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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2025

or

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

For the transition period from ____ to ____

Commission File Number 001-39531

Processa Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**45-1539785**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

601 21st Street, Suite 300
Vero Beach, FL 32960
(772) 453-2899

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

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

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

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

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

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

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

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

The number of outstanding shares of the registrant's common stock at August 5, 2025 was 50,349,149.

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

Processa Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets

	June 30, 2025 (unaudited)	December 31, 2024
ASSETS		
Current Assets		
Cash and cash equivalents	$ 6,936,620	$ 1,191,325
Prepaid expenses and other	217,201	682,294
Total Current Assets	7,153,821	1,873,619
Property and Equipment, net	4,414	5,016
Non-current Assets		
Prepaid expenses	993,701	1,274,442
Total Non-current Assets	993,701	1,274,442
Other Assets		
Right-of-use assets, net	24,318	70,677
Other	5,535	5,535
Total Other Assets	29,853	76,212
Total Assets	$ 8,181,789	$ 3,229,289
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Current maturities of lease liability	$ 25,584	$ 73,020
Accounts payable	785,754	880,880
Accrued expenses	1,263,243	578,731
Total Current Liabilities	2,074,581	1,532,631
Non-current Liabilities		
Non-current lease liability	-	487
Total Liabilities	2,074,581	1,533,118
Commitments and Contingencies	-	-
Stockholders' Equity		
Preferred stock, par value $0.0001, 1,000,000 shares authorized; no shares issued or outstanding at June 30, 2025 or December 31, 2024	-	-
Common stock, par value $0.0001, 100,000,000 shares authorized; 40,289,356 issued and 40,284,356 outstanding at June 30, 2025; and 3,707,628 issued and 3,702,628 outstanding at December 31, 2024	4,029	371
Additional paid-in capital	100,390,701	89,214,999
Treasury stock, 5,000 shares	(300,000)	(300,000)
Accumulated deficit	(93,987,522)	(87,219,199)
Total Stockholders' Equity	6,107,208	1,696,171
Total Liabilities and Stockholders' Equity	$ 8,181,789	$ 3,229,289

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Operating Expenses				
Research and development expenses	$ 2,447,286	$ 1,730,444	$ 4,035,767	$ 3,269,555
General and administrative expenses	1,503,497	1,351,580	2,762,006	2,622,067
Operating Loss	(3,950,783)	(3,082,024)	(6,797,773)	(5,891,622)
Other Income (Expense), net	16,865	71,698	29,450	154,915
Net Loss	$ (3,933,918)	$ (3,010,326)	$ (6,768,323)	$ (5,736,707)
Net Loss per Common Share - Basic and Diluted	$ (0.25)	$ (1.01)	$ (0.55)	$ (2.11)
Weighted Average Common Shares Used to Compute Net Loss Applicable to Common Shares - Basic and Diluted	15,569,312	2,983,283	12,401,583	2,724,903

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

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

	Common Stock		Additional Paid-In	Treasury Stock		Accumulated	
	Shares	Amount	Capital	Shares	Amount	Deficit	Total
Balance at January 1, 2024	1,291,000	$ 129	$ 80,658,111	(5,000)	$ (300,000)	$ (75,369,081)	$ 4,989,159
Stock-based compensation	13,176	1	167,642	-	-	-	167,643
Shares issued in connection with capital raise, net of transaction costs	1,555,555	156	6,282,274	-	-	-	6,282,430
Shares issued in connection with license agreement	5,000	1	188,999	-	-	-	189,000
Settlement of stock award	-	-	(8,561)	-	-	-	(8,561)
Shares withheld to pay income taxes on stock-based compensation	(3,750)	(1)	(9,923)	-	-	-	(9,924)
Net loss	-	-	-	-	-	(2,726,381)	(2,726,381)
Balance, March 31, 2024	2,860,981	286	87,278,542	(5,000)	(300,000)	(78,095,462)	8,883,366
Stock-based compensation	14,167	1	152,631	-	-	-	152,632
Shares withheld to pay income taxes on stock-based compensation	(1,265)	-	(2,008)	-	-	-	(2,008)
Net loss	-	-	-	-	-	(3,010,326)	(3,010,326)
Balance, June 30, 2024	2,873,883	$ 287	$ 87,429,165	(5,000)	$ (300,000)	$ (81,105,788)	$ 6,023,664

	Common Stock		Additional Paid-In	Treasury Stock		Accumulated	
	Shares	Amount	Capital	Shares	Amount	Deficit	Total
Balance at January 1, 2025	3,707,628	$ 371	$ 89,214,999	(5,000)	$ (300,000)	$ (87,219,199)	$ 1,696,171
Stock-based compensation	11,721	1	227,710	-	-	-	227,711
Shares issued in connection with capital raise, net of transaction costs	1,556,672	156	4,438,414	-	-	-	4,438,570
Shares withheld to pay income taxes on stock-based compensation	(1,781)	(1)	(1,438)	-	-	-	(1,439)
Net loss	-	-	-	-	-	(2,834,405)	(2,834,405)
Balance, March 31, 2025	5,274,240	$ 527	$ 93,879,685	(5,000)	$ (300,000)	$ (90,053,604)	$ 3,526,608
Stock-based compensation	143,103	15	203,236	-	-	-	203,251
Shares issued in connection with capital raise, net of transaction costs	34,894,000	3,489	6,316,743	-	-	-	6,320,232
Shares withheld to pay income taxes on stock-based compensation	(21,987)	(2)	(8,963)	-	-	-	(8,965)
Net loss	-	-	-	-	-	(3,933,918)	(3,933,918)
Balance, June 30, 2025	40,289,356	$ 4,029	$ 100,390,701	(5,000)	$ (300,000)	$ (93,987,522)	$ 6,107,208

