uncertainty concerning our ability to continue as a going concern may hinder our ability to obtain future financing. Continued operations and our ability to continue as a going concern are dependent on our ability to obtain additional funding in the future and thereafter, and no assurances can be given that such funding will be available at all, in a sufficient amount, or on reasonable terms. Without additional funds from debt or equity financing, sales of assets, sales or out-licenses of intellectual property or technologies, or other transactions providing funds, we will rapidly exhaust our resources, be unable to meet diligence obligations in license agreements, and be unable to continue operations. 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 September 30, 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, or for 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 September 30, 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 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 September 30, 2023 or December 31, 2022.

Common Stock

Increase in Our Authorized Number of Shares

Subsequent to receiving shareholder approval on June 27, 2023, we amended our Certificate of Incorporation to increase the number of authorized shares of our common stock from 50,000,000 to 100,000,000. We believe 100,000,000 authorized shares of common stock better aligns our capital structure with our future needs and have shown this retroactively in the condensed consolidated financial statements.

During the nine months ended September 30, 2023, we issued 8,432,192 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 expect to reinstate it in the future. During the nine months ended September 30, 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.

Lincoln Park Capital Fund, LLC Purchase Agreement

On March 23, 2022, we entered into a 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 nine months ended September 30, 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).

We paid the Placement Agent ("Spartan Capital" or "Spartan") 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 warrants to purchase 3,160,130 shares of our common stock with an exercise price of $1.02. The warrants 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 September 30, 2023, we had 467,735 shares available for future grants under the 2019 Plan.

Stock Compensation Expense

We recorded stock-based compensation expense for the three and nine months ended September 30, 2023 and 2022 as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	$ 76,626	$ 1,067,613	$ 286,152	$ 1,945,113
General and administrative	66,268	2,146,202	517,369	4,106,968
Total	$ 142,894	$ 3,213,815	$ 803,521	$ 6,052,081

During the nine months ended September 30, 2023, we also recorded an expense of $1.3 million related to the warrants we issued to Spartan (see Note 2), 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 nine months ended September 30, 2023, stock options to purchase 36,885 shares of common stock expired and there were no exercises or grants of stock options. At September 30, 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 2.4 years. At September 30, 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 nine months ended September 30, 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	215,000	0.73
Forfeited	(25,000)	6.65
Cancelled	(26,118)	1.72
Issued	(150,770)	1.35
Outstanding and unvested at September 30, 2023	75,000	$ 0.46

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 to align their compensation plan with their service period and changed 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 previously issued, but unvested common stock.

On July 14, 2023, we granted RSAs totaling 125,000 shares of common stock to a consultant (of which 50,000 have been issued as of September 30, 2023) for services to be provided through March 18, 2024. The remaining RSAs are subject to vesting restrictions. On August 31, 2023, in connection with the resignation of our Chief Operating Officer (COO), unvested RSAs representing 25,000 shares of common stock were forfeited and we reversed previously recognized expense of $73,000.

At September 30, 2023, unrecognized stock-based compensation expense of $30,000 for RSAs representing 75,000 shares of common stock is expected to be recognized over a weighted average period of 0.41 years. The weighted-average grant-date fair value of RSAs granted during the nine months ended September 30, 2022 was $7.74.

Restricted Stock Units

Activity with respect to our Restricted Stock Units ("RSUs") during the nine months ended September 30, 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	2,273,328	0.72
Forfeited	(144,478)	1.48
Cancelled	(335,960)	3.57
Outstanding at September 30, 2023	4,506,867	2.30
Vested and unissued	2,291,923	3.58
Unvested at September 30, 2023	2,214,944	$ 0.97

On August 8, 2023, Mr. George Ng was appointed as our Chief Executive Officer and as a Board Director. In addition to cash compensation, the Compensation Committee awarded 800,000 restricted stock units ("RSUs") to Mr. Ng. Vesting for 400,000 RSUs occurs ratably over a three-year period. The remaining 400,000 RSUs will vest on the achievement of certain performance metrics, with the first 200,000 performance-based RSUs vesting when gross proceeds of $10,000,000 is raised, and the second 200,000 performance-based RSUs vesting when additional gross proceeds of $10,000,000 is raised. On August 31, 2023, in connection with the termination of our COO, vested and unvested RSUs representing 436,043 shares of common stock were forfeited and/or cancelled and we reversed previously recognized expense of $38,000.

