August 28, 2024

Processa Pharmaceuticals Provides Product Pipeline and Financial Update

Phase 2 trial with NGC-Cap in breast cancer underway

NGC-Cap Phase 1b trial demonstrated a favorable safety profile with preliminary anti-tumor activity

Preclinical studies demonstrated NGC-Iri delivers more cancer-killing SN-38 molecules to tumor than either irinotecan or Onivyde®

HANOVER, Md., Aug. 28, 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 six months ended June 30, 2024.

“We made significant progress in advancing our three development programs year-to-date, with a particular focus on our lead candidate NGC-Cap,” said George Ng, Chief Executive Officer of Processa Pharmaceuticals. “Upon receiving FDA clearance of our NGC-Cap IND application, we initiated a Phase 2 clinical trial in metastatic breast cancer. We look forward to enrolling patients in this multicenter, open-label study and expect to have an initial data readout in mid-2025.”

Key Program Updates
Processa is focused on developing next-generation chemotherapies (NGC) by improving widely used U.S. Food and Drug Administration (FDA)-approved oncology drugs to extend a patient’s 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.

Processa’s updated corporate presentation, including its product pipeline, is available on the company’s website.

- *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.
  - In July 2024, the FDA cleared the Company’s Investigational New Drug application (IND) application for a Phase 2 trial with NGC-Cap in metastatic or advanced breast cancer. Subsequently, Processa initiated the Phase 2 study (NCT06568692) , which 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. As agreed to with the FDA, the breast cancer indication should lead to a more efficient development program while providing a greater likelihood of approval.
    - The NGC-Cap Phase 1b study evaluated ascending doses of capecitabine when combined with a fixed dose of PCS6422 in patients with advanced, relapsed or refractory progressive gastrointestinal cancer. These patients had to relapse from or fail all other treatments. NGC-Cap demonstrated greater 5-FU exposure and lower fluoro-beta-alanine (FBAL) exposure with a better or similar side-effect profile compared with monotherapy capecitabine, as well as preliminary anti-tumor activity. In all evaluable patients who received one dose of PCS6422 and seven days of capecitabine, partial responses or stable disease was observed in 66.7% (8 out of 12) of patients with progression-free survival of approximately 5 to 11 months across these patients.
    - In April 2024, Processa presented an abstract at the American Association for Cancer Research (AACR) Annual Meeting 2024, including new Phase 1b data on NGC-Cap in patients with advanced, relapsed or refractory progressive gastrointestinal cancer. NGC-Cap demonstrated 5-10 times greater 5-FU exposure than monotherapy capecitabine at a significantly lower dose, along with a favorable safety profile. As such, NGC-Cap holds potential for improved efficacy in more patients due to a higher distribution of 5-FU to cancer cells. Further, the extremely low exposure of FBAL, the primary catabolite formed from the metabolism of 5-FU, across all NGC-Cap doses resulted in fewer catabolite-related side effects, with only one patient having Grade 1 hand-foot-syndrome, an FBAL side effect that often requires dose modifications.

- *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 plans to meet with the FDA in late 2024 or early 2025 to discuss potential trial designs, including implementation of the Project Optimus initiative.

- *PCS11T: Next-Generation Irinotecan (NGC-Iri)*

    - NGC-Iri is an analog of SN38, the active metabolite of irinotecan, that is expected to have an improved safety-efficacy profile in every type of cancer where irinotecan is used.
    - As announced earlier this month, 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®.

- In April 2024, Processa presented a second abstract at AACR titled “Application of phase 1 and pre-clinical data to assist in determining the optimal dosage regimen for cancer drugs using the principles of Project Optimus.” This abstract describes the FDA Project Optimus Initiative and draft optimal dosage regimen (ODR) guidance, which requires an ODR justified by a dose-ranging efficacy and safety study, as opposed to a maximum tolerated dose approach. Processa provided NGC-Iri preclinical study examples to demonstrate how the shape of the exposure-response relationships for safety and efficacy can be determined from these pre-clinical studies. By better understanding the exposure-response relationship earlier in the development process, defining the recommended dose range and optimal dosage regimen becomes easier in an efficacy-safety study, in a pivotal study, and for FDA approval.
- 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 include defining the target patient population and the type of cancer, with the expectation to conduct IND-enabling toxicology studies in 2025.

Second Quarter Financial Results

Research and development expenses for the second quarter of 2024 were $1.7 million, unchanged from the second quarter of 2023. General and administrative expenses for the second quarter of 2024 were $1.4 million, compared with $1.0 million for the second quarter of 2023, primarily due to an increase in professional fees.

The net loss for the second quarter of 2024 was $3.0 million, or $1.01 per share, compared with the net loss for the second quarter of 2023 of $2.6 million, or $1.94 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 $5.6 million as of June 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)

	June 30, 2024	December 31, 2023
ASSETS		
Current Assets		
Cash and cash equivalents	$ 5,571	$ 4,706
Prepaid expenses and other	1,907	926
Total Current Assets	7,478	5,632
Property and Equipment, net	2	3
Other Assets		
Lease right-of-use assets, net of accumulated amortization	115	146
Security deposit	6	6
Total Other Assets	121	152
Total Assets	$ 7,601	$ 5,787
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Current maturities of lease liabilities	$ 93	$ 84
Accounts payable	953	312
Due to licensor	-	189

Due to related parties	-	-
Accrued expenses	505	146
Total Current Liabilities	1,551	731
Non-current Liabilities		
Non-current lease liabilities	26	67
Total Liabilities	1,577	798
Commitments and Contingencies	-	-
Stockholders' Equity		
Common stock, par value $0.0001, 100,000,000 shares authorized: 2,873,883 issued and 2,868,883 outstanding at June 30, 2024; and 1,291,000 issued and 1,286,000 outstanding at December 31, 2023	1	-
Additional paid-in capital	87,429	80,658
Treasury stock at cost — 5,000 shares at June 30, 2024 and December 31, 2023	(300)	(300)
Accumulated deficit	(81,106)	(75,369)
Total Stockholders' Equity	6,024	4,989
Total Liabilities and Stockholders' Equity	$ 7,601	$ 5,787

PROCESSA PHARMACEUTICALS, INC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating Expenses				
Research and development expenses	$ 1,730	$ 1,688	$ 3,270	$ 3,343
General and administrative expenses	1,352	1,026	2,622	3,477
Operating Loss	(3,082)	(2,714)	(5,892)	(6,820)
Other Income (Expense), net	72	102	155	185
Net Operating Loss Before Income Tax Benefit	(3,010)	(2,612)	(5,737)	(6,635)
Income Tax Benefit	-	-	-	-

Net Loss	$ (3,010)	$ (2,612)	$ (5,737)	$ (6,635)
Net Loss per Common Share - Basic and Diluted	$ (1.01)	$ (1.94)	$ (2.11)	$ (5.34)
Weighted Average Common Shares Used to Compute Net Loss Applicable to Common Shares - Basic and Diluted	2,983,283	1,346,808	2,724,903	1,243,475

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Source: Processa Pharmaceuticals, Inc.