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

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

	Six Months Ended June 30,	
	2025	2024
Cash Flows From Operating Activities		
Net Loss	$ (6,768,323)	$ (5,736,707)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	602	278
Non-cash lease expense for right-of-use assets	46,359	42,670
Stock-based compensation	430,962	320,275
Net changes in operating assets and liabilities:		
Prepaid expenses and other	745,834	(980,554)
Operating lease liability	(45,073)	(41,228)
Accounts payable	(95,126)	641,469
Due from related parties	-	(39)
Accrued expenses	684,512	359,123
Net cash used in operating activities	(5,000,253)	(5,394,713)
Cash Flows From Financing Activities		
Net proceeds from issuance of stock	10,758,802	6,282,430
Shares withheld to pay taxes on stock-based compensation	(10,404)	(11,932)
Settlement of stock award	-	(8,561)
Payment of finance lease obligation	(2,850)	(2,301)
Net cash provided by financing activities	10,745,548	6,259,636
Net Decrease in Cash and Cash Equivalents	5,745,295	864,923
Cash and Cash Equivalents - Beginning of Period	1,191,325	4,706,197
Cash and Cash Equivalents - End of Period	$ 6,936,620	$ 5,571,120
Supplemental Cash Flow Information:		
Cash paid for interest	$ 1,880	$ -
Cash paid for income taxes	$ -	$ -
Non-Cash Financing Activities		
Issuance of 5,000 shares of common stock in connection with a licensing agreement which had previously been recorded as a due to licensor	$ -	$ 189,000
New right-of-use asset	$ -	$ 11,804
Financing lease liability	-	(11,804)
Net	$ -	$ -

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

Note 1 – Organization and Summary of Significant Accounting Policies

Organization

We are a clinical-stage biopharmaceutical company focused on incorporating our Regulatory Science Approach into the development of our Next Generation Cancer therapy ("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 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, 2024, as filed with the SEC. The results of operations for the interim periods shown in this report are not necessarily indicative of the results that may be expected for any other interim period or for the full year.

Liquidity

Our consolidated financial statements have been prepared on a going concern basis, which contemplates the continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. We have incurred losses since inception, currently devoting substantially all our efforts toward research and development of our NGC drug product candidates, including conducting clinical trials and providing general and administrative support for these operations, and have an accumulated deficit of $94.0 million at June 30, 2025. During the six months ended June 30, 2025, we generated a net loss of $6.8 million and used $5.0 million in net cash for operating activities from continuing operations. To date, none of our drug candidates have been approved for sale, and therefore we have not generated any product revenue and do not expect positive cash flow from operations in the foreseeable future. We expect that we will continue to be dependent upon equity and/or debt financing until we are able to generate positive cash flows from its operations.

On January 29, 2025, we closed a public offering where we sold 1,030,972 shares of our common stock, pre-funded warrants to purchase up to 7,019,700 shares of our common stock, and accompanying Series A warrants to purchase up to 8,050,672 shares of our common stock (the "Series A Warrants") and Series B warrants to purchase up to 4,025,336 shares of our common stock (the "Series B Warrants") for net proceeds of $4.4 million, after deducting placement agent fees and offering-related expenses (see Note 2 for additional details). On June 18, 2025, we closed another public offering where we sold 14,310,000 shares of common stock, pre-funded warrants to purchase up to 13,690,000 shares of common stock, and common warrants to purchase up to 28,000,000 shares of common stock for net proceeds of $6.2 million, after deducting placement agent fees and offering-related expenses (see Note 2 for additional details). As of June 30, 2025, all Pre-Funded Warrants from both public offerings were exercised. During the six months ended June 30, 2025, we also received $100,000 for the exercise of warrants to purchase 400,000 shares of common stock from the June PO.

On August 4, 2025, we entered into a Securities Purchase Agreement with an accredited investor and sold 5,467,181 shares for $1.3 million in gross proceeds. We also sold 4,597,612 shares for $1.1 million in gross proceeds under our ATM agreement. Following these investments, we are exploring options to pursue a cryptocurrency treasury strategy.

At June 30, 2025, we had cash and cash equivalents totaling $6.9 million. Based on our current business plans, we believe these funds, together with the $2.4 million in gross proceeds we received in August 2025, will satisfy our capital needs into the first quarter of 2026. Our ability to execute our longer-term operating plans, including future preclinical studies and clinical trials for our portfolio of drugs depend on our ability to obtain additional funding from the sale of equity and/or debt securities, a strategic transaction or other funding transactions.

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

Absent additional funding, we believe that our cash and cash equivalents will not be sufficient to fund our operations for a period of one year or more after the date that these 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 consolidated financial statements are available to be issued. The accompanying 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 June 30, 2025 and December 31, 2024, 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 ASC 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 2025 and the foreseeable future since we expect to generate taxable net operating losses.

Concentration of Credit Risk

Financial instruments that potentially subject us to significant concentration of credit risk consist primarily of our cash and cash equivalents. We utilize only well-established banks and financial institutions with high credit ratings. Balances on deposit are insured by the Federal Deposit Insurance Corporation (FDIC) up to specified limits. Total cash held by our banks at June 30, 2025, 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

Common Stock

During the six months ended June 30, 2025, we issued the following shares of common stock:

- On January 29, 2025, we sold 1,030,972 shares of our common stock, pre-funded warrants to purchase up to 7,019,700 shares of our common stock, and accompanying Series A Warrants to purchase up to 8,050,672 shares of our common stock and Series B Warrants to purchase up to 4,025,336 shares of our common stock for net proceeds of $4.4 million, after deducting placement agent fees and offering-related expenses under a best efforts public offering (the "January PO") at a combined purchase price of $0.615 for institutional investors and $0.7975 for the Company's Chief Executive Officer and certain board members who participated in the offering. The Series A and B Warrants both have an exercise price of $0.65 per share of common stock, and were subject to stockholder approval, which was obtained at our annual stockholder meeting on July 18, 2025. The Series A Warrants will expire on July 18, 2030 and the Series B Warrants will expire on January 18, 2027. At June 30, 2025, all pre-funded warrants sold in this offering were exercised;

