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

FORM 8-K
CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): October 2, 2024

Commission file number 001-39531

PROCESSA PHARMACEUTICALS, INC.
(Exact name of Registrant as Specified in its Charter)

Delaware	**45-1539785**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**

7380 Coca Cola Drive, Suite 106, Hanover, Maryland 21076
(Address of Principal Executive Offices, Including Zip Code)

(443) 776-3133
(Registrant's Telephone Number, Including Area Code)

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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: Par value $.0001	PCSA	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

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

Item 8.01. Other Event.

On October 2, 2024, Processa Pharmaceuticals, Inc. (the "Company") issued a press release announcing the dosing of a patient in a Phase 2 clinical trial of NGC-Cap which satisfies the diligence milestone under the Company's license agreement for PCS6422 with Elion Oncology, Inc. Multiple trial sites have been established and are now recruiting patients. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference.

The Company has now timely satisfied all of the Company's diligence obligations, as enumerated in Article V, in its license agreement with Elion Oncology, Inc. The Company has previously referred to the Condition Precedent Satisfaction Date for its diligence obligations as October 2, 2024, but has determined that such statements should have been October 6, 2024 which is the anniversary of the funding event that triggers the calculation of the Condition Precedent Satisfaction Date.

Safe Harbor Statement

Information provided in this Current Report on Form 8-K contain forward-looking statements. The statements in this Current Report on Form 8-K 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. Although the Company believes the expectations reflected in any forward-looking statements are based on reasonable assumptions, the Company can give no assurance these expectations will be attained, and it is possible actual results may differ materially from those indicated by these forward-looking statements due to a variety of risks and uncertainties. Please refer to the documents filed by the Company 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.

These forward-looking statements are made only as of the date hereof, and the Company undertakes no obligation to update or revise the forward-looking statements, whether

as a result of new information, future events or otherwise, except as and to the extent required by law.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Exhibit Description
99.1	Press Release dated October 2, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

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, hereunto duly authorized, on October 2, 2024.

PROCESSA PHARMACEUTICALS, INC.
Registrant

By: */s/ George Ng*
George Ng
Chief Executive Officer

Exhibit 99.1

Processa Pharmaceuticals

Processa Pharmaceuticals Announces First Patient Dosed in Phase 2 Clinical Trial of NGC-Cap in Metastatic Breast Cancer

- Phase 2 trial is an adaptive designed randomized study comparing NGC-Cap to monotherapy capecitabine
- Results from this Phase 2 trial will evaluate NGC-Cap's safety-efficacy profile and help to define the optimal dosage regimen in patients with metastatic breast cancer

HANOVER, Md., October 2, 2024 – 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, today announced that the first patient has been dosed in a Phase 2 clinical trial evaluating NGC-Cap for the treatment of advanced or metastatic breast cancer.

"Dosing the first patient in this Phase 2 trial is a significant step in the development of NGC-Cap as a more effective and better tolerated treatment than widely used capecitabine and 5-FU," stated David Young, PharmD, Ph.D., President of Research and Development at Processa. "We expect this Phase 2 trial to build upon NGC-Cap's positive Phase 1b findings and we look forward to announcing the results from our interim analysis of this Phase 2 trial in mid-2025."

The Phase 2 trial (NCT06568692) is a global multicenter, open-label, adaptive designed safety-efficacy trial comparing two different doses of NGC-Cap to FDA-approved monotherapy capecitabine in approximately 60 to 90 patients with advanced or metastatic breast cancer. 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.

To date, three clinical trial sites, including some with multiple clinical locations, have received institutional review board approval to participate in this study and are recruiting patients. Processa plans to activate approximately 30 sites worldwide.

Breast cancer is the second most common cancer and a leading cause of cancer-related death. More than 2 million cases of breast cancer were diagnosed in 2022 with more than 665,000 deaths globally. The five-year survival rate for those diagnosed with metastatic breast cancer is approximately 30%.

About Capecitabine Administered with PCS6422 (NGC-Cap)

NGC-Cap combines the administration of PCS6422, the Company's irreversible dihydropyrimidine dehydrogenase (DPD) enzyme inhibitor, with low doses of capecitabine. Capecitabine is the oral prodrug of 5-fluorouracil (5-FU), and along with 5-FU is among the most widely used chemotherapy drugs, particularly for the treatment of solid tumors. When metabolized (after oral ingestion) it becomes 5-FU in the body, which, in turn, metabolizes to molecules called anabolites that actively kill duplicating cells, such as cancer cells, and to molecules called catabolites that only cause side effects. The presence of the DPD enzyme plays an integral role in the undesirable conversion of 5-FU to catabolites causing side effects while simultaneously decreasing tumor exposure to 5-FU and its cancer-killing anabolites.

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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