
**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, 2019

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))

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 Disclosure.

A copy of a slide presentation (Presentation Materials”) that Processa Pharmaceuticals, Inc. (“Processa Pharmaceuticals”) intends to use during presentations before groups and in hosting one-on-one meetings with individual investors, is attached to this Current Report on Form 8-K and Exhibit 99.1. The Presentation Materials speak as of the date of this Current Report on Form 8-K. While Processa Pharmaceuticals may elect to update the Presentation Materials in the future or reflect events and circumstances occurring or existing after the date of this Current Report on Form 8-K, Processa Pharmaceuticals specifically disclaims any obligation to do so. The information contained in this Item 7.01 and Exhibit 99.1 hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by reference in such a filing.

Exhibit No. Exhibit Description

99.1 [Processa Pharmaceuticals Investor Presentation dated February 23, 2019](#)

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, 2019.

PROCESSA PHARMACEUTICALS, INC.
Registrant

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



Processa Pharmaceuticals

Developing Products to Improve the Survival and/or Quality of Life
for Patients Who Have a High Unmet Medical Need

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

February 23, 2019

Disclaimer: Forward Looking Statements

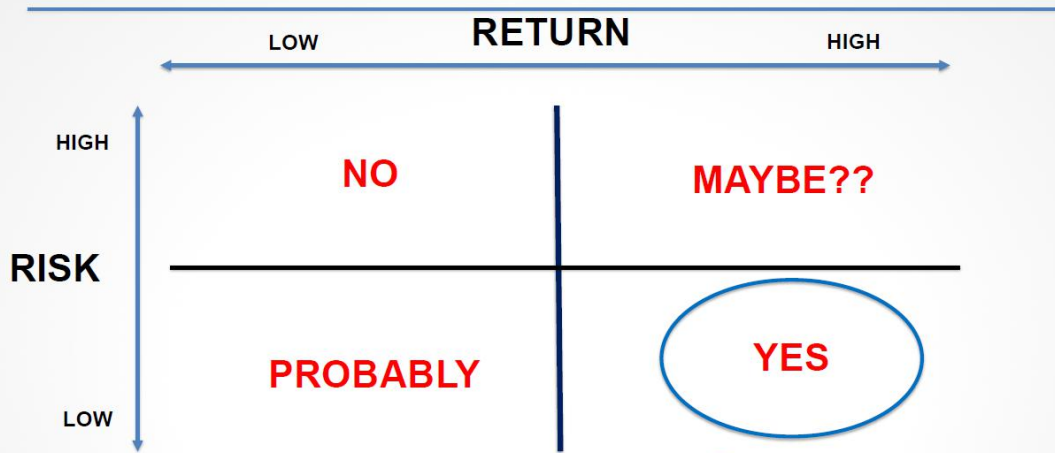
The following summary is provided for informational purposes only and does not constitute an offer or solicitation to acquire interests in the investment or any related or associated company.

The information contained here is general in nature and is not intended as legal, tax or investment advice. Furthermore, the information contained herein may not be applicable to or suitable for an individual's specific circumstances or needs and may require consideration of other matters. The Company, their members, directors, officers, employees and consultants assume any obligation to inform any person of any changes or other factors that could affect the information contained herein.

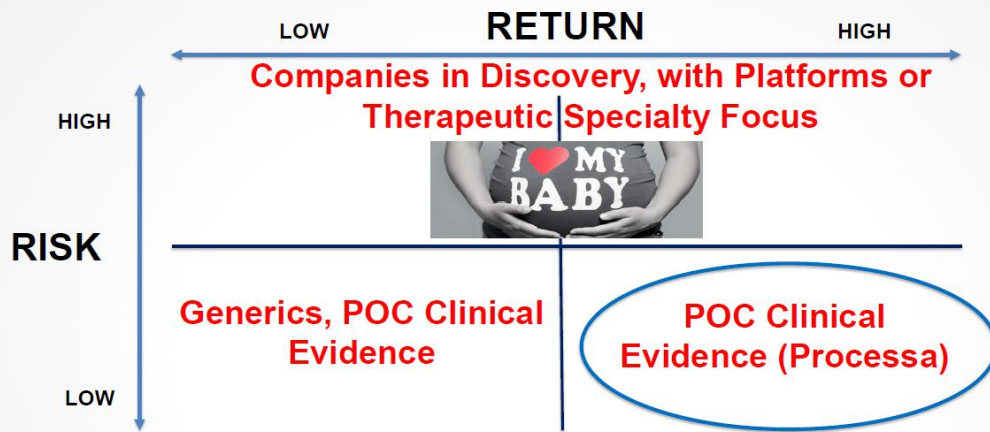
These materials may include forward-looking statements including financial projections, plans, target and schedules on the basis of currently available information and are intended only as illustrations of potential future performance, and all have been prepared internally. Forward-looking statements, by their very nature, are subject to uncertainties and contingencies and assume certain known and unknown risks. Since the impact of these risks, uncertainties and other factors is unpredictable, actual results and financial performance may substantially differ from the details expressed or implied herein. The Company does not assume any obligation to release updates or revisions to forward-looking statements contained herein.