- On June 18, 2025, we sold 14,310,000 shares of our common stock, pre-funded warrants to purchase up to 13,690,000 shares of our common stock. and accompanying common warrants to purchase up to 28,000,000 shares of our common stock for net proceeds of $6.2 million, after deducting placement agent fees and offering-related expenses under a best efforts public offering (the "June PO"). We sold one share of our common stock and accompanying common warrant at a combined price of $0.25 per share, and a pre-funded warrant and accompanying common warrant at a combined price of $0.2499 per share. The common warrants have an exercise price of $0.25 per share, are immediately exercisable and expire five years after their original issuance. The pre-funded warrants have an exercise price of $0.0001 and are also immediately exercisable. We issued placement agent warrants to purchase up to 1,120,000 shares of common stock at an exercise price of $0.31 per share. During the six months ended June 30, 2025, warrants to purchase 400,000 shares of common stock for $100,000 and all pre-funded warrants sold in this offering were exercised;

- 74,804 shares of common stock to employees, net of 23,768 shares of common stock withheld for income and FICA taxes owed upon the distribution of the shares; and

- 56,252 shares of common stock in connection with consulting agreements.

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 800,000 shares of our common stock. At June 30, 2025, we have 357,420 shares available for future grants.

Stock Compensation Expense

We recorded stock-based compensation expense for the three and six months ended June 30, 2025 and 2024 as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Research and development	$ 8,613	$ 45,583	$ 55,333	$ 76,704
General and administrative	194,635	107,049	375,626	243,571
Total	$ 203,248	$ 152,632	$ 430,959	$ 320,275

Stock Options

No stock options to purchase shares of common stock were forfeited or expired during the six months ended June 30, 2025. At June 30, 2025, we had outstanding and exercisable options for the purchase of 2,747 shares with a weighted average exercise price of $409.09 and a weighted average remaining contractual life of 3.2 years. At June 30, 2025, we did not have any unrecognized stock-based compensation expense related to our granted stock options.

Restricted Stock Units

Activity with respect to our Restricted Stock Units ("RSUs") during the six months ended June 30, 2025 was as follows:

	Number of shares	Weighted-average grant-date fair value per share
Outstanding at January 1, 2025	383,636	$ 19.87
Granted	-	-
Forfeited	(27,547)	53.08
Issued	(74,804)	58.78
Outstanding at June 30, 2025	281,285	6.27
Vested and unissued	(229,905)	5.47
Unvested at June 30, 2025	51,380	$ 9.84

At June 30, 2025, unrecognized stock-based compensation expense of approximately $148,000 for RSUs is expected to be fully recognized over a weighted average period of 0.7 years. The unrecognized expense excludes approximately $253,000 of expense related to certain grants of RSUs with performance milestones that are being accounted for as though the performance milestones are not probable of occurring at this time.

Holders of our vested RSUs will be issued shares of our common stock upon meeting the distribution restrictions contained in their Restricted Stock Unit Award Agreement. The distribution restrictions are different (longer) than the vesting schedule, imposing an additional restriction on the holder. While certain employees may hold fully vested RSUs, the individual does not hold any shares or have any rights of a stockholder 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 six months ended June 30, 2025, we sold 7,019,700 pre-funded warrants, and accompanying Series A Warrants to purchase up to 8,050,672 shares of our common stock and Series B Warrants to purchase up to 4,025,336 shares of our common stock in the January PO. We also sold 13,690,000 pre-funded warrants and accompanying common warrants to purchase up to 28,000,000 shares of common stock, as well as issued placement agent warrants to purchase up to 1,120,000 shares of common stock in the June PO. During the six months ended June 30, 2025, warrants to purchase 400,000 shares of common stock from the June PO and all pre-funded warrants from the January PO and June PO were exercised.

At June 30, 2025, we had outstanding exercisable stock purchase warrants excluding the Series A and B Warrants for the purchase of 30,495,784 shares with a weighted average exercise price of $0.35 and a weighted average remaining contractual life of 4.9 years. We have excluded the Series A and B Warrants sold under the January PO from the calculation of the weighted average remaining contractual life since we did not receive stockholder approval for these warrants until July 18, 2025.

We did not have any unrecognized stock-based compensation expense related to our granted stock purchase warrants at June 30, 2025.

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 stockholders by the weighted average number of shares of common stock outstanding (which includes vested RSUs and unexercised pre-funded warrants) during the period. Diluted loss per share is computed by dividing our net loss available to common stockholders by the diluted weighted average number of shares of common stock (which includes the potentially dilutive effect of stock options, unvested RSUs and warrants) during the period. Since we experienced a net loss for both periods presented, basic and diluted net loss per share are the same. As such, diluted loss per share for the three and six months ended June 30, 2025 and 2024 excludes the impact of potentially dilutive common shares since those shares would have an anti-dilutive effect on net loss per share.

The computation of net loss per share for the three and six months ended June 30, 2025 and 2024 was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Basic and diluted net loss per share:				
Net loss available to common stockholders	$ (3,933,918)	$ (3,010,326)	$ (6,768,323)	$ (5,736,707)
Weighted average number of common shares-basic and diluted	15,569,312	2,983,283	12,401,583	2,724,903
Basic and diluted net loss per share	$ (0.25)	$ (1.01)	$ (0.55)	$ (2.11)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Weighted-average number of common shares outstanding – basic and diluted	15,545,266	2,849,192	12,371,909	2,590,530
Weighted-average number of vested RSUs– basic and diluted	24,046	134,091	29,674	134,373
Weighted-average number of common shares-basic and diluted	15,569,312	2,983,283	12,401,583	2,724,903

We have excluded the following potentially dilutive securities from the calculation of diluted net loss per share since they would have had an anti-dilutive effect:

	June 30,	
	2025	**2024**
Stock options	2,747	2,747
Restricted stock units (unvested)	51,380	95,028
Warrants for common stock	30,495,784	1,778,284
Total	30,549,911	1,876,059

We have not included any potential impact of the Series A and B Warrants from the January PO since they were subject to shareholder approval as of June 30, 2025.

