
**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): February 25, 2020

Commission file number 333-184948

PROCESSA PHARMACEUTICALS, INC.

(Exact name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction of
Incorporation or Organization)

45-1539785

(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	OTCQB

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 February 25, 2020 attached as Exhibit 99.1, which contains a letter to the shareholders from the CEO.

<u>Exhibit No.</u>	<u>Exhibit Description</u>
99.1	<u>Press release – letter to Shareholders from CEO.</u>

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 February 25, 2020.

PROCESSA PHARMACEUTICALS, INC.
Registrant

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

PROCESSA PHARMACEUTICALS PROVIDES SHAREHOLDER UPDATE

HANOVER, MD, February 25, 2020 (GLOBE NEWSWIRE) — Processa Pharmaceuticals, Inc. (OTCQB: PCSA), a clinical stage biopharmaceutical company developing drugs to improve the survival and/or quality of life for patients who have a high unmet medical need condition, provides a year-end review and an outline of their drug development and business plans for 2020.

To Our Shareholders:

Last year was a year of significant accomplishments for Processa, and we have no plans to slow down in 2020. Our mission is to develop drug products for patients who have medical conditions where there are no treatment or inadequate treatment options. We are focused on building a pipeline of drugs whose pharmacological properties have already exhibited some clinical evidence of efficacy in a targeted patient population who need better treatment options. We believe that developing drugs with some existing clinical evidence in an unmet medical need condition increases the probability for an increased return on investment while decreasing the risk of drug development failure.

Over the last 4 years moving from a private company to an OTCQB company we have accomplished a tremendous amount and have established the foundation to continue building Processa into a successful clinical stage biopharmaceutical company. With the total financial support of only \$11.8 M raised over that period, we have:

- Brought together an outstanding, experienced team.
- Licensed in two drugs for indications with potential maximum annual sales of \$1 billion each, leveraging the over \$40M spent on these products by the previous owners.
- Demonstrated the efficacy and safety of our first drug, PCS-499, as well as identified a regulatory path to approval.
- Created the ability to initiate a pivotal trial for our first drug with additional funding.
- Expanded our pipeline to include a number of potential blockbuster drugs.

Some of the major accomplishments we completed in 2019 include:

Development of Drug Assets and Diversification of Portfolio

- Initiated and completed a PCS-499 Phase 2 trial in Necrobiosis Lipoidica (NL) patients, a condition with no effective treatment options and no FDA approved drugs.
 - Obtained the safety and efficacy evidence demonstrating that PCS-499 in severe NL patients completely closed open ulcers.
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- Granted a meeting by FDA in March 2020 to discuss the single pivotal trial required to obtain PCS-499 NL approval.
- Licensed in PCS-100 (an anti-fibrotic, anti-inflammatory drug demonstrated to have some clinical anti-fibrotic effect in children) which we plan to develop first in an adult related disease.

Corporate Achievements

- Controlled our overhead and non-clinical research and development spending with these costs totaling less than \$2.5 million in 2019.
- Obtained \$805,000 in convertible bridge loans and an undrawn \$1.4 M line of credit.
- Completed a 1:7 reverse split to meet requirements for a NASDAQ up-list.
- Submitted an application to the NASDAQ Capital Market to up-list our common stock from the OTCQB.

We believe that our 2019 clinical progress and the diversification of our portfolio is the beginning of Processa becoming a successful public biopharmaceutical company. We know that Processa will be more widely known in the investment and medical communities as our patient data matures and we continue to deliver on our stated milestones. As we continue into 2020, our focus will be to support the rapid clinical development of our programs in order to maximize shareholder value. Depending on funding, some of the 2020 milestones our shareholders can look forward to include, but are not limited to:

Development of Drug Assets and Diversification of Portfolio

- Defining our next steps in the PCS-499 development program with the FDA.
- Initiating the single FDA required pivotal PCS-499 NL trial.
- Meeting with FDA on the use of PCS-100 in an adult unmet medical need condition.
- Further diversifying our portfolio with the acquisition of at least 1 more drug.

Corporate

- Up-listing our common stock to the Nasdaq Capital Market in the first half of 2020, concurrent with a capital raise.
- Continuing to build the corporate foundation to efficiently manage our drug development process, our Company on the NASDAQ market, and our visibility to the investment community.

Overall, we are excited to share our achievements with our shareholders. We are fully committed to combining operational excellence with an efficient capital plan to advance our programs. Building a biopharmaceutical company with a value-added portfolio does not happen quickly. We appreciate your patience and continued support and we look forward to sharing with you the next steps as Processa continues to expand near- and long-term shareholder value.

Sincerely,
David Young, Pharm.D., Ph.D.
CEO

About Processa Pharmaceuticals, Inc.

Processa Pharmaceuticals, Inc. was founded in October 2017 in Hanover, Maryland after the acquisition of Promet Therapeutics, LLC (formed in January 2016). 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 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 that could cause actual results to differ from those contained in the forward-looking statements.

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