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): July 30, 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 July 30, 2024, Processa Pharmaceuticals, Inc., (The "Company") issued a press release announcing FDA clearance of IND application for a Phase 2 clinical trial of NGC-Cap in breast cancer.

Safe Harbor Statement

Information provided in this Current Report on Form 8-K may contain statements relating to current expectations, estimates, forecasts and projections about future events that are "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These forward-looking statements generally relate to the Company's plans, objectives and expectations for compensation matters related to Mr. Skibsted's service as the Company's Chief Financial Officer and Mr. Skibsted's start date. Actual future results may differ materially from those projected as a result of certain risks and uncertainties. For a discussion of such risks and uncertainties, see "Risk Factors" as described in the Company's Annual Report for the year ended December 31, 2023 on Form 10-K filed with the Commission on March 30, 2023, the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2024 filed with the Commission on May 10, 2024, and other reports on file with the Commission.

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.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Exhibit Description
99.1	Press Release announcing FDA clearance of IND application for a Phase 2 clinical trial of NGC-Cap in breast cancer.

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 July 30, 2024.

PROCESSA PHARMACEUTICALS, INC.
Registrant

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

Exhibit 99.1

Processa Pharmaceuticals

Processa Pharmaceuticals Announces FDA Clearance of IND Application for a Phase 2 Clinical Trial of NGC-Cap in Breast Cancer

Open-label Phase 2 trial in breast cancer to begin this quarter

Initial data expected mid-2025

HANOVER, Md., July 30, 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 U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application for Next Generation Capecitabine (NGC-Cap), its lead product candidate. The IND supports the initiation of a Phase 2 clinical trial in patients with advanced or metastatic breast cancer, which is expected to begin enrollment this quarter.

"We are proud to achieve this significant milestone for NGC-Cap and look forward to entering the clinic for the treatment of advanced or metastatic breast cancer, where capecitabine is a standard of care. We previously demonstrated in our Phase 1b study that NGC-Cap is more potent than monotherapy capecitabine, providing up to 5-10 times more 5-fluorouracil exposure to cancer cells. This greater exposure resulted in a greater efficacy, with a safety profile better or similar to existing monotherapy with capecitabine," stated David Young, PharmD, Ph.D., President of Research and Development. "Initial data from the Phase 2 trial are expected mid-2025."

"Although capecitabine is among the most widely used chemotherapy drugs, particularly for the treatment of solid tumors, there remains the need for a more effective chemotherapy treatment with fewer or less-severe side effects," he added. "We believe that NGC-Cap can fulfill this need."

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 disease is approximately 30%.

The Phase 2 study will be 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 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. Processa expects to enroll the first patient into this trial in the third quarter of 2024.

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-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 while simultaneously decreasing tumor exposure to 5-FU and it's anabolites.

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 tract cancer. These patients had to relapse from or fail all other treatments. NGC-Cap demonstrated greater 5-fluorouracil (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.

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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