Note 5 – Leases

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

Lease costs included in our condensed consolidated statements of operations totaled $22,461 for both three months ending June 30, 2025 and 2024 and $44,922 for both six months ending June 30, 2025 and 2024. The weighted average remaining lease terms and discount rate for our operating leases were as follows at June 30, 2025:

Remaining lease term (years) for our facility lease	0.3
Remaining lease term (years) for our equipment lease	0.6
Weighted average discount rate for our facility and equipment leases	8.0%

Annual lease liabilities for the operating lease were as follows at June 30, 2025:

Remainder of 2025	$ 23,347
Total lease payments	23,347
Less: Interest	(1,515)
Present value of lease liabilities	21,832
Less: current maturities	(21,832)
Non-current lease liability	$ -

Annual lease liabilities for the financing lease were as follows at June 30, 2025:

Remainder of 2025	$ 3,360
2026	560
Total lease payments	3,920
Less: Interest	(168)
Present value of lease liabilities	3,752
Less: current maturities	(3,752)
Non-current lease liability	$ -

Note 6 – Related Party Transactions

CorLyst, LLC ("CorLyst") reimburses us for shared costs related to payroll, health insurance and rent based on actual costs incurred, which are recognized as a reduction of our general and administrative operating expenses being reimbursed in our condensed consolidated statement of operations. Included in our general and administrative expenses is approximately $31,000 and $27,000 of reimbursements from CorLyst during the three months ended June 30, 2025 and 2024, respectively, and $60,000 and $50,000 for the six months ended June 30, 2025 and 2024. At June 30, 2025, we included approximately $29,000 due from CorLyst as a current asset in Prepaid and Other. Our President, Research and Development is the CEO of CorLyst, and CorLyst is a stockholder.

Note 7 – Segment Reporting

We manage our operations as a single segment, focused on developing the next generation of cancer therapy drugs. As our chief operating decision maker (CODM), our CEO manages and allocates resources at a consolidated level. He assesses performance, monitors budget versus actual results, and decides how to allocate resources based on net loss that also is reported on the consolidated statement of operations and comprehensive loss as consolidated net loss.

The following table presents reportable segment profit and loss, including significant expense categories, attributable to our reportable segment for the three and six months ended June 30, 2025 and 2024:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Preclinical, clinical trial and other costs	$ 2,142,229	$ 1,261,720	$ 3,339,263	$ 2,293,001
Research and development personnel expense[(1)]	305,057	468,724	696,504	976,554
General and administrative personnel expense[(2)]	628,330	445,620	1,302,167	964,409
Administrative and facilities expense[(3)]	875,167	905,960	1,459,839	1,657,658
Other income, net	(16,865)	(71,698)	(29,450)	(154,915)
Total	$ 3,933,918	$ 3,010,326	$ 6,768,323	$ 5,736,707

(1) Research and development personnel costs include employee stock-based compensation expense of $8,613 and $45,583 for the three months ended June 30, 2025 and 2024, respectively, and $55,333 and $76,704 for the six months ended June 30, 2025 and 2024, respectively.

(2) General and administrative personnel costs include employee stock-based compensation expense of $122,655 and $40,309 for the three months ended June 30, 2025 and 2024, respectively, and $245,310 and 79,180 for the six months ended June 30, 2025 and 2024, respectively, and are net of reimbursements received from CorLyst, LLC.

(3) Administrative & facilities expense primarily consists of facilities expenses, office expenses, legal costs, insurance, consulting, travel, and other administrative costs.

Note 8 – PCS12852

On June 17, 2025, we entered into a binding term sheet ("Term Sheet") with Intact Therapeutics ("Intact") granting Intact the exclusive option to license PCS12852, a highly specific and potent 5HT5 agonist that is Phase 2B ready as potentially the first meaningful treatment for diabetic gastroparesis patients. Upon execution of the Term Sheet, Intact agreed to pay a non-refundable standstill payment of $20,000 and upon execution of a license agreement, the Company will receive a 3.5% equity interest in Intact and a payment of $2.5 million, with $1.0 million paid within thirty days of closing and the remaining $1.5 million paid within twelve months of closing. The Term Sheet also provides that the license agreement will provide for development and regulatory milestone payments, commercial milestone payments based on net product sales and a 12% royalty on worldwide net sales of licensed products, excluding South Korea.

The obligations of the parties to enter into the license agreement are subject to additional diligence by Intact. Pursuant to the Term Sheet, the parties have one hundred and twenty (120) days to finish any remaining due diligence and enter into the license agreement, which period may be extended for an additional one hundred and twenty days for an additional fee of $30,000. There can be no assurance that the Company and Intact will enter into a license agreement.

In connection with the Term Sheet, Yuhan Corporation executed Amendment No. 1 to our existing license agreement dated August 19, 2020 (the "Yuhan Agreement"), effective June 11, 2025, which, among other things, extended the deadline to dose the first patient in a Phase 2B clinical trial, Phase 3 clinical trial or other pivotal clinical trial from 48 months to 108 months from the effective date of the original agreement.

Note 9 – Commitments and Contingencies

Purchase Obligations

We enter into contracts in the normal course of business with contract research organizations (CROs) and subcontractors to further develop our products. The contracts are cancelable, with varying provisions regarding termination. If we terminated a cancelable contract with a specific vendor, we would only be obligated for products or services that we received at the effective date of the termination and any applicable cancellation fees. At June 30, 2025, we are contractually obligated to pay up to $13.1 million of future services under the agreements with the CROs. Our actual contractual obligations will also vary depending on the progress and results of the remaining clinical trials.