At September 30, 2023, unrecognized stock-based compensation expense of $1.1 million for RSUs is expected to be fully recognized over a weighted average period of 1.4 years. The unrecognized expense excludes $441,000 of expense related to certain RSUs with a performance milestone that is not probable of occurring at this time. The weighted-average grant-date fair value of RSUs granted during the nine months ended September 30, 2022 was $3.11.

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 nine months ended September 30, 2023, we granted warrants 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 described in Note 2. The warrants were issued and exercisable on April 17, 2023 with an exercise price of $1.02 and expiration date of April 17, 2026. The warrants contain both call and cashless exercise provisions. We recorded $1,310,875 as a general and administrative expense representing the fair value of these warrants on February 14, 2023, the date we amended the consulting agreement since there were no contingent conditions on that date through April 17, 2023, the date of issuance. At September 30, 2023, we had outstanding and exercisable stock purchase warrants 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 2.3 years.

At September 30, 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 all periods presented, basic and diluted net loss per share are the same. As such, diluted loss per share for the three- and nine-month periods ended September 30, 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- and nine-month periods ended September 30, 2023 and 2022 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Basic and diluted net loss per share:				
Net loss available to common stockholders	$ (2,081,951)	$ (6,020,410)	$ (8,716,589)	$ (14,411,909)
Weighted average number of common shares-basic and diluted	27,002,908	16,200,222	25,585,222	15,991,653
Basic and diluted net loss per share	$ (0.08)	$ (0.37)	$ (0.34)	$ (0.90)

Our diluted net loss per share for the three- and nine-month periods ended September 30, 2023 and 2022 excluded 5,798,035 and 2,760,527 of potentially dilutive common shares, respectively, related to outstanding stock options, stock purchase warrants and unvested restricted stock since those shares would have had an anti-dilutive effect on net loss per share during the periods then ended.

Note 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% to determine the present value of the lease payments based on the information available at the lease commencement date.

Lease costs included in our condensed consolidated statements of operations totaled $24,000 for both three-month periods ended September 30, 2023 and 2022 and approximately $73,000 for both nine-month periods ended September 30, 2023 and 2022. The weighted average remaining lease terms and discount rate for our operating leases were as follows at September 30, 2023:

Remaining lease term (years) for our facility lease	2.0
Remaining lease term (years) for our equipment lease	0.5
Weighted average remaining lease term (years) for our facility and equipment leases	2.0
Weighted average discount rate for our facility and equipment leases	8.0%

Annual lease liabilities for all operating leases were as follows at September 30, 2023:

2023	$ 24,109
2024	92,356
2025	70,040
Total lease payments	186,505
Less: Interest	(14,984)
Present value of lease liabilities	171,521
Less: current maturities	(82,744)
Non-current lease liability	$ 88,777

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 in our condensed consolidated statements of operations. We recorded $89,980 and $94,642 in reimbursements during the nine months ended September 30, 2023 and 2022, respectively. No amounts were due from CorLyst at September 30, 2023 or 2022. 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 and subcontractors to further develop our products. The contracts are cancellable, with varying provisions regarding termination. If we terminated a cancellable contract with a specific vendor, we would only be obligated for products or services that we received as of the effective date of the termination and any applicable cancellation fees. As of September 30, 2023, we are contractually obligated to pay up to approximately $1.8 million of future services under the agreements with the CROs, but our actual contractual obligations will vary depending on the progress and results of the clinical trials.

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

Forward Looking Statements

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

The Processa 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.

The FDA has more recently 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, 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.

In January 2023, we announced our strategic prioritization 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.

