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): May 18, 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 May 18, 2023, Processa Pharmaceuticals, Inc. (the "Company") issued a press release announcing that PCS6422 has received guidance from the FDA regarding the Company's Phase 2 safety-efficacy trial for Next Generation Chemotherapy-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 will conduct a Next Generation Chemotherapy-Capecitabine Phase 2 Trial Based on FDA Guidance and Project Optimus Oncology Initiative for PCS6422.
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 May 18, 2023.

PROCESSA PHARMACEUTICALS, INC.
Registrant

By: */s/ David Young*
David Young
Chief Executive Officer

Exhibit 99.1

Processa Pharmaceuticals to Conduct Next Generation Chemotherapy-Capecitabine Phase 2 Trial Based on FDA Guidance and Project Optimus Oncology Initiative

HANOVER, MD, May 18, 2023 (GLOBE NEWSWIRE) – Processa Pharmaceuticals, Inc. (Nasdaq: PCSA) ("Processa" or the "Company") today announces it has received guidance from the U.S. Food and Drug Administration ("FDA") regarding the Company's next trial for Next Generation Chemotherapy-Capecitabine ("NGC-Cap"). The trial for NGC-Cap, the combination of PCS6422 and capecitabine, will be a Phase 2 safety-efficacy trial in colorectal cancer patients following the principles of FDA's Project Optimus Oncology Initiative, the recent FDA recommendation on how oncology drugs are to be developed going forward.

David Young, Pharm.D., Ph.D., Processa's President and CEO, commented, "Our communications with the FDA have been extremely productive. One of the most important advantages of NGC-Cap and all our NGC drugs is that they have been designed to decrease the side effects associated with the treatment while increasing the exposure of cancer cells to proven cancer-killing molecules. These changes are expected to increase the number of patients who will benefit from each NGC drug given fewer side effects as well as have a significant impact on a patient's response.

"By combining our NGCs and the Processa Regulatory Science Approach with FDA's Project Optimus, Processa can efficiently provide better therapeutic options to cancer patients while increasing the likelihood of successful marketing approval. In addition, prior to approval, we expect to show that there are significant advantages to treating patients with our NGC drugs over both existing chemotherapy and oncology drugs directed toward new targets or new mechanisms. We look forward to continued collaboration with FDA and to providing continued updates to our shareholders," concluded Dr. Young.

The Phase 2 trial will be designed to determine the dose-and exposure-response relationships for both anti-tumor activity and safety/tolerability by evaluating different dosage regimens. The final dosage regimens to be used in the Phase 2 trial will be defined following the determination of the maximum tolerated dose from the Company's ongoing Phase 1b trial and in collaboration with the FDA. To expedite the enrollment of the first patient, Processa has begun the upfront study preparation tasks, including protocol preparation for submission to the existing IND and clinical enrollment planning.

About Processa Pharmaceuticals, Inc.

Processa is a clinical stage pharmaceutical company focused on developing Next Generation Chemotherapy (NGC) drugs intended to improve the safety, tolerability, and efficacy of cancer treatment. Some of the key advantages of Processa's NGCs are expected to be fewer patients experiencing side effects that lead to dose discontinuation, more significant cancer response, and an increase in the number of patients who will benefit from each NGC drug. The 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. By combining the proven cancer-killing active molecules and the Processa Regulatory Science Approach with FDA's new Project Optimus Oncology Initiative, Processa can provide better therapeutic options to cancer patients more efficiently while increasing the probability of FDA approval. Using its Regulatory Science Approach, the Processa team has consistently demonstrated its ability to obtain FDA approvals as evidenced by over 30 approvals for indications across almost every division of the FDA. Our pipeline includes 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, biliary duct, lung, ovarian, breast, and other cancers), and Next Generation Irinotecan (PCS11T to treat lung, colorectal, gastrointestinal, pancreatic, and other cancers).

For more information, please 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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