NGC-Gem (also identified as PCS3117)

On June 27, 2025, we provided a 120-day written notice of termination of our licensing agreement with Ocuphire Pharma, Inc. (now Opus Genetics) dated June 16, 2021, rescinding all rights and licenses previously granted to us for NGC-Gem.

Note 10 – Subsequent Events

RSU Grants

On July 24, 2025, the Compensation Committee of our Board of Directors granted RSUs for the future issuance of up to 356,310 shares of common stock to our employees and independent directors. The RSUs vest over a 1-3 year period.

Equity Sales

On August 4, 2025, we entered into a Securities Purchase Agreement with an accredited investor and sold 5,467,181 shares for $1.3 million in gross proceeds. We also sold 4,597,612 shares for $1.1 million in gross proceeds under our ATM agreement. Following these investments, we are exploring options to pursue a cryptocurrency treasury

strategy.

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 cash and history of losses; our ability to achieve profitability; our ability to obtain adequate financing to fund our business operations in the future; our ability to secure required FDA or other governmental approvals for our product candidates and the breadth of the indication sought; the impact of competitive or alternative products, technologies and pricing; whether we are successful in developing and commercializing our technology, including through licensing; the adequacy of protections afforded to us and/or our licensors by the anticipated patents that we own or license and the cost to us of maintaining, enforcing and defending those patents; our and our licensors' ability to protect non-patented intellectual property rights; our exposure to and ability to defend third-party claims and challenges to our and our licensors' anticipated patents and other intellectual property rights; our ability to remain listed on the Nasdaq Capital Market; 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" herein and in the Company's Annual Report on Form 10-K for the year ended December 31, 2024, 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.

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 developing a pipeline of Next Generation Cancer therapy ("NGC") small molecules, one of which is currently in a Phase 2 trial, while the other is in pre-clinical development. Our risk-mitigated strategy is to identify existing cancer therapies where the mechanism of action is well understood and that are cornerstones of current treatment regimens, but are highly toxic, with side effects that are often treatment limiting. We devise technologies to change the way the body metabolizes them, or the way they are distributed within the body, to improve the therapeutic effect and reduce toxicity. We then efficiently develop our pipeline of Next Generation Cancer therapies utilizing our proprietary Regulatory Science Approach, which we believe will further increase the likelihood of regulatory approval. Since the underlying active metabolites of these drugs are already commonly used in cancer therapy, we believe that if our clinical trials are successful and are showing better efficacy and tolerability than the currently used drugs, the commercial adoption for our NGC therapies will be rapid and broad.

Our oncology pipeline currently consists of NGC-Cap and NGC-Iri (also identified as PCS6422 and PCS11T, respectively) and two non-oncology drugs (PCS12852 and PCS499). We are exploring options for our non-oncology drugs, which may include out-licensing or partnership opportunities. The current status of our drug pipeline is set forth below:

Our Drug Pipeline

Recent Developments

Over the last nine months since the first patient was dosed in the NGC-Cap Phase 2 advanced or metastatic breast cancer trial, the study has been actively adding additional U.S. clinical study sites and screening and enrolling more patients. We plan to obtain preliminary safety-efficacy data from these breast cancer patients in order to provide insight into the benefit of NGC-Cap over existing treatments. This preliminary data should provide information that could also help to adaptively modify the protocol to increase the efficiency and/or improve the information obtained from the study.

Since FDA now accepts surrogate endpoints for nephrology diseases, such as primary glomerular diseases (PGDs), we have recently begun to re-evaluate the potential clinical safety and efficacy of PCS499 in PGDs. These analyses have been based on PCS499 and pentoxifylline (PTX) safety-efficacy in diabetic nephropathy and, for PTX, in primary glomerular diseases. PTX is a generic drug with similar pharmacological properties to PCS499 and is approved for the treatment of patients with intermittent claudication. The data suggests that PCS499 may not only be safer, but also more efficacious in more patients than PTX or other drugs presently used on- and off-label for PGDs.

Public Offerings

As described in Note 2, during the six months ended June 30, 2025, we raised net proceeds of $10.6 million from the January and June POs. We sold a cumulative 15,340,972 shares of common stock, pre-funded warrants to purchase up to 20,709,700 shares of common stock, accompanying Series A Warrants to purchase up to 8,050,672 shares of our common stock and Series B Warrants to purchase up to 4,025,336 shares of common stock in the January PO and common accompanying warrants to purchase up to 28,000,000 shares of common stock in the June PO. During the six months ended June 30, 2025, all pre-funded warrants were exercised.

We plan to use the net proceeds from both financings for continued research and development for NCG-Cap, and for working capital and general corporate purposes.

PCS12852 Update: Intact Therapeutics and Yuhan Corporation

On June 17, 2025, we entered into a binding term sheet ("Term Sheet") with Intact Therapeutics ("Intact") granting Intact the exclusive option to license PCS12852, a highly specific and potent 5HT5 agonist that is Phase 2B ready as potentially the first meaningful treatment for diabetic gastroparesis patients. Upon execution of the Term Sheet, Intact agreed to pay a non-refundable standstill payment of $20,000 and upon execution of a license agreement, the Company will receive a 3.5% equity interest in Intact and a payment of $2.5 million, with $1.0 million paid within thirty days of closing and the remaining $1.5 million paid within twelve months of closing. The Term Sheet also provides that the license agreement will provide for development and regulatory milestone payments, commercial milestone payments based on net product sales and a 12% royalty on worldwide net sales of licensed products, excluding South Korea.

