

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, 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)

|                                                                                                                   |                                                           |
|-------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|
| <b>Delaware</b><br>(State or other jurisdiction of<br>incorporation or organization)                              | <b>45-1539785</b><br>(IRS Employer<br>Identification No.) |
| <b>601 21<sup>st</sup> Street, Suite 300</b><br><b>Vero Beach, FL</b><br>(Address of principal executive offices) | <b>32960</b><br>(Zip Code)                                |

**(772) 453-2899**  
(Registrant’s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the 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 (§232.405 of this chapter) 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 an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

|                         |                                     |                           |                                     |
|-------------------------|-------------------------------------|---------------------------|-------------------------------------|
| Large accelerated filer | <input type="checkbox"/>            | Accelerated filer         | <input type="checkbox"/>            |
| Non-accelerated filer   | <input checked="" type="checkbox"/> | Smaller reporting company | <input checked="" type="checkbox"/> |
|                         |                                     | Emerging growth company   | <input type="checkbox"/>            |

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 November 3, 2025 was 56,644,223.

PROCESSA PHARMACEUTICALS, INC.  
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**Part I: Financial Information**

**Item 1: Financial Statements**

Processa Pharmaceuticals, Inc.  
Condensed Consolidated Balance Sheets

|                                                                                                                                                                                                          | September 30, 2025<br>(unaudited) | December 31, 2024   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|---------------------|
| <b>ASSETS</b>                                                                                                                                                                                            |                                   |                     |
| <b>Current Assets</b>                                                                                                                                                                                    |                                   |                     |
| Cash and cash equivalents                                                                                                                                                                                | \$ 6,308,420                      | \$ 1,191,325        |
| Prepaid expenses and other                                                                                                                                                                               | 278,342                           | 687,829             |
| Total Current Assets                                                                                                                                                                                     | 6,586,762                         | 1,879,154           |
| <b>Non-current Assets</b>                                                                                                                                                                                |                                   |                     |
| Prepaid expenses                                                                                                                                                                                         | 993,701                           | 1,274,442           |
| Property and equipment, net                                                                                                                                                                              | 4,113                             | 5,016               |
| Right-of-use assets, net                                                                                                                                                                                 | -                                 | 70,677              |
| <b>Total Assets</b>                                                                                                                                                                                      | <b>\$ 7,584,576</b>               | <b>\$ 3,229,289</b> |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>                                                                                                                                                              |                                   |                     |
| <b>Current Liabilities</b>                                                                                                                                                                               |                                   |                     |
| Current maturities of lease liability                                                                                                                                                                    | \$ -                              | \$ 73,020           |
| Accounts payable                                                                                                                                                                                         | 727,172                           | 880,880             |
| Accrued expenses                                                                                                                                                                                         | 1,023,806                         | 578,731             |
| Total Current Liabilities                                                                                                                                                                                | 1,750,978                         | 1,532,631           |
| <b>Non-current Liabilities</b>                                                                                                                                                                           |                                   |                     |
| Non-current lease liability                                                                                                                                                                              | -                                 | 487                 |
| <b>Total Liabilities</b>                                                                                                                                                                                 | <b>1,750,978</b>                  | <b>1,533,118</b>    |
| <b>Commitments and Contingencies</b>                                                                                                                                                                     |                                   |                     |
|                                                                                                                                                                                                          | -                                 | -                   |
| <b>Stockholders' Equity</b>                                                                                                                                                                              |                                   |                     |
| Preferred stock, par value \$0.0001, 1,000,000 shares authorized; no shares issued or outstanding at September 30, 2025 or December 31, 2024                                                             | -                                 | -                   |
| Common stock, par value \$0.0001, 100,000,000 shares authorized; 52,867,926 issued and 52,862,926 outstanding at September 30, 2025; and 3,707,628 issued and 3,702,628 outstanding at December 31, 2024 | 5,287                             | 371                 |
| Additional paid-in capital                                                                                                                                                                               | 103,552,406                       | 89,214,999          |
| Treasury stock, 5,000 shares, at cost                                                                                                                                                                    | (300,000)                         | (300,000)           |
| Accumulated deficit                                                                                                                                                                                      | (97,424,095)                      | (87,219,199)        |
| <b>Total Stockholders' Equity</b>                                                                                                                                                                        | <b>5,833,598</b>                  | <b>1,696,171</b>    |
| <b>Total Liabilities and Stockholders' Equity</b>                                                                                                                                                        | <b>\$ 7,584,576</b>               | <b>\$ 3,229,289</b> |

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<br>September 30, |                       | Nine Months Ended<br>September 30, |                       |
|------------------------------------------------------------------------------------------------------------|-------------------------------------|-----------------------|------------------------------------|-----------------------|
|                                                                                                            | 2025                                | 2024                  | 2025                               | 2024                  |
| Operating Expenses                                                                                         |                                     |                       |                                    |                       |
| Research and development expenses                                                                          | \$ 1,661,646                        | \$ 2,287,525          | \$ 5,696,691                       | \$ 5,556,694          |
| General and administrative expenses                                                                        | 1,827,197                           | 1,137,328             | 4,589,925                          | 3,759,781             |
| Operating Loss                                                                                             | (3,488,843)                         | (3,424,853)           | (10,286,616)                       | (9,316,475)           |
| Other Income, net                                                                                          | 52,270                              | 40,150                | 81,720                             | 195,065               |
| Net Loss                                                                                                   | <u>\$ (3,436,573)</u>               | <u>\$ (3,384,703)</u> | <u>\$ (10,204,896)</u>             | <u>\$ (9,121,410)</u> |
| Net Loss per Common Share - Basic and Diluted                                                              | <u>\$ (0.07)</u>                    | <u>\$ (1.03)</u>      | <u>\$ (0.41)</u>                   | <u>\$ (3.13)</u>      |
| Weighted Average Common Shares Used to Compute Net Loss<br>Applicable to Common Shares - Basic and Diluted | <u>47,525,522</u>                   | <u>3,275,998</u>      | <u>24,838,859</u>                  | <u>2,909,941</u>      |

