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): December 19, 2023

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 December 19, 2023, Processa Pharmaceuticals, Inc. (the "Company") issued a press release providing interim analysis from ongoing Phase 1b trial of Next Generation Capecitabine showing improved safety over Capecitabine.

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 that Processa providing interim analysis from ongoing Phase 1b trial of Next Generation Capecitabine showing improved safety over Capecitabine.
104	Cover Page Interactive Data File (embedded within the iXBRL (Inline eXtensible Business Reporting Language) 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 December 19, 2023.

PROCESSA PHARMACEUTICALS, INC.
Registrant

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

Exhibit 99.1

Processa Pharmaceuticals

Processa Pharmaceuticals Provides Interim Analysis from Ongoing Phase 1b Trial of Next Generation Capecitabine Showing Improved Safety Over Capecitabine

FDA acknowledges that NGC-Cap is a New Chemical Entity given the changes to metabolism and distribution of its major metabolite 5-FU

Interim analysis of the NGC-Cap Phase 1b data shows improved safety, even with 5-FU exposure much greater than that from capecitabine

Company to conduct Fireside Chat at 4:30PM ET on December 20, 2023

HANOVER, MD, December 19, 2023 (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 safety and efficacy for more cancer patients, provides an interim analysis from its Phase 1b study of its Next Generation Capecitabine (NGC-Cap).

"These initial data provide our first confirmatory clinical evidence that NGC-Cap is metabolized differently than capecitabine and, as a result, may offer significant improvements in safety and efficacy over capecitabine, a commonly used chemotherapeutic agent across multiple cancer indications. We are encouraged to be near completion of the Phase 1b trial as we make preparations for a subsequent Phase 2 trial with NGC-Cap," said David Young, Pharm.D., Ph.D., President of Research and Development at Processa.

Thus far in the Phase 1b study, patients have received doses of NGC-Cap ranging from 75 mg once a day to 225 mg twice a day, significantly less than the 1,600 mg to 2,500 mg twice a day dose administered for FDA-approved capecitabine. More importantly, these much lower doses for NGC-Cap result in 5-FU (5-fluorouracil, the main metabolite of capecitabine that further metabolizes into desirable cancer-killing molecules called anabolites and undesirable molecules called catabolites that cause unwanted side effects) exposure up to 10 times greater than the higher FDA-approved capecitabine doses due to NGC-Cap's unique metabolic pathway. One would anticipate that the much greater 5-FU exposure would result in greater and/or more severe side effects when, in fact, the side effect profile for 5-FU exposures from NGC-Cap had a similar anabolite side effect profile to FDA-approved capecitabine.

In addition, the side effects associated with FBAL (fluoro-beta-alanine, the primary catabolite formed from the metabolism of 5-FU), such as hand-foot syndrome, that can lead to capecitabine intolerance, were almost non-existent, likely because FBAL exposure was approximately 1% of the exposure seen after FDA-approved capecitabine administration.

Important to FDA's request that we evaluate multiple dosage regimens to determine an Optimal Dosage Regimen, the interim analysis also shows that an improvement in the side effect profile was observed at a 5-FU NGC-Cap exposure of 5-6 times greater than FDA-approved capecitabine.

"We are very encouraged with the interim results from the Phase 1b trial." added Dr. Young. "We also appreciate our recent interactions with FDA and their guidance on the future development of NGC-Cap, including determining the dosing regimens that will provide the best safety and efficacy profile for patients receiving NGC-Cap across many types of cancers. In addition, it is gratifying to receive confirmation from the FDA on NGC-Cap's status as a new chemical entity, which may provide additional commercial advantages."

These data confirm that the metabolic pathways that regulate how NGC-Cap is processed in the body suggest NGC-Cap may offer higher efficacy at lower doses of the underlying capecitabine agent, while simultaneously offering a better safety profile from less production of the side-effect producing catabolite FBAL that causes many of the dose-limiting side effects from treatment with capecitabine alone. It is believed that NGC-Cap's ability to inhibit the production of catabolites like FBAL is key to the success of NGC-Cap. Further clinical studies are needed to confirm these interim observations.

The Company will conduct a Fireside Chat on December 20, 2023 at 4:30PM ET to discuss these data in further detail and lay out the Company's corporate strategy with regard to the NGC platform. Investors interested in listening may register early for the event at https://event.choruscall.com/mediaframe/webcast.html?webcastid=7RISI7Mv. This link will also connect listeners to the Fireside Chat when it goes live. Content from the Fireside Chat will be archived through June 20, 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 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 a uracil analog 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.

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 the Processa 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. 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 company's approach to drug development is based on more than 30 years of drug development expertise to efficiently design and conduct clinical trials that demonstrate a positive benefit/risk relationship. The Processa team has a track record of obtaining over 30 approvals for indications across almost every division of FDA. Using its proven Regulatory Science Approach, the Processa Team has experience defining the Optimal Dosage Regimen using the principles of the FDA's Project Optimus Oncology initiative. 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 — in excess of 200,000 for each NGC 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 metastatic colorectal, gastrointestinal, breast, 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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