The obligations of the parties to enter into the license agreement are subject to additional diligence by Intact. Pursuant to the Term Sheet, the parties have one hundred and twenty (120) days to finish any remaining due diligence and enter into the license agreement, which period may be extended for an additional one hundred and twenty days for an additional fee of $30,000. There can be no assurance that the Company and Intact will enter into a license agreement.

In connection with the Term Sheet, Yuhan Corporation executed Amendment No. 1 to our existing license agreement dated August 19, 2020 (the "Yuhan Agreement"), effective June 11, 2025, which, among other things, extended the deadline to dose the first patient in a Phase 2B clinical trial, Phase 3 clinical trial or other pivotal clinical trial from 48 months to 108 months from the effective date of the original agreement.

NGC-Gem (also identified as PCS3117)

On June 27, 2025, we provided a 120-day written notice of termination of our licensing agreement with Ocuphire Pharma, Inc. (now Opus Genetics) dated June 16, 2021, rescinding all rights and licenses previously granted to us for NGC-Gem.

Results of Operations

Comparison of the three and six months ended June 30, 2025 and 2024

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

	Three Months Ended June 30,			Six Months Ended June 30,		
	2025	2024	Change	2025	2024	Change
Operating Expenses						
Research and development expenses	$ 2,447,286	$ 1,730,444	$ 716,842	$ 4,035,767	$ 3,269,555	$ 766,212
General and administrative expenses	1,503,497	1,351,580	151,917	2,762,006	2,622,067	139,939
Operating Loss	(3,950,783)	(3,082,024)		(6,797,773)	(5,891,622)	
Other Income (Expense), net	16,865	71,698	(54,833)	29,450	154,915	(125,465)
Net Loss	$ (3,933,918)	$ (3,010,326)		$ (6,768,323)	$ (5,736,707)	

Revenues

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

Research and Development Expenses

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

Costs for the three- and six-month periods for the periods ended June 30, 2025 and 2024 were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Research and development salaries and benefits	305,057	468,724	696,504	976,554
Preclinical, clinical trial and other costs	2,142,229	1,261,720	3,339,263	2,293,001
Total	$ 2,447,286	$ 1,730,444	$ 4,035,767	$ 3,269,555

The increase in research and development expenses was due to an increase in preclinical, clinical trial and other costs for our Phase 1B and Phase 2 clinical trials for NGC-Cap during the three and six months ended June 30, 2025 when compared to the same period in 2024. During the same period in 2024, the majority of the costs incurred were related to our Phase 1B trial for NGC-Cap, as well as the IND/initiation of our Phase 2 trial for NGC-Cap. The increase was offset by a decrease in salaries and benefits from the voluntary departures of research and development employees since March 2024.

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 June 30, 2025 increased by approximately $152,000 to $1.5 million from $1.4 million for the three months ended June 30, 2024. This increase was due primarily to increases in salaries and other-payroll related costs of $105,000, primarily due to salary increases to our C-suite executives; an increase in employee stock-based compensation of $82,000 (our 2024 stock grant was contingent on receiving stockholder approval to increase the number of shares available for issuance under our Incentive Plan, so we did not recognize any expense related to grants made during the first quarter of 2024 and awards that were previously not probable of occurring that vested in 2025); and net increases in taxes and other miscellaneous office expenses of $24,000. The increases were offset by decreases in office expenses of $32,000; professional fees of $19,000 and travel expenses of $4,000. We received approximately $4,000 more in reimbursements from CorLyst during the three months ended June 30, 2025 when compared to the same period in 2024.

Our general and administrative expenses for the six months ended June 30, 2025 increased by approximately $140,000 to $6.8 million from $5.9 million for the three months ended June 30, 2024. This increase was due primarily to increases in salaries and other-payroll related costs of $182,000, primarily due to salary increases to our C-suite executives; an increase in employee stock-based compensation of $166,000 (our 2024 stock grant was contingent on receiving stockholder approval to increase the number of shares available for issuance under our Incentive Plan, so we did not recognize any expense related to grants made during the first quarter of 2024 and awards that were previously not probable of occurring that vested in 2025); and net increases in taxes and other miscellaneous office expenses of $23,000. The increases were offset by decreases in office expenses of $42,000; professional fees of $170,000; insurance of $5,000; and travel expenses of $4,000. We received approximately $10,000 more in reimbursements from CorLyst during the six months ended June 30, 2025 when compared to the same period in 2024.

Other Income

Other income for the three and six months ended June 30, 2025 includes our portion of the Intact payment of $8,000 along with interest income of approximately $9,000 and $72,000 for the three months ended June 30, 2025 and 2024, respectively, and approximately $21,000 and $155,000 for the six months ended June 30, 2025 and 2024, respectively.

Income Tax Benefit

We did not recognize any income tax benefit for the three or six months ended June 30, 2025 or 2024.

Cash Flows

The following table sets forth our sources and uses of cash and cash equivalents for the six months ended June 30, 2025 and 2024:

	Six months ended June 30,	
	2025	2024
Net cash (used in) provided by:		
Operating activities	$ (5,000,253)	$ (5,394,713)
Financing activities	10,745,548	6,259,636
Net increase in cash	$ 5,745,295	$ 864,923

Net cash used in operating activities

We used net cash in our operating activities of $5,000,253 and $5,394,713 during the six months ended June 30, 2025 and 2024, respectively. The decrease in cash used in operating activities was primarily due to the timing of our use and/or payment of amounts recorded as prepaid assets with our CROs. During 2024, we continued to incur costs related to our Phase 1B trial for NGC-Cap and, we made a prepayment to the CRO for our Phase 2 trial for NGC-Cap as we began the trial.

As we continue our development of NGC-Cap and evaluate the other NGC drug in our portfolio, we anticipate our research and development efforts and ongoing general and administrative costs will continue to generate negative cash flows from operating activities for the foreseeable future. As we continue our Phase 2 clinical trial for NGC-Cap in 2025, we anticipate our clinical trial costs will increase when compared to prior periods since activities in 2024 were primarily related to the completion of our Phase 1B trial and setup of our Phase 2 trial for NGC-Cap.

