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 25, 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 Events.

On January 25, 2024, Processa Pharmaceuticals, Inc. (the "Company") issued a press release announcing the successful completion of Phase 1b safety evaluation of NGC-Cap in patients with advanced cancer resulting in recommended Phase 2 doses.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	**Exhibit Description**
99.1	Press release announcing the successful completion of Phase 1B safety evaluation of NGC-Cap in patients with advanced cancer resulting in recommended Phase 2 doses.
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 25, 2024.

PROCESSA PHARMACEUTICALS, INC.
Registrant

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

Exhibit 99.1

Processa Pharmaceuticals Announces Successful Completion of Phase 1b Safety Evaluation of NGC-Cap in Patients with Advanced Cancer Resulting in Recommended Phase 2 Doses

Next Generation Capecitabine (NGC-Cap) provides patients with 2-10 times greater exposure to its 5-FU cancer treatment metabolite than capecitabine administration

NGC-Cap was better tolerated with positive preliminary efficacy results than FDA-approved capecitabine

HANOVER, MD, January 25, 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 the successful completion of the safety tolerability evaluation in its Phase 1b trial of Next Generation Capecitabine ("NGC-Cap"). From the Phase 1b data, two dosage regimens have been selected for the Phase 2 trial. The Phase 2 trial will be in advanced or metastatic breast cancer given FDA's agreement that the Phase 1b data can be used to support the design of the Phase 2 trial in breast cancer.

NGC-Cap is PCS6422 administered in combination with capecitabine, a precursor of the cancer drug 5-FU. PCS6422 is administered as a single dose 12-24 hours prior to receiving seven days of capecitabine followed by seven drug-free days. The NGC-Cap Phase 1b trial evaluated capecitabine doses from 75 mg once a day (QD) to 225 mg twice a day (BID).

The 5-FU drug exposure for the 18 total patients that received NGC-Cap treatment across four different dosing regimens was 2-10 times that of FDA-approved capecitabine. Sixteen of these patients received at least two cycles of NGC-Cap with the other two patients discontinuing treatment before completing two cycles because of progressing disease. Four of the 16 patients are still receiving treatment in the study. At this time, only one of the 16 patients (6%) has experienced a mild case of hand-foot-syndrome (HFS), a side effect associated with the 5-FU metabolite fluoro-beta-alanine (FBAL). This lower incidence of HFS was expected given PCS6422 inhibits the metabolism of 5-FU to FBAL. The 6% incidence of HFS differs from the incidence reported for FDA-approved capecitabine, where greater than 50% of patients on capecitabine developed HFS and greater than 10% of the patients developed severe HFS.

The incidence of myelosuppression in patients on the high dose of NGC-Cap (225 mg BID) is currently approximately 71%, with more severe myelosuppression occurring in approximately 57% of the patients. The overall myelosuppression incidence rate after patients received the high dose of NGC-Cap is comparable to the 80% rate reported in the capecitabine label. As expected, given the greater 5-FU exposure, the incidence rate of more severe myelosuppression after the high dose of NGC-Cap was greater than the 3% rate reported for capecitabine. For the lower NGC-Cap dose of 150 mg BID, which also has a greater 5-FU exposure than capecitabine, the incidence of myelosuppression (33%) and more severe myelosuppression (0%) was lower for NGC-Cap compared to capecitabine.

Although the primary objective of the Phase 1b trial in patients with advanced gastrointestinal (GI) cancer was not to evaluate efficacy, the Phase 1b trial was designed to provide some preliminary data on efficacy. At this time, of the 11 cancer patients receiving one of the two highest doses of NGC-Cap, five have completed an efficacy evaluation at this time, and four of these five patients (or 80%) showed a positive response. One of these four patients had a partial response, and three patients demonstrated stable disease. Two patients receiving the highest dose will potentially become eligible for an efficacy evaluation by the end of the first quarter of 2024. Of the remaining four patients in the two highest doses, two dropped out prior to their evaluation because of disease progression and two dropped out because of side effects.

"Processa is very grateful to the patients and their physicians who participated in this trial and have been instrumental in our reaching these impactful findings. We are encouraged that NGC-Cap in the Phase 1b trial was tolerated better than or similar to the existing FDA-approved capecitabine even though the exposure to NGC-Cap's 5-FU cancer-treating metabolite was 2-10 times that of capecitabine," said David Young, PharmD, Ph.D., President of Research and Development at Processa. "This greater exposure suggests that NGC-Cap can distribute more 5-FU to the cancer cells, potentially forming more cancer-killing metabolites that, in our small number of patients, has shown to improve the cancer-killing effect of NGC-Cap over capecitabine."

"Given the beneficial 5-FU exposure findings, the safety results, and the preliminary efficacy evaluation, we believe that NGC-Cap may be able to provide patients with a better efficacy profile along with fewer side effects than the presently prescribed capecitabine. Assuming this is confirmed in subsequent clinical studies, this would allow us to treat more patients with an NGC-Cap optimal dose rather than having to decrease the dose or discontinue therapy because of the tolerability with approved capecitabine. The data obtained from the Phase 1b trial — together with the feedback from the FDA — have allowed us to develop a Phase 2 and 3 strategy that will likely be more efficient in terms of time and cost as well as lead to a greater likelihood of FDA approval as we expand into advanced or metastatic breast cancer in Phase 2," concluded Dr. Young.

About the Study

This Phase 1b dose-escalation study assessed overall safety, pharmacokinetics, and anti-tumor activity of capecitabine administered in combination with PCS6422 (NGC-Cap) in 18 patients after a single dose of PCS6422 followed 12-24 hours with seven days of capecitabine and seven drug-free days. Patients had advanced GI cancer even after multiple types of treatment. The primary objective was to estimate the recommended Phase 2 dose and the maximum tolerated dose. Patients received a single dose of PCS6422 (40 mg) to inhibit the metabolism of 5-FU followed by seven days of capecitabine (75 mg QD to 225 mg BID) and seven days drug-free for each cycle.

The most common treatment related to adverse events were myelosuppression (e.g., anemia, neutropenia), GI-related adverse events (e.g., vomiting, diarrhea), and mucositis. The maximum number of cycles received across all doses has been 26 cycles with four patients presently still on treatment. At the two highest dosing cohorts, there were four advanced GI cancer patients with disease control responses out of the five patients who 1) received at least two cycles of one of the two highest doses of NGC-cap and 2) had a cancer response evaluation. This includes three patients with stable disease and one patient who had a partial response.

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.

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