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): January 19, 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 7.01. Regulation FD Disclosure.

On January 19, 2024, Processa Pharmaceuticals, Inc. (the "Company") issued a press release announcing the expansion of NGC-Cap program into advanced or metastatic breast cancer and that the FDA has agreed that existing data and studies can be used to support the Phase 2 breast cancer trial design.

The information contained in this Item 7.01 and Exhibit 99.1 hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	**Exhibit Description**
99.1	Press release announcing the expansion of NGC-Cap program into advanced or metastatic breast cancer.
104	Cover Page Interactive Data File (formatted as Inline XBRL)

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 January 19, 2024.

PROCESSA PHARMACEUTICALS, INC.
Registrant

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

Exhibit 99.1

Processa Pharmaceuticals

Processa Pharmaceuticals Announces Expansion of NGC-Cap Program into Advanced or Metastatic Breast Cancer

FDA and Processa agree to expand NGC-Cap development into breast cancer providing a more efficient path to approval

FDA agrees that existing data and studies can be used to support the Phase 2 breast cancer trial design

HANOVER, MD, January 19, 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 to improve the efficacy and safety for more patients suffering from cancer, announces it plans to expand the development of Next Generation Capecitabine ("NGC-Cap") into the treatment of advanced or metastatic breast cancer beginning with its next Phase 2 trial. Following the Processa meeting with the FDA, Processa has decided the next NGC-Cap trial would be a Phase 2 trial in breast cancer. This decision was supported through discussions with the FDA where Processa agreed with the FDA that pursuing breast cancer will lead to a more efficient development program while providing a greater likelihood of FDA approval. The FDA stated that the previously generated data in past and existing studies could be used to directly support the Phase 2 trial in breast cancer.

"We believe the pursuit of an advanced or metastatic breast cancer indication for NGC-Cap is a logical progression for Processa as it represents a larger market than colorectal cancer with the potential to differentiate NGC-Cap from the presently approved capecitabine as well as other treatments for breast cancer. The FDA and Processa discussed the advantages and disadvantages of developing NGC-Cap in breast cancer and concluded that the development would be a more efficient and straightforward path to approval with an easier enrolment process for the Phase 2 and 3 trials," said David Young, PharmD, Ph.D., President of Research and Development at Processa. "Capecitabine is already approved as both monotherapy and combination therapy in breast cancer, which contributes to the logic and efficiency of our current direction. In addition, the FDA's agreement that our present data would support a Phase 2 trial in breast cancer makes the expansion seamless. We believe our Phase 2 trial will provide the safety-efficacy data to preliminarily demonstrate the benefit of NGC-Cap over capecitabine and other treatment options."

"Based on this expansion to breast cancer we have identified breast cancer key opinion leaders to join our scientific advisory board, have already determined the Phase 2 study design which we expect to share with the FDA soon, and plan to initiate our Phase 2 study in the third quarter of 2024," concluded Young.

Breast cancer is the most diagnosed cancer, representing approximately 15% of all new cancer patients in 2023. It has a prevalence of more than 3.8 million patients, with nearly 300,000 new diagnoses last year. Over 150,000 women are currently living with advanced or metastatic breast cancer. The NGC-Cap potential market for breast, colorectal and other cancers is greater than 250,000 patients per year.

About Capecitabine Administered with PCS6422 (NGC-Cap)

NGC-Cap combines the administration of PCS6422, the Company's irreversible dihydropyrimidine dehydrogenase (DPD) enzyme inhibitor, with the administration of low doses of the commonly used chemotherapy Capecitabine.

Capecitabine is the oral form of 5-FU and, along with 5-FU, is among the most widely used chemotherapy drugs available, particularly for 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.

PCS6422 is an analog of uracil that irreversibly inhibits DPD. PCS6422 is neither toxic nor active as a single agent in animals at comparable dose levels. However, when administered in combination with Capecitabine or 5-FU, PCS6422 decreases the metabolism of 5-FU to the catabolites that only cause side effects, allowing more of the 5-FU to distribute to cancer cells.

About Processa Pharmaceuticals, Inc.

Processa is a clinical stage pharmaceutical company focused on developing the Next Generation Chemotherapy (NGC) drugs to improve the safety and efficacy of cancer treatment. By combining Processa's novel oncology pipeline with proven cancer-killing active molecules and Processa's Regulatory Science Approach as well as experience in defining Optimal Dosage Regimens for FDA approvals, Processa not only will be providing better therapy options to cancer patients but also increase the probability of FDA approval for its Next Generation Chemotherapy (NGC) drugs following an efficient path to approval. The company's approach to drug development, based on more than 30 years of drug development experience, uses its proven Regulatory Science Approach, including the determination of the Optimal Dosage Regimen using the principles of the FDA's Project Optimus Oncology initiative. Processa's NGC drugs are modifications of existing FDA-approved oncology drugs resulting in an alteration of the metabolism and/or distribution of these FDA-approved drugs while maintaining the existing mechanisms of killing the cancer cells. The advantages of Processa's NGCs are expected to include fewer patients experiencing side effects that lead to dose discontinuation, more significant cancer response, and a greater number of patients —- over 250,000 patients treated each year for each drug —— who will benefit from each NGC drug. Currently under development are three next generation chemotherapy oncology treatments: Next Generation Capecitabine (PCS6422 and capecitabine to treat breast, metastatic colorectal, gastrointestinal, pancreatic, and other cancers), Next Generation Gemcitabine (PCS3117 to treat pancreatic, lung, ovarian, breast, and other cancers), and Next Generation Irinotecan (PCS11T to treat lung, colorectal, gastrointestinal, pancreatic, and other cancers).

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.

For More Information:

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