The three NGC treatments in our pipeline are as follows:

- NGC-Capecitabine (NGC-Cap) is a combination of PCS6422 and capecitabine, capecitabine being the oral prodrug of the cancer drug 5-fluorouracil (5-FU). PCS6422, without having any clinically meaningful biological effect itself, alters the metabolism of 5-FU, resulting in more 5-FU distribution to the cancer cells. In clinical trials, NGC-Cap has shown a safety profile different than capecitabine when administered alone. Side effects such as Hand-Foot Syndrome (HFS) and cardiotoxicity typically occur in up to 50-70% of patients treated with capecitabine and are caused by specific capecitabine metabolites. These types of toxicities frequently result in decreased doses, interrupted doses, or discontinuation of treatment with capecitabine. Since a much smaller amount of these metabolites are formed with NGC-Cap, these side effects appear in less patients and are less severe when they do occur. In addition, NGC-Cap has been found to be up to 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-Cap could be used to treat patients with various cancers, such as metastatic colorectal, gastrointestinal, breast, and pancreatic. We plan on meeting with the FDA to further discuss the Phase 2 study, which we plan to initiate in 2024. We estimate at least 200,000 patients in the United States were newly diagnosed in 2022 with metastatic colorectal, gastrointestinal, breast, and pancreatic cancers.

- PCS3117, also referred to as NGC-Gemcitabine (NGC-Gem), 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-Gem could be used to treat patients with various cancers such as pancreatic, biliary tract, lung, ovarian, and breast. We estimate more than 275,000 patients in the United States were newly diagnosed in 2022 with pancreatic, biliary tract, lung, ovarian, and breast cancer. We plan to meet with the FDA to discuss potential study designs including implementation of the Project Optimus initiative as part of the design, and then submit a Phase 2 study protocol to our existing Investigational New Drug (IND) in 2024.

- PCS11T, also referred to as NGC-Irinotecan (NGC-Iri), is a prodrug of the active metabolite of irinotecan (SN-38). The chemical structure of NGC-Iri influences the uptake of the drug into cancer cells, resulting in more NGC-Iri entering cancer cells than normal cells in mice. These levels were significantly greater than those seen with irinotecan, resulting in lower doses of NGC-Iri having greater efficacy than irinotecan and improved safety in animal models. Like irinotecan, NGC-Iri 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 newly diagnosed in 2022 with lung, colorectal, gastrointestinal, and pancreatic cancer. We plan to conduct IND-enabling and toxicology studies in 2024.

We have completed our Phase 2A trial for PCS12852 in gastroparesis patients with positive results. Additionally, 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 in February 2023 and terminated the trial. We did not experience any safety concerns during the conduct of either the PCS12852 or PCS499 trial. We are currently evaluating options to monetize these non-core drug assets, which may include out-licensing or partnering these assets with one or more third parties.

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 approach is to take three current FDA-approved cancer drugs and modify and improve how the human body metabolizes and/or distributes these NGC treatments compared to their presently approved counterpart 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 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

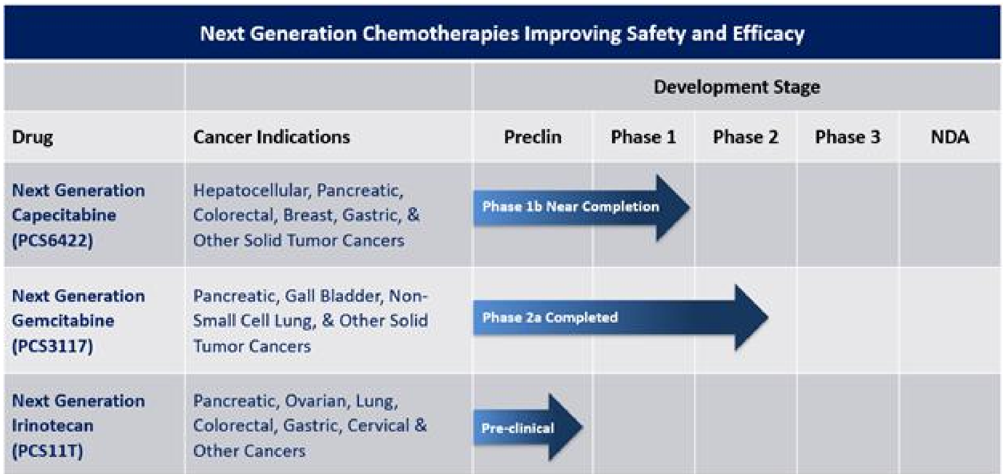
Our strategy is to develop our pipeline of Next Generation Chemotherapy (NGC) proprietary small molecule oncology drugs using our Regulatory Science Approach to determine the optimal dosage regimen of our oncology drugs.