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           | Treasury Stock |                     | Accumulated            |                     |
|--------------------------------------------------------------------------|------------------|---------------|----------------------|----------------|---------------------|------------------------|---------------------|
|                                                                          | Shares           | Amount        | Paid-In<br>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        |
| Stock-based compensation                                                 | 26,010           | 3             | 154,188              | -              | -                   | -                      | 154,191             |
| Shares issued in connection with capital raise, net of transaction costs | 374,190          | 37            | 931,254              | -              | -                   | -                      | 931,291             |
| Shares withheld to pay income taxes on stock-based compensation          | (2,139)          | -             | (3,658)              | -              | -                   | -                      | (3,658)             |
| Net loss                                                                 | -                | -             | -                    | -              | -                   | (3,384,703)            | (3,384,703)         |
| Balance, September 30, 2024                                              | <u>3,271,944</u> | <u>\$ 327</u> | <u>\$ 88,510,949</u> | <u>(5,000)</u> | <u>\$ (300,000)</u> | <u>\$ (84,490,491)</u> | <u>\$ 3,720,785</u> |

  

|                                                                                                | Common Stock      |                 | Additional            | Treasury Stock |                     | Accumulated            |                     |
|------------------------------------------------------------------------------------------------|-------------------|-----------------|-----------------------|----------------|---------------------|------------------------|---------------------|
|                                                                                                | Shares            | Amount          | Paid-In<br>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                                                                         | <u>40,289,356</u> | <u>\$ 4,029</u> | <u>\$ 100,390,701</u> | <u>(5,000)</u> | <u>\$ (300,000)</u> | <u>\$ (93,987,522)</u> | <u>\$ 6,107,208</u> |
| Stock-based compensation                                                                       | 1,385             | -               | 303,047               | -              | -                   | -                      | 303,047             |
| Shares issued in connection with capital raise and warrant exercises, net of transaction costs | 12,577,215        | 1,258           | 2,858,658             | -              | -                   | -                      | 2,859,916           |
| Net loss                                                                                       | -                 | -               | -                     | -              | -                   | (3,436,573)            | (3,436,573)         |
| Balance, September 30, 2025                                                                    | <u>52,867,956</u> | <u>\$ 5,287</u> | <u>\$ 103,552,406</u> | <u>(5,000)</u> | <u>\$ (300,000)</u> | <u>\$ (97,424,095)</u> | <u>\$ 5,833,598</u> |

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, |                     |
|-------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|---------------------|
|                                                                                                                                           | 2025                            | 2024                |
| <b>Cash Flows From Operating Activities</b>                                                                                               |                                 |                     |
| Net Loss                                                                                                                                  | \$ (10,204,896)                 | \$ (9,121,410)      |
| Adjustments to reconcile net loss to net cash used in operating activities:                                                               |                                 |                     |
| Depreciation                                                                                                                              | 903                             | 481                 |
| Non-cash lease expense for right-of-use assets                                                                                            | 70,677                          | 64,700              |
| Stock-based compensation                                                                                                                  | 734,009                         | 474,466             |
| Net changes in operating assets and liabilities:                                                                                          |                                 |                     |
| Prepaid expenses and other                                                                                                                | 690,228                         | (1,020,375)         |
| Operating lease liability                                                                                                                 | (66,905)                        | (61,776)            |
| Accounts payable                                                                                                                          | (153,708)                       | 400,093             |
| Due from related parties                                                                                                                  | -                               | (39)                |
| Accrued expenses                                                                                                                          | 445,075                         | 266,539             |
| Net cash used in operating activities                                                                                                     | <u>(8,484,617)</u>              | <u>(8,997,321)</u>  |
| <b>Cash Flows From Investing Activities</b>                                                                                               |                                 |                     |
| Payment of finance lease obligation                                                                                                       | -                               | (3,244)             |
| Net cash used in investing activities                                                                                                     | <u>-</u>                        | <u>(3,244)</u>      |
| <b>Cash Flows From Financing Activities</b>                                                                                               |                                 |                     |
| Net proceeds from the sale of stock and exercise of warrants                                                                              | 13,618,718                      | 7,213,721           |
| Shares withheld to pay taxes on stock-based compensation                                                                                  | (10,404)                        | (15,590)            |
| Settlement of stock award                                                                                                                 | -                               | (8,561)             |
| Payment of finance lease obligation                                                                                                       | (6,602)                         | (3,738)             |
| Net cash provided by financing activities                                                                                                 | <u>13,601,712</u>               | <u>7,185,832</u>    |
| <b>Net Increase (Decrease) in Cash and Cash Equivalents</b>                                                                               | 5,117,095                       | (1,814,733)         |
| <b>Cash and Cash Equivalents - Beginning of Period</b>                                                                                    | 1,191,325                       | 4,706,197           |
| <b>Cash and Cash Equivalents - End of Period</b>                                                                                          | <u>\$ 6,308,420</u>             | <u>\$ 2,891,464</u> |
| <b>Supplemental Cash Flow Information:</b>                                                                                                |                                 |                     |
| Cash paid for interest                                                                                                                    | \$ 5,589                        | \$ -                |
| Cash paid for income taxes                                                                                                                | \$ -                            | \$ -                |
| <b>Non-Cash Financing Activities</b>                                                                                                      |                                 |                     |
| Issuance of 5,000 shares of common stock in connection with a licensing agreement which had previously been recorded as a due to licensor | <u>\$ -</u>                     | <u>\$ 189,000</u>   |
| New right-of-use asset                                                                                                                    | \$ -                            | \$ 11,804           |
| Financing lease liability                                                                                                                 | -                               | (11,804)            |
| Net                                                                                                                                       | <u>\$ -</u>                     | <u>\$ -</u>         |

