

**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): March 30, 2020

Commission file number 333-184948

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	PCSA	OTC

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.

Incorporated by reference is a press release issued by the Registrant on March 30, 2020 attached as Exhibit 99.1, announces they will move forward with a PCS499 Phase 3 trial after a successful FDA meeting.

Item 9.01. Financial Statements and Exhibits.

Exhibit No. Exhibit Description

99.1 [Processa Pharmaceuticals to move forward with a PCS499 Phase 3 trial after a successful FDA meeting.](#)

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 March 30, 2020.

PROCESSA PHARMACEUTICALS, INC.
Registrant

By: *s/ David Young*

David Young
Chief Executive Officer

FOR IMMEDIATE RELEASE

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PROCESSA PHARMACEUTICALS TO MOVE FORWARD WITH A
PCS499 PHASE 3 TRIAL AFTER A SUCCESSFUL FDA MEETING

HANOVER, MD – March 30, 2020 – Processa Pharmaceuticals, Inc. (OTCQB: PCSA), announced the successful completion of their meeting with the U.S. Food and Drug Administration (FDA) for PCS499, its investigational product targeting the treatment of Necrobiosis Lipoidica (NL).

During the meeting Processa and the FDA discussed the clinical program as well as the nonclinical and clinical pharmacology plans to support the submission of the PCS499 New Drug Application (NDA) in the U.S. for the treatment of ulcers in NL patients. With input from the FDA through a Special Protocol Assessment, Processa will be designing and conducting a Phase 3 trial to evaluate the ability of PCS499 to completely close ulcers in patients with NL. Processa initially planned to begin recruiting for this trial in Q4 2020 but with the COVID-19 pandemic, it is expected that this trial will begin recruiting patients in 2021. FDA will determine if a second confirmatory Phase 3 trial is required after reviewing the results from this first trial.

“We are pleased with the outcome of the FDA meeting and the feedback we received from the FDA. We believe that the results from our completed Phase 2 trial in NL patients, especially those with more severe ulcerated forms of NL, are encouraging and we appreciate the guidance provided by the FDA regarding our next clinical trial and the requirements to support our NDA submission. We look forward to working with the FDA in designing a Phase 3 trial that will demonstrate the efficacy and safety of PCS499 for a NDA approval,” said Dr. David Young, Chief Executive Officer at Processa.

NL is a chronic, disfiguring condition affecting the skin and tissue under the skin typically on the lower extremities with no currently approved FDA treatments. More severe complications can occur, such as deep tissue infections and osteonecrosis threatening life of the limb. Approximately 74,000 - 185,000 people in the United States and more than 200,000 – 500,000 people outside the United States are affected by NL with the prevalence of open ulcers being approximately 30% of all NL patients. The degeneration of tissue occurring at the NL lesion site is caused by a number of pathophysiological changes which has made it extremely difficult to develop effective treatments for this condition. At this time there is no approved FDA treatment for NL and PCS499 could be the first drug approved. PCS499 and its metabolites affect a number of biological pathways, several of which contribute to the pathophysiology associated with NL.

About Processa Pharmaceuticals, Inc.

The mission of Processa has been to develop products where existing clinical evidence of efficacy already exists in unmet medical need conditions, medical conditions where patients need treatment options that will improve survival and/or quality of life. The Company has assembled a proven regulatory science development team, management team, and Board of Directors. The Processa development team has been involved with more than 30 drug approvals by the FDA (including drug products targeted to orphan disease conditions) and 100 FDA meetings. For more information, please visit <http://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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