By changing either the metabolism, distribution, and/or elimination of already FDA-approved cancer drugs (e.g., capecitabine, gemcitabine, and irinotecan) or their active metabolites, we believe that our three new oncology drugs represent the next generation of chemotherapy with an improved safety profile, improved efficacy profile and/or potentially benefiting more patients while maintaining the mechanism of how the drug kills cancer cells. 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 anticipate that we will be able to increase the probability of FDA approval, improve the safety-efficacy profile over the existing counterparts of our NGC drugs, which is important to patients and prescribers, and to 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-Cap, NGC-Gem and NGC-Iri (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 Pipeline

- Next Generation Capecitabine (NGC-Cap), also identified as PCS6422, 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. 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-Cap significantly more potent than capecitabine alone (up to 50 times more potent) 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 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 by the end of 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 and safety. The specific dosage regimens for the trial will be defined following the determination of the MTD from our ongoing Phase 1B trial. We recently completed Cohort 3 in the Phase 1B trial, which dosed patients with PCS6422 in combination with capecitabine at 150 mg BID (twice a day), with no dose-limiting toxicities. Enrollment in Cohort 4 is currently ongoing, as it has been expanded to include six patients to further evaluate the safety at this dose. To date, no DLTs have been observed in this Cohort, but safety evaluation for this Cohort is still ongoing. Once the Cohort is fully enrolled and the safety evaluation is complete, the need for any additional cohorts will be further evaluated. Based on the data from the Phase 1B study and ongoing discussions with the FDA, we have begun Phase 2 trial preparation tasks and will collaborate with the FDA to further define the Phase 2 dosage regimens and final design prior to the trial. The trial is planned for 2024, but we will need to obtain additional funding before we can conduct this trial.

Our license agreement with Elion Oncology, Inc. ("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 in the summer of 2024.

- 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-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 cancer 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 and then submit the Phase 2 protocol to the IND. 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 negotiating with Ocuphire to extend these deadlines.

- 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 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 are exploring options for PCS12852, which may include licensing, partnering and/or collaborating 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 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 completed the Phase 2B uNL trial for those currently enrolled but halted further efforts to enroll new patients in the trial and have terminated the trial. There were 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 was likely to be 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 four patients. We are exploring options for PCS499, which may include licensing, partnering and/or collaborating opportunities.

Recent Developments

Through the date of this Form 10-Q, we had the following significant developments:

- On August 8, 2023, Mr. George Ng was appointed as our Chief Executive Officer and as a Board Director. Mr. Ng is a seasoned life sciences industry executive with significant experience successfully leading small-cap public companies including through product development and fundraising activities. In connection with his employment, Mr. Ng will be paid an annual base salary of $400,000 and will be eligible to receive bonus compensation of up to $100,000 contingent on Mr. Ng. meeting certain performance milestones during 2023 and 2024. In addition, the Compensation Committee awarded 800,000 restricted stock units (“RSUs”) to Mr. Ng. Vesting for 400,000 RSUs occurs ratably over a three-year period. The remaining 400,000 RSUs will vest on the achievement of certain performance metrics, with the first 200,000 performance-based RSUs vesting when gross proceeds of $10,000,000 is raised, and the second 200,000 performance-based RSUs vesting when additional gross proceeds of $10,000,000 is raised. He will also be eligible for other benefits as described in the Employment Agreement.

  Given his oncology and drug development expertise, Dr. David Young transitioned to be our President, Research and Development, concentrating his fulltime effort to drug development of our NGC drugs. By mutual agreement, Mr. R. Michael Floyd resigned as Chief Operating Officer of the Company, effective August 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 to strengthen our balance sheet and allow us to prepare for our next trial for NGC-Cap:
  - 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.
- Due to enrollment difficulties that we experienced in our rare disease Phase 2 trial for PCS499 in uNL, we decided to cease further enrollment in the PCS499 trial in February 2023 and terminated the trial. There were no safety concerns noted during the trial.