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

Processa Pharmaceuticals, Inc.  
Notes to Condensed Consolidated Financial Statements  
(Unaudited)

**Note 1 – Organization and Summary of Significant Accounting Policies**

*Organization*

Processa Pharmaceuticals, Inc. (“Processa,” “we” or the “Company”) is a publicly listed 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.

On August 7, 2025 we announced that we were evaluating corporate cryptocurrency treasury strategies as part of our broader financial and growth objectives. We are in the process of developing and implementing a corporate cryptocurrency treasury strategy, including acquiring and holding stablecoin, and other cryptocurrencies, tokens, and rights of a similar nature (collectively referred to as, “Digital Assets”), using cash reserves that exceed working capital requirements, and from time to time, subject to market conditions, issuing equity or debt securities or engaging in other capital raising transactions with the objective of using the proceeds to purchase Digital Assets. We believe that strategic engagement with emerging financial technologies, including select Digital Assets with potential yield-generating capabilities, may offer novel avenues to diversify our capital base and enhance financial flexibility, while providing an opportunity for long-term value creation. One of the potential benefits of a cryptocurrency treasury strategy is the potential of blockchain-based assets to contribute meaningfully to the funding of our clinical development programs.

*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 \$97.4 million at September 30, 2025. During the nine months ended September 30, 2025, we generated a net loss of \$10.2 million and used \$8.5 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 September 30, 2025, all Pre-Funded Warrants from both public offerings were exercised. During the nine months ended September 30, 2025, we also received approximately \$728,000 for the exercise of warrants to purchase 2,912,422 shares of common stock. As of November 3, 2025, warrants to purchase an additional 3,781,267 of common stock were exercised for approximately \$945,000.

On August 4, 2025, we entered into a Securities Purchase Agreement with an accredited investor and sold 5,467,181 shares of our common stock for \$1.2 million in net proceeds. In August 2025, we also sold 4,597,612 shares for \$1.0 million in net proceeds under our ATM program.

At September 30, 2025, we had cash and cash equivalents totaling \$6.3 million. Based on our current business plans, we believe these funds, together with the \$945,000 in gross proceeds we received subsequent to September 30, 2025 from the exercise of previously issued stock purchase warrants, 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. Subject to market conditions, we also expect to issue equity or debt securities or engage in other capital raising transactions with the objective of using the proceeds to purchase Digital Assets. We believe that strategic engagement with emerging financial technologies, including select Digital Assets with potential yield-generating capabilities, may offer returns that can contribute meaningfully to the funding of our clinical development programs. However, 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 September 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 September 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 – Digital Assets and Stablecoin Holdings**

As of September 30, 2025, we held Digital Assets, consisting of USD-backed stablecoins, totaling \$350,000, which are recorded as cash and cash equivalents on the consolidated balance sheet. These stablecoins are held in custodial wallets with third-party service providers and are redeemable on a one-to-one basis for U.S. dollars. We classify these stablecoins as cash equivalents under ASC 230, as they are fully collateralized by U.S. dollar reserves, readily convertible to known amounts of cash, and subject to insignificant risk of changes in value.

Subsequent to September 30, 2025, we transferred an additional \$500,000 to our third-party custodial wallet and we now hold a total of \$850,000 in Digital Assets.

## **Note 3 – Stockholders' Equity**

### ***Common Stock***

During the nine months ended September 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 offering”) 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 September 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 offering”). 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. Warrants to purchase 2,912,422 shares of common stock for \$728,000 and all pre-funded warrants were exercised during the nine months ended September 30, 2025;
- On August 4, 2025, we sold 5,467,181 shares of our common stock at an offering price of \$0.23 per share to an accredited investor for net proceeds of \$1.2 million, after deducting transaction-related expenses. We also sold 4,597,612 shares of our common stock for net proceeds of \$1.0 million under our ATM agreement;
- 76,189 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.

As of November 3, 2025, warrants to purchase an additional 3,781,267 of common stock were exercised for approximately \$945,000.

## **Note 4 – Stock-based Compensation**

On June 19, 2019, our stockholders approved, and we adopted, the Processa Pharmaceuticals Inc. 2019 Omnibus Equity Incentive Plan (the “2019 Plan”). The 2019 Plan allows us, under the direction of our Board of Directors or a committee thereof, to make grants of stock options, restricted and unrestricted stock and other stock-based awards to employees, including our executive officers, consultants and directors. On July 18, 2025, shareholders approved to increase the shares available under the 2019 Plan, and it now provides for the aggregate issuance of 10,800,000 shares of our common stock. At September 30, 2025, we have 10,357,420 shares available for future grants.

