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): October 2, 2018

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))

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. [X]

Item 8.01 Other Event.

On October 2, 2018, Processa Pharmaceuticals, Inc. issued a press release announcing that the U.S. Food and Drug Administration (FDA) has granted Processa clearance to proceed with a Phase 2 clinical trial of PCS-499 in patients with Necrobiosis Lipoidica under a recently submitted Investigational New Drug (IND) application.

A press release announcing the FDA clearance is filed as Exhibit 99.1 hereto.

Item 9.01 Exhibits and Financial Statements

Exhibit No.	Exhibit Description
99.1	Press Release, dated October 2, 2018.

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 October 2, 2018.

PROCESSA PHARMACEUTICALS, INC.
Registrant

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

FOR IMMEDIATE RELEASE

For More Information:
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PROCESSA PHARMACEUTICALS RECEIVES FDA CLEARANCE OF IND TO BEGIN PHASE 2 CLINICAL DEVELOPMENT OF PCS-499 IN NECROBIOSIS LIPOIDICA PATIENTS

HANOVER, MD – October 2, 2018 – Processa Pharmaceuticals, Inc. (OTC: PCSA), a clinical stage biopharmaceutical company developing products to improve the survival and/or quality of life for patients who have high unmet medical need conditions, announced today that the U.S. Food and Drug Administration (FDA) has granted Processa clearance to proceed with a Phase 2 clinical trial of PCS-499 in patients with Necrobiosis Lipoidica (NL) under a recently submitted Investigational New Drug (IND) application.

NL is a chronic, disfiguring condition affecting the skin and the tissue under the skin typically on the lower extremities with no currently approved FDA treatments. NL presents more commonly in women than in men and ulceration can occur in approximately 30% of NL patients. 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 200,000 – 500,000 people worldwide are affected by NL.

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.

“Since there are no approved treatments for this devastating condition, we are pleased that the FDA not only granted PCS-499 orphan designation for NL but also agreed with our proposal to move immediately to Phase 2. We plan to work closely with the FDA to efficiently demonstrate the efficacy and safety of the drug in this patient population,” said Dr. David Young, CEO of Processa Pharmaceuticals. “We hope that the IND clearance for the Phase 2 trial represents the first of many milestones for the PCS-499 NL program.”

Information about our Phase 2 trial in NL patients can be found atwww.clinicaltrials.gov within the next 5-7 days.

About Processa Pharmaceuticals, Inc.

Processa Pharmaceuticals, Inc. was founded in 2017 in Hanover, Maryland, with a mission to develop products that can improve the survival and/or quality of life for patients who have a high unmet medical need. The Company acquired the assets of Promet Therapeutics, LLC in October of 2017 and assembled a proven regulatory science development team, management team, and Board of Directors. The Processa drug development team members have been involved with more than 30 drug approvals by the FDA (including drug products targeted to orphan disease conditions) and 100 FDA meetings. PCS-499 represents the first Processa drug that can potentially be used in a number of unmet medical need conditions. 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 that could cause actual results to differ from those contained in the forward-looking statements.

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