Net cash provided by financing activities

During the six months ended June 30, 2025, as described in Note 2, we sold a cumulative 15,340,972 shares of common stock, pre-funded warrants to purchase up to 20,709,700 shares of common stock, accompanying Series A Warrants to purchase up to 8,050,672 shares of our common stock and Series B Warrants to purchase up to 4,025,336 shares of common stock in the January PO and common accompanying warrants to purchase up to 28,000,000 shares of common stock in the June PO. We also received $100,000 from the exercise of warrants to purchase 400,000 shares of common stock sold in the June PO. We used cash classified as financing activities of approximately $10,000 to pay income taxes owed on stock-based compensation, and $3,000 for payments owed under a financing lease obligation.

During the six months ended June 30, 2024, we sold 476,000 shares of common stock, pre-funded warrants to purchase up to 1,079,555 shares of common stock in lieu of shares of common stock, all of which were exercised into shares of our common stock, and warrants to purchase up to 1,555,555 shares of our common stock pursuant to a public offering for net proceeds of $6.3 million. We also used cash classified as financing activities of $12,000 to pay income taxes owed on stock-based compensation, $8,600 for the settlement of a stock award and $2,300 for payments owed under a financing lease obligation.

Liquidity

At June 30, 2025, we had cash and cash equivalents totaling $6.9 million. Based on our current business plans, we believe these funds, together with the $2.4 million in gross proceeds we received in August 2025, will satisfy our capital needs into the first quarter of 2026. However, absent additional funding, our current cash and cash equivalents will not be sufficient to fund our planned operations for a period of one year or more after the date that these condensed consolidated financial statements were available to be issued based on the timing and amount of our projected net loss from continuing operations and the related amount of cash to be used in operating activities during that period of time. Our ability to execute our longer-term operating plans, including future preclinical studies and clinical trials for our portfolio of drugs depend on our ability to obtain additional funding from the sale of equity and/or debt securities, a strategic transaction or other funding transactions.

We have incurred losses since inception, currently devoting substantially all our efforts toward research and development of our next generation cancer therapy drug product candidates, including conducting clinical trials and providing general and administrative support for these operations, and have an accumulated deficit of $94.0 million at June 30, 2025. During the six months ended June 30, 2025, we generated a net loss of $6.8 million and used $5.0 million in net cash for operating activities from continuing operations. To date, none of our drug candidates have been approved for sale, and therefore we have not generated any product revenue and do not expect positive cash flow from operations in the foreseeable future. We will continue to be dependent upon equity and/or debt financing until we are able to generate positive cash flows from its operations.

On January 29, 2025, we sold 1,030,972 shares of common stock, pre-funded warrants to purchase up to 7,019,700 shares of common stock, and accompanying Series A Warrants to purchase up to 8,050,672 shares of our common stock and Series B Warrants to purchase up to 4,025,336 shares of common stock for net proceeds of $4.4 million, after deducting placement agent fees and offering-related expenses. On June 18, 2025, we sold 14,310,000 shares of common stock, pre-funded warrants to purchase up to 13,690,000 shares of common stock, and accompanying common warrants to purchase up to 28,000,000 shares of common stock for net proceeds of $6.2 million, after deducting placement agent fees and offering-related expenses. On August 4, 2025, we entered into a Securities Purchase Agreement with an accredited investor and sold 5,467,181 shares for $1.3 million in gross proceeds. We also sold 4,597,612 shares for $1.1 million in gross proceeds under our ATM agreement. Following these investments, we are exploring options to pursue a cryptocurrency treasury strategy.

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

Contractual Obligations and Commitments

There have been no significant changes to the contractual obligations reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024.

Off Balance Sheet Arrangements

At June 30, 2025, we did not have any off-balance sheet arrangements.

Critical Accounting Policies and Use of Estimates

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

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

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

Recently Issued Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

At June 30, 2025, management, with the participation of the Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on the evaluation of its disclosure controls and procedures, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at June 30, 2025 to provide reasonable assurance that information required to be disclosed in our reports under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2025 that have materially affected, or are reasonably likely to materially affect the Company's internal control over financial reporting.

Part II. Other Information

Item 1. Legal Proceedings

On May 7, 2024, the Company received notification from Elion purporting to terminate the license agreement by and between the Company and Elion as a result of the Company's alleged breach thereof. The Company believes that Elion's claims are without merit and disputes that the license agreement has been validly terminated. On July 5, 2024, the Company filed a complaint in the Commercial Division of the Supreme Court of the State of New York, New York County seeking monetary damages, declaratory judgement and injunctive relief. On August 14, 2024, the Company received Elion's answer and counterclaims. On October 10, 2024, the Company filed its response to Elion's counterclaims. The Company intends to enforce its rights under the license agreement and will pursue such other remedies as it determines are appropriate. The discovery phase of the matter has commenced.

On December 3, 2024, Jason Assad and Marc Gyimesi, two of the investors in our February 2021 private offering, filed a lawsuit that has been assigned to the Commercial Division of the Supreme Court of the State of New York, New York County alleging fraud and negligent misrepresentation in connection therewith regarding alleged company communication and statements and are seeking monetary damages. In addition to being an investor, Mr. Assad was a former investor relations and communications consultant to the Company from September 1, 2021 through June 30, 2024. On April 25, 2025, the Company filed a motion to dismiss the complaint in its entirety. The motion is fully submitted to the court and is awaiting decision. The discovery phase of the matter has commenced.

We intend to vigorously defend ourselves in these lawsuits and cannot at this time predict the likely outcome of any litigation, reasonably determine either the probability of a material adverse result or any estimated range of potential exposure, or reasonably determine how these matters or any future matters might impact our business, our financial condition, or our results of operations, although such impact, including the costs of defense, as well as any judgments or indemnification obligations, among other things, could be materially adverse to us.