### Stock Compensation Expense

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

|                            | Three Months Ended<br>September 30, |                   | Nine Months Ended<br>September 30, |                   |
|----------------------------|-------------------------------------|-------------------|------------------------------------|-------------------|
|                            | 2025                                | 2024              | 2025                               | 2024              |
| Research and development   | \$ 110,239                          | \$ 54,018         | \$ 165,572                         | \$ 130,722        |
| General and administrative | 192,808                             | 100,173           | 568,434                            | 343,744           |
| Total                      | <u>\$ 303,047</u>                   | <u>\$ 154,191</u> | <u>\$ 734,006</u>                  | <u>\$ 474,466</u> |

### Stock Options

No stock options to purchase shares of common stock were forfeited or expired during the nine months ended September 30, 2025. At September 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 2.9 years. At September 30, 2025, we did not have any unrecognized stock-based compensation expense related to our granted stock options.

On October 1, 2025, we granted stock options to purchase 3,267,000 shares of our common stock to our directors and officers with an exercise price of \$0.198 that expire on October 1, 2035. These stock options vest 33.3% on October 1, 2026 and the remaining 66.7% vest ratably monthly for the following two years.

### Restricted Stock Units

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

|                                   | Number of<br>shares | Weighted-average<br>grant-date fair<br>value per share |
|-----------------------------------|---------------------|--------------------------------------------------------|
| Outstanding at January 1, 2025    | 383,636             | \$ 19.87                                               |
| Granted                           | -                   | -                                                      |
| Forfeited                         | (27,547)            | 53.08                                                  |
| Vested and issued                 | (76,189)            | 60.84                                                  |
| Outstanding at September 30, 2025 | 279,900             | 5.45                                                   |
| Vested and unissued               | (253,836)           | 5.16                                                   |
| Unvested at September 30, 2025    | <u>26,064</u>       | <u>\$ 8.23</u>                                         |

At September 30, 2025, unrecognized stock-based compensation expense of approximately \$108,000 for RSUs is expected to be fully recognized over a weighted average period of 0.8 years. The unrecognized expense excludes approximately \$12,000 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.

On October 1, 2025, we granted RSUs for the future issuance of 1,089,000 shares of common stock to our directors and officers. These RSUs vest 33.3% on October 1, 2026 and the remaining 66.7% vest monthly for the following two years.

## Warrants

During the nine months ended September 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 offering. 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 offering. During the nine months ended September 30, 2025, warrants to purchase 2,912,422 shares of common stock from the June offering, and all pre-funded warrants from the January offering and June offering, were exercised.

At September 30, 2025, we had outstanding exercisable stock purchase warrants for the purchase of 40,059,370 shares with a weighted average exercise price of \$0.63 and a weighted average remaining contractual life of 4.2 years. We did not have any unrecognized stock-based compensation expense related to our granted stock purchase warrants at September 30, 2025.

As of November 3, 2025, warrants to purchase an additional 3,781,267 of common stock were exercised for approximately \$945,000.

## **Note 5 – Net Loss per Share of Common Stock**

### Net Loss Per Share

Basic net loss per share is computed by dividing our net loss available to common 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 nine months ended September 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 nine months ended September 30, 2025 and 2024 was as follows:

|                                                                          | Three Months Ended<br>September 30, |                  | Nine Months Ended<br>September 30, |                  |
|--------------------------------------------------------------------------|-------------------------------------|------------------|------------------------------------|------------------|
|                                                                          | 2025                                | 2024             | 2025                               | 2024             |
| <b>Basic and diluted net loss per share:</b>                             |                                     |                  |                                    |                  |
| Net loss available to common stockholders                                | \$ (3,436,573)                      | \$ (3,384,703)   | \$ (10,204,896)                    | \$ (9,121,410)   |
| Weighted average number of common shares-basic and diluted               | 47,525,522                          | 3,275,998        | 24,838,859                         | 2,909,941        |
| Basic and diluted net loss per share                                     | <u>\$ (0.07)</u>                    | <u>\$ (1.03)</u> | <u>(0.41)</u>                      | <u>\$ (3.13)</u> |
|                                                                          | Three Months Ended<br>September 30, |                  | Nine Months Ended<br>September 30, |                  |
|                                                                          | 2025                                | 2024             | 2025                               | 2024             |
| Weighted-average number of common shares outstanding – basic and diluted | 47,202,268                          | 3,118,029        | 24,611,454                         | 2,767,647        |
| Weighted-average number of vested RSUs– basic and diluted                | 323,254                             | 157,969          | 227,405                            | 142,294          |
| Weighted-average number of common shares-basic and diluted               | <u>47,525,522</u>                   | <u>3,275,998</u> | <u>24,838,859</u>                  | <u>2,909,941</u> |

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:

|                                   | September 30,     |                  |
|-----------------------------------|-------------------|------------------|
|                                   | 2025              | 2024             |
| Stock options                     | 2,747             | 2,747            |
| Restricted stock units (unvested) | 26,064            | 240,349          |
| Warrants for common stock         | 40,059,370        | 1,775,784        |
| Total                             | <u>40,088,181</u> | <u>2,018,880</u> |

## 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 \$24,000 and \$33,000 of reimbursements from CorLyst during the three months ended September 30, 2025 and 2024, respectively, and \$84,000 and \$83,000 for the nine months ended September 30, 2025 and 2024. At September 30, 2025, we included approximately \$19,000 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 nine months ended September 30, 2025 and 2024:

|                                                             | Three Months Ended<br>September 30, |                     | Nine Months Ended<br>September 30, |                     |
|-------------------------------------------------------------|-------------------------------------|---------------------|------------------------------------|---------------------|
|                                                             | 2025                                | 2024                | 2025                               | 2024                |
| Preclinical, clinical trial and other costs                 | \$ 1,204,017                        | \$ 1,850,812        | \$ 4,543,279                       | \$ 4,143,813        |
| Research and development personnel expense <sup>(1)</sup>   | 457,629                             | 436,713             | 1,153,412                          | 1,412,881           |
| General and administrative personnel expense <sup>(2)</sup> | 855,089                             | 493,144             | 2,157,979                          | 1,457,941           |
| Administrative and facilities expense <sup>(3)</sup>        | 972,108                             | 644,184             | 2,431,946                          | 2,301,840           |
| Other income, net                                           | (52,270)                            | (40,150)            | (81,720)                           | (195,065)           |
| Total                                                       | <u>\$ 3,436,573</u>                 | <u>\$ 3,384,703</u> | <u>\$ 10,204,896</u>               | <u>\$ 9,121,410</u> |

