October 30, 2024

Processa Pharmaceuticals

Processa Pharmaceuticals Reports Third Quarter Business Highlights and Financial Results

First patient dosed in Phase 2 clinical trial with NGC-Cap for metastatic breast cancer

Positive data from preclinical studies support NGC-Iri's ability to deliver more SN-38 to tumors compared with either irinotecan or Onivyde®

HANOVER, Md., Oct. 30, 2024 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (Nasdaq: PCSA) (Processa or the Company), a clinical-stage pharmaceutical company focused on developing the next generation of chemotherapeutic drugs with improved efficacy and safety, provides updates on its product pipeline, upcoming milestones and business activities, and reports financial results for the three and nine months ended September 30, 2024.

"We continued to make progress with our programs as we further demonstrate the potential benefits of our oncology therapeutics," said George Ng, Chief Executive Officer of Processa Pharmaceuticals. "Our NGC-Cap Phase 2 clinical trial in metastatic breast cancer is underway with the first patient dosed. As this is an open-label trial, we anticipate sharing initial data in the second half of 2025. Additionally, we reported positive findings from preclinical studies that support NGC-Iri's potential for improved efficacy and a superior side effect profile compared with the commonly used FDA-approved chemotherapy drugs irinotecan and Onivyde®. We are pleased with our progress and remain committed to improving the lives of people with cancer."

Key Program Updates

Processa is focused on developing next-generation chemotherapies (NGC) by improving widely used U.S. Food and Drug Administration (FDA)-approved drugs to extend cancer patients' survival and/or improve their quality of life. This is achieved by altering how drugs are metabolized and/or distributed in the body, including how they reach cancer cells. In addition, Processa utilizes its Regulatory Science Approach, including the principles associated with FDA's Project Optimus Oncology initiative, in the development of its NGC drug products to achieve a more favorable benefit-risk profile.

- *PCS6422: Next-Generation Capecitabine (NGC-Cap)*
  - NGC-Cap is a combination of PCS6422 and capecitabine, which is the oral prodrug of the cancer drug 5-fluorouracil (5-FU). PCS6422 alters the metabolism of 5-FU, resulting in more 5-FU distributed to cancer cells.
  - Earlier this month, the first patient was dosed in a Phase 2 clinical trial (NCT06568692) evaluating NGC-Cap for the treatment of advanced or metastatic breast cancer. The Phase 2 study is a global, multicenter, open-label, adaptive-design trial comparing two different doses of NGC-Cap to FDA-approved

monotherapy capecitabine in approximately 60 to 90 patients. The trial is designed to evaluate the safety-efficacy profile of NGC-Cap versus monotherapy capecitabine, to determine the potential optimal dosage regimens of NGC-Cap as required by the FDA Project Optimus Initiative and to evaluate the possibility of personalizing NGC-Cap therapy. The Company expects to announce interim data from this trial in the second half of 2025.

- *PCS3117: Next-Generation Gemcitabine (NGC-Gem)*
    - NGC-Gem is an oral analog of gemcitabine (Gemzar®) that is converted to its active metabolite by a different enzyme system, with potential for a positive response in gemcitabine patients including those inherently resistant to or who acquire resistance to gemcitabine.
    - Processa is evaluating the potential of NGC-Gem in patients with pancreatic and other cancers, as well as ways to identify patients who are more likely to respond to NGC-Gem than gemcitabine alone. The Company is requesting a meeting with the FDA to discuss potential trial designs, including implementation of the Project Optimus initiative.

- *PCS11T: Next-Generation Irinotecan (NGC-Iri)*
    - NGC-Iri is an analog of SN-38, the active metabolite of irinotecan, that is expected to have an improved safety-efficacy profile in every type of cancer where irinotecan is currently used.
    - As announced in August, two studies in a human melanoma xenograft mouse model measured SN-38 in tumors, plasma and other tissues following administration of NGC-Iri, irinotecan and Onivyde®, the liposomal formulation of irinotecan. One study compared NGC-Iri with irinotecan, and the other compared irinotecan with Onivyde®. The results found that mice administered NGC-Iri had greater accumulation of SN-38 in the tumor compared with other tissues and that less SN-38 accumulated in non-cancer tissues, which could lead to improved efficacy with a more favorable adverse event profile compared with irinotecan and Onivyde®.
    - The Company is currently evaluating the manufacturing process and potential sites for NGC-Iri. In addition, Processa is defining the potential paths to approval, which includes defining the target patient population and the type of cancer, and expects to conduct IND-enabling toxicology studies in 2025.