Item 1A. Risk Factors

Except as set forth below, there have been no material changes to our risk factors as described in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2024.

Disruptions at the FDA and other government agencies could hinder new or modified products from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and other government agencies to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, staffing cuts, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. The ability of the FDA and other government agencies to properly administer their functions is highly dependent on the levels of government funding and the ability to fill key leadership appointments, among various factors.

Recent actions by the United States federal government have caused concern in the industry that the FDA will experience staffing reductions and budget cuts. In addition, some senior FDA employees with responsibility for regulation of drugs and biologics have already resigned from the FDA. There are also reports that the United States federal government intends to request Congress to reduce FDA funding in upcoming budgets. Such funding cuts may also delay the development and approval of our products.

Nasdaq may delist our securities from trading on its exchange which could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.

Our securities are currently listed on Nasdaq. If Nasdaq delists our securities from trading on its exchange, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity with respect to our securities;
- a determination that shares of our common stock are "penny stock" which will require brokers trading in our shares to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our shares;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

On February 4, 2025, we received a deficiency letter from the Nasdaq Listing Qualifications Department (the "Staff") notifying us that, for the last 30 consecutive business days, the closing bid price for the Company's common stock has been below the minimum $1.00 per share required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) ("Rule 5550(a)(2)"). As a result, the Company is not in compliance with the $1.00 minimum bid price requirement for the continued listing on the Nasdaq Capital Market. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company had been given 180 calendar days, or through August 4, 2025, to regain compliance with Rule 5550(a)(2). Nasdaq has indicated that they will review our Form 10-Q for the six months ended June 30, 2025 before making a final determination regarding our extension request.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as "covered securities." Because our common stock is listed on Nasdaq, our securities are covered securities. If we are no longer listed on Nasdaq, our securities would not be covered securities and we would be subject to regulation in each state in which our securities are offered.

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

During the quarter ended June 30, 2025, we issued a total 50,000 shares of common stock to RedChip Companies, Inc. in connection with a consulting agreement. The shares were issued pursuant to exemptions from the registration requirements of the Securities Act of 1933, as amended, in reliance on Section 4(a)(2) of the Securities Act, Rule 701 promulgated under the Securities Act or Regulation D promulgated under the Securities Act, relating to transactions by an issuer not involving a public offering. All of the foregoing securities are deemed restricted securities for purposes of the Securities Act.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

During the three months ended June 30, 2025, none of our directors or officers adopted or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

SEC Ref. No.	Title of Document
4.1	Form of Common Warrant (incorporated by reference to Exhibit 4.1 to Form 8-K filed June 18, 2025)
4.2	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.2 to Form 8-K filed June 18, 2025)
4.3	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.2 to Form 8-K filed June 18, 2025)
10.1	Binding Term Sheet by and between Processa Pharmaceuticals and Intact Therapeutics (incorporated by reference to Exhibit 10.1 to Form 8-K filed June 17, 2025)
10.2	Form of Securities Purchase Agreement, dated June 17, 2025, by and between Processa Pharmaceuticals, Inc. and each of the Purchasers (as defined therein) (incorporated by reference to Exhibit 10.1 to Form 8-K filed June 18, 2025)
10.3	Amendment No. 1 to License Agreement with Yuhan Corporation (incorporated by reference to Exhibit 10.1 to Form 8-K filed June 30, 2025)
10.4	Termination of Licensing Agreement dated June 27, 2025 (incorporated by reference to Exhibit 10.1 to Form 8-K filed July 1, 2025)
10.5	Form of Securities Purchase Agreement, dated August 4, 2025, by and between Processa Pharmaceuticals, Inc. and the Purchaser (as defined therein) (incorporated by reference to Exhibit 10.1 to Form 8-K filed August 7, 2025)
31.1*	Rule 153-14(a) Certification by Principal Executive Officer
31.2*	Rule 153-14(a) Certification by Principal Financial Officer
32.1*++	Section 1350 Certification of Principal Executive Officer and Principal Financial Officer
99.1	XBRL Files
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

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

SIGNATURES

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

PROCESSA PHARMACEUTICALS, INC.

By: */s/ George Ng*
George Ng
Chief Executive Officer
(Principal Executive Officer)
Dated: August 7, 2025

By: */s/ Russell Skibsted*
Russell Skibsted
Chief Financial Officer
(Principal Financial and Accounting Officer)
Dated: August 7, 2025

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 six months ended June 30, 2025;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant at, and for, the periods presented in this report;

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

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

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

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

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

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

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

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

By: */s/ George Ng*
George Ng
Chief Executive Officer
(Principal Executive Officer)
Date: August 7, 2025

Exhibit 31.2

CERTIFICATION

I, Russell Skibsted, 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 six months ended June 30, 2025;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant at, and for, the periods presented in this report;

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

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

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

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

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

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

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

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

By: */s/ Russell Skibsted*
Russell Skibsted
Chief Financial Officer
(Principal Financial and Accounting Officer)
Date: August 7, 2025

Exhibit 32.1

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

Solely for the purposes of complying with 18 U.S.C. §1350, I, the undersigned Chief Executive Officer of Processa Pharmaceuticals, Inc. (the "Company"), hereby certify, to the best of my knowledge, that the quarterly report on Form 10-Q of the Company for the quarter ended June 30, 2025 (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: August 7, 2025

Solely for the purposes of complying with 18 U.S.C. §1350, I, the undersigned Chief Financial Officer of Processa Pharmaceuticals, Inc. (the "Company"), hereby certify, to the best of my knowledge, that the quarterly report on Form 10-Q of the Company for the quarter ended June 30, 2025 (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/ Russell Skibsted*
Russell Skibsted
Chief Financial Officer
(Principal Financial and Accounting Officer)
Date: August 7, 2025