(1) Research and development personnel costs include employee stock-based compensation expense of \$110,239 and \$54,018 for the three months ended September 30, 2025 and 2024, respectively, and \$165,572 and \$130,722 for the nine months ended September 30, 2025 and 2024, respectively.

(2) General and administrative personnel costs include employee stock-based compensation expense of \$192,808 and \$53,725 for the three months ended September 30, 2025 and 2024, respectively, and \$438,118 and \$132,905 for the nine months ended September 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 – Option to License 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. On October 11, 2025, Intact opted to extend the due diligence deadline by an additional one hundred and twenty (120) days for a 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 September 30, 2025, we are contractually obligated to pay up to \$12.0 million of future services under the agreements with the CROs. Our actual contractual obligations will also vary depending on the progress and results of the remaining clinical trials.

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

Forward Looking Statements

This Quarterly Report on Form 10-Q contains “forward-looking statements” that reflect, when made, the Company’s expectations or beliefs concerning future events that involve risks and uncertainties. Forward-looking statements frequently are identified by the words “believe,” “anticipate,” “expect,” “estimate,” “intend,” “project,” “will be,” “will continue,” “will likely result,” or other similar words and phrases. Similarly, statements herein that describe the Company’s objectives, plans or goals also are forward-looking statements. Actual results could differ materially from those projected, implied or anticipated by the Company’s forward-looking statements. Some of the factors that could cause actual results to differ include: our limited 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; our ability to successfully execute our cryptocurrency treasury strategy, fluctuations in the market price of Digital Assets that we may acquire, the risks of holding Digital Assets on our balance sheet, our limited operating history in the cryptocurrency business, risks associated with the current or future regulation of Digital Assets; 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](http://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

Processa Pharmaceuticals, Inc. (“Processa,” “we” or the “Company”) is a publicly listed clinical-stage biopharmaceutical company. We are 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 Drug Pipeline

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 status of our drug pipeline is set forth below:

| Oncology                                        | Target / Indications                                                                 | Preclinical                                                                                                                                  | Phase 1 | Phase 2 | Phase 3 |
|-------------------------------------------------|--------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|---------|---------|---------|
| NGC-Cap<br>(PCS6422)<br><i>Capecitabine</i>     | Breast, Colorectal, Hepatocellular, Pancreatic, Gastric, & Other Solid Tumor Cancers | Phase 2 In Process for Metastatic Breast Cancer          |         |         |         |
| NGC-Iri<br>(PCS11T)<br><i>Irinotecan</i>        | Lung, Pancreatic, Ovarian, Colorectal, Gastric, Cervical & Other Cancers             | Predinical                                               |         |         |         |
| Non-Oncology                                    | Target / Indications                                                                 | Preclinical                                                                                                                                  | Phase 1 | Phase 2 | Phase 3 |
| PCS12852<br><i>Binding Term Sheet</i>           | Gastroparesis, Constipation Disorders                                                | Phase 2a Completed                                       |         |         |         |
| PCS499<br><i>Seeking Partner for Nephrology</i> | Primary Glomerular Disease (eg, FSGS, Membranous Nephropathy), Diabetic Nephropathy  | Phase 2b Completed for Ulcerative Necrobiosis Lipoidica  |         |         |         |

## Recent Developments

### *Cryptocurrency Treasury Strategy*

On August 7, 2025, we announced that we were evaluating corporate cryptocurrency treasury strategies as part of our broader financial and growth objectives. We believe that strategic engagement with emerging financial technologies, including select Digital Assets with potential yield-generating capabilities, may offer novel avenues to diversify our capital base and enhance financial flexibility, while providing an opportunity for long-term value creation. One of the potential benefits of a cryptocurrency treasury strategy is the potential of blockchain-based assets to contribute meaningfully to the funding of our clinical development programs.

As of November 3, 2025, we owned \$850,000 in Digital Assets. Subject to market conditions, we expect to issue equity or debt securities or engage in other capital raising transactions with the objective of using the proceeds to purchase Digital Assets.

### *Clinical Pipeline Update*

Over the last year 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 proteinuria as an endpoint 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. We plan to meet with the FDA in the fourth quarter of 2025 to further define the design of the Phase 3 study.

### *Public Offerings*

As described in Note 2, during the nine months ended September 30, 2025, we raised net proceeds of \$10.6 million in public offerings in January and June through the sale of 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 our January offering and common accompanying warrants to purchase up to 28,000,000 shares of common stock in our June offering. During the nine months ended September 30, 2025, all pre-funded warrants, and warrants to purchase 2,912,422 shares of common stock, 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 5HT4 irreversible agonist that is Phase 2B ready as potentially the first meaningful treatment for 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. On October 11, 2025, Intact opted to extend the due diligence deadline by an additional one hundred and twenty (120) days for a fee of \$30,000. There can be no assurance that we will enter into a license agreement with Intact.

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 PCS3117 (NGC-Gem). On October 24, 2025, the termination period ended and all rights were reassigned to Opus.