Results of Operations

Comparison of the three and nine months ended September 30, 2023 and 2022

The following table summarizes our operations during the periods indicated:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2023	2022	Change	2023	2022	Change
Operating Expenses						
Research and development	$ 1,151,740	$ 3,136,838	$ (1,985,098)	$ 4,478,793	$ 8,319,907	$ (3,841,114)
General and administrative	1,015,872	2,920,280	(1,904,408)	4,508,818	6,137,674	(1,628,856)
Operating Loss	(2,167,612)	(6,057,118)		(8,987,611)	(14,457,581)	
Other Income (Expense)						
Interest income, net	85,661	36,708	48,953	271,022	45,672	225,350
Net Loss	$ (2,081,951)	$ (6,020,410)		$ (8,716,589)	$ (14,411,909)	

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) internal research and development staff related salaries and other payroll costs including stock-based compensation, payroll taxes and employee benefits and (ii) program and testing related expenses, including external consulting and professional fees related to the product testing and our development activities. In 2022, we also had expenses related to the amortization of the exclusive PCS499 license intangible asset. Non-refundable advance payments for goods and services to be used in future research and development activities are recorded as prepaid expenses and expensed when the research and development activities are performed.

Our research and development expenses decreased during both the three- and nine-month periods ended September 30, 2023 when compared to the same periods in 2022 as shown below.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Amortization of intangible assets	$ -	$ 197,124	$ -	$ 591,372
Research and development salaries and benefits	448,071	1,502,065	1,480,909	3,068,241
Preclinical, clinical trial and other costs	703,669	1,437,649	2,997,884	4,660,294
Total	$ 1,151,740	$ 3,136,838	$ 4,478,793	$ 8,319,907

The decrease in preclinical, clinical trial and other costs during the three and nine months ended September 30, 2023 when compared to the same period in 2022 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 in 2023, as we fully impaired our intangible asset at December 31, 2022. During the same three- and nine-month periods in 2022, we had three active clinical trials and amortization expense for our intangible asset.

During the three and nine months ended September 30, 2023, when compared to the same period in 2022, we also experienced decreases in stock-based compensation of $991,000 and $1.7 million, respectively, as a result of a reduction in stock awards granted. During the three months ended September 30, 2023, we experienced a decrease in payroll and related costs of $63,000 while during the nine months ended September 30, 2023, we experienced an increase in payroll and related costs of $72,000. While we have promoted and/or increased salary rates for some personnel, we have fewer full-time R&D employees in 2023 than 2022.

Until we begin our next clinical trial, we anticipate our research and development costs to remain consistent as we continue incurring costs in our clinical trial for NGC-Cap (PCS6422) and we close out and receive final reports related to our clinical trials for PCS499 and PCS12852. We are also incurring costs in preparation for our planned Phase 2 trial for NGC-Cap, including the cost of having drug product manufactured and other pre-trial tasks, as well as costs we may incur in connection with the submission of any Phase 2B protocol for NGC-Gem.

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 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 September 30, 2023 decreased by approximately $1.9 million to $1.0 million from $2.9 million for the three months ended September 30, 2022. This decrease is attributable to a decrease in employee stock-based compensation of $1.9 million due to a reduction in stock awards granted. Reimbursements from CorLyst totaled $26,000 for rent and other costs during the three months ended September 30, 2023, approximately $5,300 less than reimbursements received during the same period in 2022.

During the nine months ended September 30, 2023, our general and administrative expenses decreased by $1.6 million to $4.5 million from $6.1 million for the nine months ended September 30, 2022. We experienced decreases in employee stock-based compensation of $3.3 million due to a reduction in stock awards granted. This decrease was offset primarily by net increases in professional fees of $1.3 million related to the warrants we issued to Spartan Capital and in payroll and related costs of $430,000 related to our new CEO and the termination of our COO. Reimbursements from CorLyst totaled $90,000 for rent and other costs during the nine months ended September 30, 2023, approximately $4,700 less than reimbursements received during the same period in 2022.

Other Income

Other income represents interest income of $86,000 and $37,000 for the three months ended September 30, 2023 and 2022, respectively, and $271,000 and $46,000 for the nine months ended September 30, 2023 and 2022, respectively.

Income Tax Benefit.

We did not recognize any income tax benefit for the three or nine months ended September 30, 2023 or 2022.

