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): August 4, 2022

PROCESSA PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-39531**	**45-1539785**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

7380 Coca Cola Drive, Suite 106,
Hanover, Maryland, 27106

(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (443) 776-3133

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, $0.0001 par value per share	PCSA	The Nasdaq Stock Market LLC

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.

Processa Pharmaceuticals, Inc. ("***Processa***") announces today the launch of a new study-specific website (www.necrobiosislipoidicastudy.com) designed and implemented to increase awareness of Ulcerative Necrobiosis Lipoidica and to Inform Patients of the ongoing Phase 2B Study of PCS 499.

Processa undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time through the filing of other reports or documents with the Securities Exchange Commission, through press releases, or through other public disclosure, including in the "Investors" section of Processa's website. Processa routinely uses its website as a means of disclosing material non-public information and for complying with its disclosure obligations under Regulation FD.

The information in this Item 7.01 and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release Dated 08042022
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL documents)

SIGNATURES

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.

PROCESSA PHARMACEUTICALS, INC.

Date: August 4, 2022

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

Exhibit 99.1

Processa Pharmaceuticals Announces Launch of Website to Increase Awareness of Ulcerative Necrobiosis Lipoidica and to Inform Patients of the ongoing Phase 2B Study of PCS499

HANOVER, MD, August 4, 2022 (GLOBE NEWSWIRE) — Processa Pharmaceuticals, Inc. (NASDAQ: PCSA), ("Processa" or the "Company"), a clinical-stage biopharmaceutical company developing products to improve the survival and/or quality of life for patients who have unmet medical need conditions, announces today that it has launched a new website Necrobiosislipoidicastudy.com. The website is designed to increase awareness of ulcerative Necrobiosis Lipoidica ("uNL"), an extremely rare condition, and to inform patients about the ongoing Phase 2 study that is investigating the use of PCS499 for the treatment of this rare condition.

Necrobiosis Lipoidica (NL) is a chronic skin condition with no currently approved U.S. Food and Drug Administration (FDA) treatment. It is believed that NL affects 22,000 – 50,000 people in the United States and is more common in individuals with diabetes and women, with an average age of onset between 20 and 60 years. People with NL experience a persistent skin condition that develops into ulcerated lesions in about one-third of cases. Ulceration can cause severe complications, such as life-threatening infections and necrosis.

Processa Pharmaceuticals is conducting a randomized, double blind, placebo-controlled study that will evaluate the efficacy and safety of PCS499 as compared to placebo for the treatment of ulcerations of patients with Necrobiosis Lipoidica (NCT#NCT04800562). This study is currently recruiting in the United States and is expected to enroll a total of 20 patients.

Sian Bigora, Pharm.D., Chief Development Officer, said, "For patients with NL, the tissue below the skin can become necrotic forming open ulcers which can last from months to years with complications such as infections, amputation, and cancer. Currently there is no FDA approved treatment for uNL or NL, no standard of care, and the treatments that are used are generally inadequate. We are conducting the Phase 2b study to hopefully show that PCS499 can be an option for these patients who currently have little to no options available"

For more information on the clinical study of PCS499, please visitNecrobiosislipoidicastudy.com

PCS499

PCS499, is a deuterated analog of a major metabolite of pentoxifylline (PTX or Trental®). PCS499 and its active metabolites have a diverse pharmacology profile and can act on multiple targets that play vital roles in the treatment of various conditions. Investigators postulate that PCS499 may provide a novel treatment solution for NL thanks to its metabolites, which affect many of the biological pathways that contribute to the physiological processes associated with NL.

About Processa Pharmaceuticals, Inc.

The mission of Processa is to develop products with existing clinical evidence of efficacy for patients with unmet or underserved medical conditions who need treatment options that improve survival and/or quality of life. The Company uses these criteria for selection to further develop its pipeline programs to achieve high-value milestones effectively and efficiently. Active clinical pipeline programs include: PCS6422 (metastatic colorectal cancer and breast cancer), PCS499 (ulcerative necrobiosis lipoidica) and PCS12852 (gastroparesis). The members of the Processa development team have been involved with more than thirty drug approvals by the FDA (including drug products targeted to orphan disease conditions) and more than 100 FDA meetings throughout their careers. For more information, visit the company's 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 that 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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