**Results of Operations**

*Comparison of the three and nine months ended September 30, 2025 and 2024*

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

|                                     | Three Months Ended<br>September 30, |                       |              | Nine Months Ended<br>September 30, |                       |             |
|-------------------------------------|-------------------------------------|-----------------------|--------------|------------------------------------|-----------------------|-------------|
|                                     | 2025                                | 2024                  | Change       | 2025                               | 2024                  | Change      |
| <b>Operating Expenses</b>           |                                     |                       |              |                                    |                       |             |
| Research and development expenses   | \$ 1,661,646                        | \$ 2,287,525          | \$ (625,879) | \$ 5,696,691                       | \$ 5,556,694          | \$ 139,997  |
| General and administrative expenses | 1,827,197                           | 1,137,328             | 689,869      | 4,589,925                          | 3,759,781             | 830,144     |
| <b>Operating Loss</b>               | (3,488,843)                         | (3,424,853)           |              | (10,286,616)                       | (9,316,475)           |             |
| <b>Other Income, net</b>            | 52,270                              | 40,150                | 12,120       | 81,720                             | 195,065               | (113,345)   |
| <b>Net Loss</b>                     | <u>\$ (3,436,573)</u>               | <u>\$ (3,384,703)</u> | (51,870)     | <u>\$ (10,204,896)</u>             | <u>\$ (9,121,410)</u> | (1,083,486) |

*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 nine-month periods for the periods ended September 30, 2025 and 2024 were as follows:

|                                                | Three Months Ended<br>September 30, |                     | Nine Months Ended<br>September 30, |                     |
|------------------------------------------------|-------------------------------------|---------------------|------------------------------------|---------------------|
|                                                | 2025                                | 2024                | 2025                               | 2024                |
| Research and development salaries and benefits | \$ 457,629                          | \$ 436,713          | \$ 1,153,412                       | \$ 1,412,881        |
| Preclinical, clinical trial and other costs    | 1,204,017                           | 1,850,812           | 4,543,279                          | 4,143,813           |
| <b>Total</b>                                   | <u>\$ 1,661,646</u>                 | <u>\$ 2,287,525</u> | <u>\$ 5,696,691</u>                | <u>\$ 5,556,694</u> |

The \$626,000 decrease in research and development expenses during the three months ended September 30, 2025 was due to a decrease in preclinical, clinical trial and other costs for the Phases 1 and 2 clinical trial for NGC-Cap when compared to the same period in 2024. During the same period in 2024, we incurred an additional \$529,000 in costs related to the IND/initiation of our Phase 2 trial for NGC-Cap, and an additional \$136,000 in costs related to our Phase 1 trial for NGC-Cap. The decrease was offset by a net \$39,000 increase in costs primarily related to PCS499 as we continue to evaluate the potential clinical safety and efficacy to target primary glomerular diseases (PGDs). We also had an increase in salaries and benefits as we increased salary rates for our R&D C-suite executives.

During the nine months ended September 30, 2025, we had a \$215,000 increase in preclinical, clinical trial, and other costs due to our ongoing Phase 2 trial of NGC-Cap and evaluation of PCS499 for PGDs, when compared to the same period in 2024. This increase was offset by a \$259,000 decrease in salaries and other payroll-related costs due to our decrease in staff in 2025.

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, 2025 increased by approximately \$681,000 to \$1.8 million from \$1.1 million for the three months ended September 30, 2024. This increase was due primarily to increases in salaries and other-payroll related costs of \$214,000, primarily due to salary increases to our C-suite executives; an increase of \$150,000 in investment management fees related to our recent digital asset transaction; an increase in employee stock-based compensation of \$139,000; an increase of \$165,000 in professional fees, and net increases in taxes and other miscellaneous office expenses of \$13,000. We received approximately \$9,000 less in reimbursements from CorLyst during the three months ended September 30, 2025 when compared to the same period in 2024.

Our general and administrative expenses for the nine months ended September 30, 2025 increased by approximately \$831,000 to \$4.6 million from \$3.8 million for the nine months ended September 30, 2024. This increase was due primarily to increases in salaries and other-payroll related costs of \$396,000, primarily due to salary increases to our C-suite executives; an increase of \$150,000 in investment management fees related to our recent cryptocurrency transaction; an increase in employee stock-based compensation of \$305,000; and net increases in taxes and other miscellaneous office expenses of \$31,000. The increases were offset by decreases in office expenses of \$38,000; insurance expenses of \$6,000; professional fees of \$5,000; and travel expenses of \$2,000. We received approximately \$1,000 more in reimbursements from CorLyst during the nine months ended September 30, 2025 when compared to the same period in 2024.

#### *Other Income*

Other income for the three and nine months ended September 30, 2025 includes our portion of the Intact payment of \$8,000 along with dividend/interest income of approximately \$52,000 and \$40,000 for the three months ended September 30, 2025 and 2024, respectively, and approximately \$74,000 and \$195,000 for the nine months ended September 30, 2025 and 2024, respectively.

### Income Tax Benefit

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

### Cash Flows

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

|                                 | Nine months ended<br>September 30, |                |
|---------------------------------|------------------------------------|----------------|
|                                 | 2025                               | 2024           |
| Net cash (used in) provided by: |                                    |                |
| Operating activities            | \$ (8,484,617)                     | \$ (8,997,321) |
| Investing activities            | -                                  | (3,244)        |
| Financing activities            | 13,601,712                         | 7,185,832      |
| Net increase (decrease) in cash | \$ 5,117,095                       | \$ (1,814,733) |

#### Net cash used in operating activities

We used net cash in our operating activities of \$8,484,617 and \$8,997,321 during the nine months ended September 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 that 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 clinical trials for NGC-Cap, 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 used in investing activities

We did not use cash in investing activities during the nine months ended September 30, 2025. During the nine months ended September 30, 2024, we used net cash in our investing activities of \$3,244 to purchase property and equipment.

