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 17, 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 [X]

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 17, 2020 attached as Exhibit 99.1, announces results from the Phase 2 study in Necrobiosis Lipoidica.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Exhibit Description
99.1	Processa Pharmaceuticals announces results from the Phase 2 study in Necrobiosis Lipoidica

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 17, 2020.

PROCESSA PHARMACEUTICALS, INC.
Registrant

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

Exhibit 99.1

FOR IMMEDIATE RELEASE

For More Information:
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925-683-3218

PROCESSA PHARMACEUTICALS ANNOUNCES RESULTS FROM THE PHASE 2 STUDY IN NECROBIOSIS LIPOIDICA

HANOVER, MD – March 17, 2020 – Processa Pharmaceuticals, Inc. (OTCQB: PCSA), a clinical stage biopharmaceutical company developing products to improve the survival and/or quality of life for patients who have a high unmet medical need condition, announced the completion of its Phase 2 Necrobiosis Lipoidica (NL) clinical trial for PCS-499 (PCS499-NL01), a deuterated analog of one of the major metabolites of pentoxifylline (Trental®).

The Phase 2 trial was a multicenter, open-label prospective study designed to determine the safety and tolerability of PCS-499 in patients with NL. The last patient completed the study in February 2020. The fully enrolled trial included twelve NL patients: two patients with open ulcers and ten patients with the mild to moderate form of NL and no ulcerations.

PCS-499 was found to be safe and well tolerated in these patients at doses of 1.8 grams/day with no serious adverse events reported. Adverse events assessed as possibly/probably related to PCS-499 were reported by seven patients and were reported as mild and occurred mostly in the first few weeks of treatment and quickly resolved. As expected, gastrointestinal adverse events were reported most often.

The two patients presenting with more severe ulcerated NL had ulcers for more than two months prior to dosing. At baseline the reference ulcer in one of the two patients measured 3.5 cm^2 and had completely closed by Month 2 of treatment. The second patient had a baseline reference ulcer of 1.2 cm^2 which completely closed by Month 9. In addition, while in the trial one of these patients also developed small ulcers at other sites as a result of contact trauma to the site and these ulcers resolved within one month. The other ten patients presenting with mild to moderate NL and no ulceration had some improvement of the NL lesions but not as dramatic as the more serious ulcerated patients.

“We are pleased to successfully complete this Phase 2 trial and are encouraged by the positive safety and efficacy results obtained from the trial. On PCS-499 all the ulcers on our two ulcerated patients were completely closed, something that we believe occurs naturally in less than 10% of the patients with ulcers. PCS-499 may offer a new treatment for this chronic disfiguring condition and we are meeting with the FDA later this month to define the Phase 3 trial for NL patients with ulcers,” said Dr. Sian Bigora, Chief Development 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. PCS-499 may provide a solution since PCS-499 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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