Investors



Biotech Companies



Why Aren't More Biotech Companies in the High Return-Low Risk Quadrant?

1. Vested in their Platform or Therapeutic Specialty
2. Stage of Development, Drug, Indication, Patient Population
3. Lack the Correct Team (Science, Development, Management)
4. Lack Experience Developing Drugs for Approval & Commercialization

Processa Pharmaceuticals (OTCQB:PCSA)

- Clinical stage biotech drug development company
- Drugs/indications with potentially high return on investment to achieve the Processa vision of becoming a multi-billion dollar company
 - Developing drugs to treat patients with high unmet medical need conditions
 - Potential gross annual sales >> cost + development time



We Know The Way
To The FDA



Processa Pharmaceuticals

How is Processa Decreasing the Risk of Failure?

1. Vested in their platform or therapeutic specialty

Regulatory Science Approach to Drug Development, Not Drug Discovery or Specific Therapeutic Area

2. Stage of development, drug, indication, patient population

Select Drugs that Have Some Evidence of Clinical Benefit and Can Achieve a Major Milestone in 2-4 Years



Processa Pharmaceuticals

How is Processa Decreasing the Risk of Failure?

3 & 4. Lack the correct team - developing drugs for approval & commercialization

Our Established Team Over Last 30 Years Taught FDA Reviewers, Assisted in Preparing FDA Guidances, Member of an FDA Advisory Committee, Involved with > 30 FDA Approvals & > 100 FDA Meetings

Proven Executive Team and Development Team Most Recently Helped Transform Questcor Pharmaceuticals from \$15M Market Cap in 2007 to \$5.6B in 2014



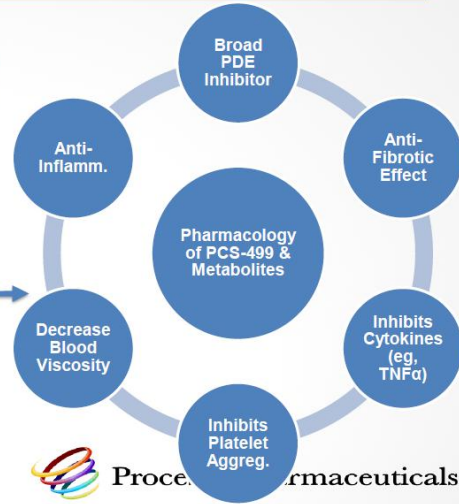
Processa Pharmaceuticals Financial Overview

OTCQB (2/8/19)	PCSA - \$3.00 per share
Market Cap (2/8/19)	\$116M
Shares Outstanding	~38.8M Shares
Cash or Cash Equivalent (2/8/19)	~\$1.5M (+ \$1.8M Investment Paid Directly to CRO - 100% Phase 2a Trial)
Insider Ownership %	> 70%
Headquarters	Hanover, MD



PCS-499: Deuterated Analog of a Major Active Metabolite of Pentoxifylline (PTX)

- PCS-499 metabolizes to same active metabolites as PTX but metabolite profile is different after PCS-499 administration than PTX (% exposure to various metabolites and administered drug)
- PCS-499 & active metabolites have a diverse pharmacology profile
- PCS-499 pre-clinical PCOL/Tox and Phase 1&2 Diabetic Nephropathy studies completed



Evidence PCS-499 Better and Different than PTX

- PTX widely used off-label with mixed results often because of dose limiting side effects
- In Phase 1 studies the exposure to key active moieties after PCS-499 administration was 2x greater than PTX at the same dose administered
- In Phase 1 studies dose limiting side effects (e.g., nausea, vomiting, headaches) occurred at a dose approx. 50% greater for PCS-499 than the PTX dose
- In pre-clinical toxicology studies the maximum tolerated dose for PCS-499 was greater than for PTX



Match a Good Drug with One or More Diseases

Necrobiosis Lipoidica (NL) - No Approved Treatment

- Occurs in women/men 20 – 60 y/o
- Potential to last for month or years
- Skin becomes necrotic; 30% of patients have painful ulcerations; complications - infections, amputation, squamous cell cancer
- No standard of care or FDA approved treatment, no known biotech or pharma company developing a drug for NL



Processa Pharmaceuticals

Necrobiosis Lipoidica (NL) Pentoxifylline (PTX) Clinical Evidence

- Dermatologists mainly use topical steroids and other drugs with poor response and undesired toxicity profiles
- PTX is used OFF-LABEL; response can start after 1 month with significant improvement 3-12 months (published case studies & clinical experience)
- PTX does not have widespread use; a small percentage of patients respond at the maximum tolerated dose of PTX; increasing dose results in PTX dose limiting side effects