#### Net cash provided by financing activities

During the nine months ended September 30, 2025, as described in Note 3, we received net proceeds of \$12.9 million from selling a cumulative 25,405,765 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 our January offering and common accompanying warrants to purchase up to 28,000,000 shares of common stock in our June offering. We also received \$728,000 from the exercise of warrants to purchase 2,912,422 shares of common stock sold in our June offering. We used net cash in our financing activities of approximately \$10,000 to pay income taxes owed on stock-based compensation, and \$7,000 for payments owed under a financing lease obligation.

During the nine months ended September 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 sold 374,190 shares of common stock under our ATM Offering for net proceeds of approximately \$931,000. We used net cash in financing activities of approximately \$16,000 to pay income taxes owed on stock-based compensation, approximately \$9,000 for the settlement of a stock award, and approximately \$4,000 for payments owed under a financing lease obligation.

## Liquidity

At September 30, 2025, we had cash and cash equivalents totaling \$6.3 million. Based on our current business plans, we believe these funds, together with the \$945,000 in gross proceeds we received subsequent to September 30, 2025 from the exercise of stock purchase warrants, 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 \$97.4 million at September 30, 2025. During the nine months ended September 30, 2025, we generated a net loss of \$10.2 million and used \$8.5 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 our operations.

Capital markets activity during the nine months ended September 30, 2025 included the following:

- 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 \$1.2 million in net proceeds.
- On August 4, 2025, we also sold 4,597,612 shares for \$1.0 million in net proceeds under our ATM agreement.
- We also received approximately \$728,000 for the exercise of warrants to purchase 2,912,422 shares of common stock from the June offering. As of November 3, 2025, warrants to purchase an additional 3,781,267 of common stock were exercised for approximately \$945,000.

During the nine months ended September 30, 2025, we entered into a Master Services Agreement with Cube Operations LLC (“Cube”) to manage our Digital Assets and transferred \$500,000 into a crypto wallet managed for us by Cube, of which \$350,000 was invested in USDC, and the remaining \$150,000 was used for initial account setup and maintenance costs. Subsequent to September 30, 2025, we transferred an additional \$500,000 to our crypto wallet and we now hold a total of \$850,000 in Digital Assets.

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. Subject to market conditions, we also expect to issue equity or debt securities or engage in other capital raising transactions with the objective of using the proceeds to purchase Digital Assets. We believe that strategic engagement with emerging financial technologies, including select Digital Assets with potential yield-generating capabilities, may offer returns than can contribute meaningfully to the funding of our clinical development programs. However, 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 September 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.

Except as disclosed herein, 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 September 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 September 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 September 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 judgment 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 was decided in September 2025. The court dismissed two of the three counts of the complaint (for constructive fraud and negligent misrepresentation) and dismissed that part of the remaining cause of action for fraud to the extent that it related to the retention of Plaintiffs' investment (leaving only the portion of the claim in which Plaintiffs allege they were fraudulently induced to invest in the Company in February 2021). The court also dismissed all claims against Patrick Lin and George Ng. Processa's and David Young's answer was submitted during October 2025. 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). On August 7, 2025, Nasdaq granted us an additional 180 calendar days, or through February 2, 2026, to regain compliance.

On September 11, 2025, our stockholders approved a reverse stock split of our common stock in order to attempt to regain compliance with Rule 5550(a)(2). We may be unable to complete the Reverse Stock Split, and even if we do, we may still be unable to meet the minimum bid price requirement and we may be unable to meet other applicable Nasdaq Capital Market listing requirements.

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.

## **Risks Related to our Cryptocurrency Treasury Strategy**

***We have recently announced exploring a new Cryptocurrency Treasury Strategy, and we may be unable to successfully implement it.***

On August 7, 2025, we announced that we are exploring a new cryptocurrency treasury strategy. While we have begun investing in Digital Assets, there is no assurance that we will be able to successfully implement this new strategy or operate Digital Asset-related activities at the scale or profitability currently anticipated. Successfully implementing this strategy may present organizational and infrastructure challenges, and we may not be able to fully implement or realize the intended benefits of our strategy. There can be no assurance that we will be successful in implementing our new business strategy. In addition, moving to a new business strategy may result in a loss of established efficiency, which may have a negative impact on our business. We may also face an increased amount of competition as we attempt to expand and grow our business, which may negatively impact our results of operations, cash flows and financial condition.

Digital Assets have also historically experienced, and are expected to continue to experience, high price volatility. Such price fluctuations are likely to influence our financial results and the market price of our common stock. Our financial results and the market price of our common stock would be adversely affected, and our business and financial condition would be negatively impacted, if the price of Digital Assets we hold decreases substantially, resulting in a loss of capital.

Our Digital Assets are or will be held in custody accounts. We could have a high concentration of Digital Assets in one location or with one custodian, which may be prone to losses arising out of hacking, loss of passwords, comprised access credentials, malware, or cyberattacks. Security breaches and cyberattacks are of particular concern with respect to our Digital Asset holdings. Digital Assets and the entities that provide services to participants in the Digital Asset ecosystem have been, and may in the future be, subject to security breaches, cyberattacks, or other malicious activities. We and our custodians likely will not have sufficient amounts of insurance to recover our full investment. Accordingly, a successful security breach or cyberattack could result in a partial or total loss of our Digital Assets in a manner that may not be covered by insurance or the liability provisions of the custody agreements with the custodians who hold our Digital Assets.