Cash Flows

The following table sets forth our sources and uses of cash and cash equivalents for the nine months ended September 30, 2023 and 2022:

	Nine months ended September 30,	
	2023	2022
Net cash (used in) provided by:		
Operating activities	$ (5,939,478)	$ (7,107,758)
Investing activities	(2,776)	-
Financing activities	6,299,331	(335,247)
Net (decrease) increase in cash	$ 357,077	$ (7,443,005)

Net cash used in operating activities

We used net cash in our operating activities of $5,939,478 and $7,107,758 during the nine months ended September 30, 2023 and 2022, respectively.

As we continue our clinical trial for 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. Until we raise additional funds and begin a new clinical trial, we anticipate clinical trial costs will decrease when compared to prior periods since we are currently only conducting one clinical trial for NGC-Cap.

Net cash used in investing activities

We used net cash in our investing activities of $2,776 during the nine months ended September 30, 2023 to purchase property and equipment. We did not have a similar expense during the same period in 2022.

Net cash (used in) provided by financing activities

During the nine months ended September 30, 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 nine months ended September 30, 2022 of $300,000 to purchase 100,000 shares of our common stock from a licensee and $35,247 to pay income taxes owed on vested stock-based compensation.

Going Concern and Management's Plans

We have incurred losses since inception, devoting substantially all of our efforts toward research and development, and have an accumulated deficit of $73.0 million at September 30, 2023. During the nine months ended September 30, 2023, we generated a net loss of $8.7 million and used $5.9 million in net cash for operating activities from continuing operations. We expect continued operating losses and negative cash flow from operations for the foreseeable future.

During the nine months ended September 30, 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 to the condensed consolidated financial statements. We are using 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.

Our condensed consolidated financial statements have been prepared using U.S. GAAP and are based on the assumption that we will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. We face certain risks and uncertainties that are present in many emerging pharmaceutical companies regarding product development, limited working capital, recurring losses and negative cash flow from operations, future profitability, ability to obtain future capital, protection of patents, technologies and property rights, competition, rapid technological change, navigating the domestic and major foreign markets' regulatory and clinical environment, recruiting and retaining key personnel, dependence on third party manufacturing organizations, third party collaboration and licensing agreements, lack of sales and marketing activities. We currently have no customers or pharmaceutical products to sell or distribute. These risks and other factors raise substantial doubt about our ability to continue as a going concern.

At September 30, 2023, we had cash and cash equivalents totaling $6.9 million. Based on our current plans, we believe our current cash balances will enable us to complete our current clinical trial in NGC-Cap, prepare for a Phase 2 trial for NGC-Cap, and fund our administrative costs through the second quarter of 2024. Our ability to execute our longer-term operating plans, including future clinical trials for our NGC drugs, will 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, including out-licensing and/or entering into partnerships on any of our non-core assets, but there can be no assurance that we will obtain the necessary funding in the future when necessary.

We had no revenue during the nine months ended September 30, 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 for operating expenses. Cash used to fund operating expenses is impacted by the timing of when we incur and pay these expenses.

We are hoping to raise additional funds in late 2023 or early 2024 but will only do so if terms are acceptable to us. Additional funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of, or suspend our current or planned future clinical trial plans, or research and development programs. This may also cause us to not meet diligence obligations contained in certain of our license agreements and put these assets at risk. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. To the extent that we raise additional capital through 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, making capital expenditures or declaring dividends.

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

- the cost of our current Phase 1B and planned Phase 2 clinical trial for NGC-Cap along with the cost of third-party drug manufacturing;
- the initiation, progress, timing, costs and results of drug manufacturing, pre-clinical studies, and any clinical trials for NGC-Gem or NGC-Iri;
- 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.

Uncertainty concerning our ability to continue as a going concern may hinder our ability to obtain future financing. Continued operations and our ability to continue as a going concern are dependent on our ability to obtain additional funding in the future and thereafter, and no assurances can be given that such funding will be available at all, in a sufficient amount, or on reasonable terms. Without additional funds from debt or equity financing, sales of assets, sales or out-licenses of intellectual property or technologies, or other transactions providing funds, we will rapidly exhaust our resources, be unable to meet diligence obligations in license agreements and be unable to continue operations. 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.

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.