Third Quarter Financial Results

Research and development expenses for the third quarter of 2024 were $2.3 million, compared with $1.2 million for the third quarter of 2023. General and administrative expenses for the third quarter of 2024 were $1.1 million, compared with $1.0 million for the third quarter of 2023.

The net loss for the third quarter of 2024 was $3.4 million, or $1.03 per share, compared with the net loss for the third quarter of 2023 of $2.1 million, or $1.54 per share. All per-share figures reflect a 1-for-20 reverse stock split that was effective as of January 22, 2024.

Cash and cash equivalents were $2.9 million as of September 30, 2024.

About Processa Pharmaceuticals, Inc.

Processa is a clinical-stage pharmaceutical company focused on developing the Next Generation Chemotherapy (NGC) drugs with improved safety and efficacy. Processa's NGC drugs are modifications of existing FDA-approved oncology therapies resulting in an alteration of the metabolism and/or distribution of these drugs while maintaining the existing mechanisms of killing the cancer cells. By combining its novel oncology pipeline with proven cancer-killing active molecules and its Regulatory Science Approach, Processa's strategy is to develop more effective therapy options with improved tolerability for cancer patients through an efficient regulatory path.

For more information, visit our website at www.processapharma.com.

Forward-Looking Statements

This release contains forward-looking statements. The statements in this press release that are not purely historical are forward-looking statements which involve risks and uncertainties. Actual future performance outcomes and results may differ materially from those expressed in forward-looking statements. Please refer to the documents filed by Processa Pharmaceuticals with the SEC, specifically the most recent reports on Forms 10-K and 10-Q, which identify important risk factors which could cause actual results to differ from those contained in the forward-looking statements.

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[Financial Tables to follow]

PROCESSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share information)
(unaudited)

	September 30, 2024	December 31, 2023
ASSETS		
Current Assets		
Cash and cash equivalents	$ 2,891	$ 4,706

Prepaid expenses and other	1,947	926
Total Current Assets	4,838	5,632
Property and Equipment, net	5	3
Other Assets		
Lease right-of-use assets, net of accumulated amortization	93	146
Security deposit	6	6
Total Other Assets	99	152
Total Assets	$ 4,942	$ 5,787
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Current maturities of lease liabilities	$ 94	$ 84
Accounts payable	712	312
Due to licensor	-	189
Due to related parties	-	-
Accrued expenses	413	146
Total Current Liabilities	1,219	731
Non-current Liabilities		
Non-current lease liabilities	2	67
Total Liabilities	1,221	798
Commitments and Contingencies	-	-
Stockholders' Equity		
Common stock, par value $0.0001, 100,000,000 shares authorized: 3,271,944 issued and 3,266,944 outstanding at September 30, 2024; and 1,291,000 issued and 1,286,000 outstanding at December 31, 2023	-	-
Additional paid-in capital	88,511	80,658
Treasury stock at cost — 5,000 shares at September 30, 2024 and December 31, 2023	(300)	(300)
Accumulated deficit	(84,490)	(75,369)
Total Stockholders' Equity	3,721	4,989
Total Liabilities and Stockholders' Equity	$ 4,942	$ 5,787

PROCESSA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating Expenses				
Research and development	$ 2,288	$ 1,152	$ 5,557	$ 4,479
General and administrative	1,137	1,016	3,760	4,509
Operating Loss	(3,425)	(2,168)	(9,317)	(8,988)
Other Income (Expense)				
Interest income, net	40	86	195	271
Net Loss	$ (3,385)	$ (2,082)	$ (9,122)	$ (8,717)
Net Loss per Common Share - Basic and Diluted	$ (1.03)	$ (1.54)	$ (3.13)	$ (6.81)
Weighted Average Common Shares Used to Compute Net Loss Applicable to Common Shares - Basic and Diluted	3,275,998	1,350,188	2,909,941	1,279,298

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Source: Processa Pharmaceuticals, Inc.