***We could be subject to legal or regulatory action, including fines, in the event the Securities Exchange Commission, a foreign regulatory authority, or a court were to determine that a digital asset held by us is a “security” under applicable laws.***

While all investments entail a risk of loss of capital, investments in Digital Assets should be considered substantially more speculative and significantly more likely to result in a loss, including a total loss of capital, than many other forms of investment. The investment characteristics of Digital Assets differ from those of many traditional currencies, commodities, and securities. A particular Digital Asset’s status as a “security” in any relevant jurisdiction is subject to a high degree of uncertainty, and if we are unable to properly characterize a Digital Asset, we may be subject to regulatory scrutiny, investigations, fines, and other penalties, which may adversely affect our business, results of operations and/or financial condition.

***Digital Assets are novel assets, and are subject to significant legal, commercial, regulatory, and technical uncertainty.***

Digital Assets are relatively novel and are subject to rapidly evolving legal, commercial, regulatory, and technical landscapes. Because the application of federal and state securities and other applicable laws, regulations, and rules (“Applicable Law”) remain unsettled in several material respects, there is substantial risk that a governmental or regulatory authority could adopt or interpret Applicable Law in a manner that adversely affects the price of Digital Assets. Increased regulatory scrutiny may result in additional costs for us and may require our management team to devote increased time and attention to regulatory matters, change aspects of our business, or result in limits on the utility of Digital Assets. Moreover, the regulatory landscape with respect to Digital Assets is rapidly changing and we may be required to comply with any new laws, regulations, or interpretations, which may result in heightened regulatory and compliance related costs, litigation, regulatory investigations, and enforcement or other actions. Adverse changes to, or our failure to comply with Applicable Law may have an adverse effect on our reputation, brand, our business, operating results, and financial condition. Further, if any of our Digital Assets are determined to constitute a security for purposes of U.S. federal securities laws, the additional regulatory restrictions imposed by such a determination could adversely affect the market price of the Digital Assets we hold.

The U.S. federal government, states, regulatory agencies, and foreign countries may also enact new laws and regulations, or pursue regulatory, legislative, enforcement or judicial actions, that could materially impact the price of Digital Assets or the ability of individuals or institutions such as us to own or transfer Digital Assets. Regulatory authorities have been evolving in their approach to Digital Assets. It is not possible to predict whether, or when, any of these developments will lead to U.S. Congress granting additional authorities to the SEC or other regulators, or whether any other federal, state, or foreign legislative bodies will take any similar actions. It is also not possible to predict the nature of any such additional authorities, how additional legislation or regulatory oversight might impact the ability of Digital Asset markets to function or the willingness of financial and other institutions to continue to provide services to the Digital Assets industry, nor how any new regulations or changes to existing regulations might impact the value of Digital Assets generally and any Digital Assets we hold specifically. The consequences of increased regulation of Digital Assets and Digital Asset-related activities could adversely affect the market price of any Digital Assets we hold and in turn adversely affect the market price of our common stock.

Moreover, the risks of engaging in a cryptocurrency treasury strategy are relatively novel and have created, and could continue to create, complications due to the lack of experience that third parties have with companies engaging in such a strategy, such as increased costs of director and officer liability insurance or the potential inability to obtain such coverage on acceptable terms in the future.

The liquidity of Digital Assets may also be impacted to the extent that changes in Applicable Laws and regulatory requirements negatively impact the ability of exchanges and trading venues to provide services for Digital Assets. The evolving regulatory landscape creates uncertainty for the Company, as new regulations or changes to existing regulations could materially and adversely affect our business operations, financial condition, and results of operations. The effect of any future regulatory change on the Company is impossible to predict, but such change could be substantial and adverse.

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

On August 4, 2025, we entered into a Securities Purchase Agreement with an accredited investor, pursuant to which we sold 5,467,181 shares of our common stock for \$1.2 million in net proceeds. On April 1, 2025, we issued a total 50,000 shares of common stock to RedChip Companies, Inc. in connection with a consulting agreement. Both the shares issued to the accredited investor and the shares issued to RedChip Companies, Inc. 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 September 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                                                                                                                                                                                                                                          |
|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3.1          | <a href="#">Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of Processa Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 to the registrant's Form 8-K.A filed September 16, 2025)</a>              |
| 10.1         | <a href="#">Amended and Restated Processa Pharmaceuticals, Inc. 2019 Omnibus Incentive Plan (incorporated by reference to Exhibit 4.1 to the registrant's Form S-8 filed September 22, 2025)</a>                                                           |
| 10.2         | <a href="#">Form of Securities Purchase Agreement, dated August 4, 2025, by and between Processa Pharmaceuticals and the Purchaser (as defined therein) (incorporated by reference to Exhibit 10.1 to the registrant's Form 8-K filed August 14, 2025)</a> |
| 31.1*        | <a href="#">Rule 153-14(a) Certification by Principal Executive Officer</a>                                                                                                                                                                                |
| 31.2*        | <a href="#">Rule 153-14(a) Certification by Principal Financial Officer</a>                                                                                                                                                                                |
| 32.1*++      | <a href="#">Section 1350 Certification of Principal Executive Officer and Principal Financial Officer</a>                                                                                                                                                  |
| 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: November 6, 2025

By: /s/ Russell Skibsted  
Russell Skibsted  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

Dated: November 6, 2025

## 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.;
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 Rules 13a-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: November 6, 2025

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## 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.;
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 Rules 13a-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: November 6, 2025

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**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, 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: November 6, 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 September 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: November 6, 2025

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