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 September 30, 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 since our most recent Annual Report on Form 10-K.

Recently Issued Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

As of September 30, 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 as of September 30, 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 September 30, 2023 that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

In addition to the information set forth in this report, you should carefully consider the risk factors discussed in Item 1A. of Part I of our Annual Report on Form 10-K for the year ended December 31, 2022.

Our financial statements contain a statement regarding a substantial doubt about the Company's ability to continue as a going concern.

We had no revenue during the nine months ended September 30, 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 for operating expenses. Cash used to fund operating expenses is impacted by the timing of when we incur and pay these expenses using U.S. GAAP, and are based on the assumption that we will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. We face certain risks and uncertainties that are present in many emerging pharmaceutical companies regarding product development, limited working capital, recurring losses and negative cash flow from operations, future profitability, ability to obtain future capital, protection of patents, technologies and property rights, competition, rapid technological change, navigating the domestic and major foreign markets' regulatory and clinical environment, recruiting and retaining key personnel, dependence on third party manufacturing organizations, third party collaboration and licensing agreements, lack of sales and marketing activities. We currently have no customers or pharmaceutical products to sell or distribute. These risks and other factors raise substantial doubt about our ability to continue as a going concern.

Our ability to continue as a going concern is dependent on our ability to obtain the necessary financing to meet our obligations and repay our liabilities arising from the ordinary course of business operations when they become due. The substantial doubt about our ability to continue as a going concern may affect the price of our common stock, may impact our relationship with third parties with whom we do business, may impact our ability to raise additional capital and may impact our ability to comply going forward with covenants in our debt agreements.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, interruptions or disruptions to operations or clinical trials, reputational harm, litigation, fines and penalties.

In the ordinary course of our business, we, or the third parties upon which we rely, process, collect, receive, store, use, transmit, transfer, make accessible, protect, secure, dispose of, disclose and share proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, and trade secrets.

Cyberattacks, malicious internet-based activity, online and offline fraud and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely.

We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to, social engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunction, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fire, flood, and other similar threats.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, drug suppliers, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to perform our research and development activities.

There have been no other 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

(a) Recent Sale of Unregistered Securities

There were no sales of unregistered securities during the three months ended September 30, 2023.

(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

During the three months ended September 30, 2023, there were no modifications, adoptions or terminations by any directors or officers to any contract, instruction or written plan for the purchase or sale of securities of the Company that is intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or non-Rule 10b5-1 trading agreements.

Item 6. Exhibits

SEC Ref. No.	Title of Document
3.1	Fourth Amended and Restated Certificate of Incorporation of Heatwurx, Inc. (incorporated by reference to Exhibit 3.1 to Form S-1/A filed on September 30, 2020)
3.2	Amendment to Fourth Amended and Restated Certificate of Incorporation of Heatwurx, Inc. (incorporated by reference to Exhibit 3.1.1 to Form S-1/A filed on September 30, 2020)
3.3	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation incorporated by reference to Exhibit 3.1.2 to Form S-1/A filed on September 30, 2020)
3.4	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1.3 to Form S-1/A filed on September 30, 2020)
3.5	Amendment to Fourth Amended and Restated Certificate of Incorporation of Processa Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1.4 to Form S-1/A filed on September 30, 2020)
3.6	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation dated June 27, 2023 (incorporated by reference to Exhibit 3.1 to Form 8-K filed on June 29, 2023)
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

* 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: November 13, 2023

By: */s/ James Stanker*
James Stanker
Chief Financial Officer
(Principal Financial and Accounting Officer)
Dated: November 13, 2023

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 period ended September 30, 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 as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules13a-15(f) and 15d-15 (f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: */s/ George Ng*
George Ng
Chief Executive Officer
(Principal Executive Officer)
Date: November 13, 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 period ended September 30, 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 as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules13a-15(f) and 15d-15 (f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting.

5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of registrant’s board of directors (or persons performing equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

By: */s/ James Stanker*
James Stanker
Chief Financial Officer
(Principal Financial and Accounting Officer)
Date: November 13, 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 September 30, 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/ George Ng*
George Ng
Chief Executive Officer
(Principal Executive Officer)
Date: November 13 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 September 30, 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: November 13, 2023