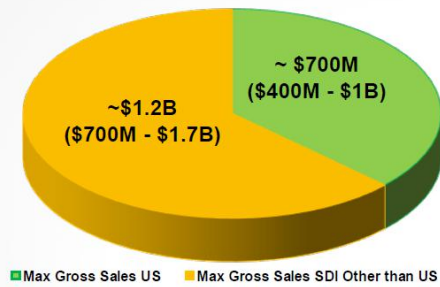


Processa Pharmaceuticals

Market Opportunity for PCS-499 in NL

Maximum Gross Annual Sales Worldwide \$1.2B - \$2.7B

Necrobiosis Lipoidica (NL)
Max Gross Sales



■ Max Gross Sales US ■ Max Gross Sales SDI Other than US

- 74,000-185,000 in US
- 200,000 – 500,000 Patients Worldwide

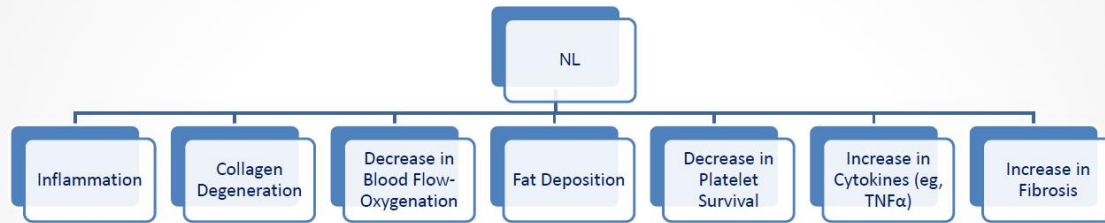


 Processa Pharmaceuticals

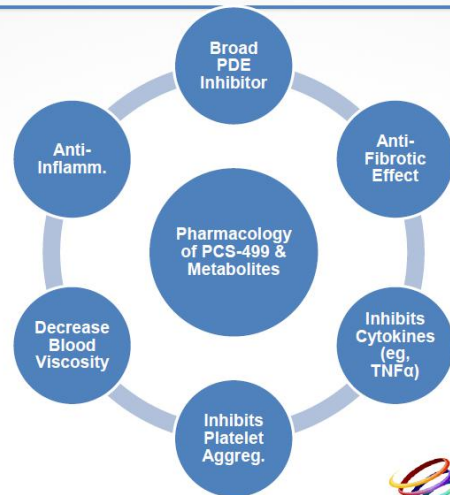
Source: Muller SA, et al. Arch Dermatol. 1966; Jockenhöfer F, et al, J Dtsch Dermatol Ges. 2016; Company

Necrobiosis Lipoidica (NL)

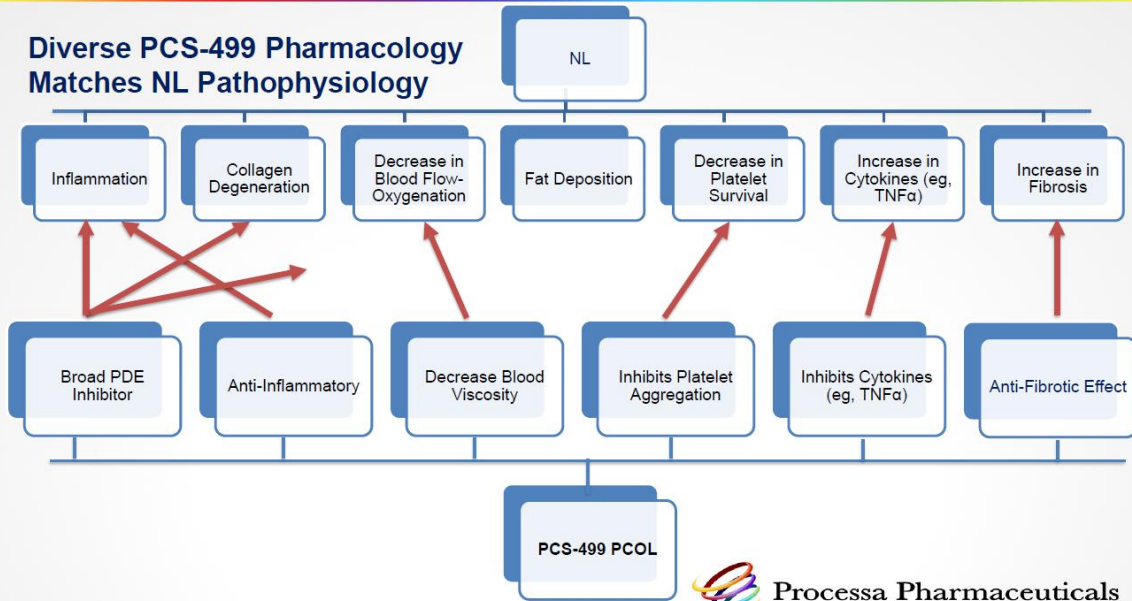
- Multi-faceted Disorder Affecting the Skin and the Tissue under the Skin



PCS-499 Pharmacology



Diverse PCS-499 Pharmacology Matches NL Pathophysiology



Status of PCS-499 NL Program

- Pre-IND collaborative meeting with FDA defining program (Oct 2017); In-licensed PCS-499 (March 2018); Orphan Designation for PCS-499 in NL (June 2018)
- PCS-499 NL IND cleared by FDA (Oct 2018) - investigating safety and tolerance of PCS-499 in NL patients with an evaluation of efficacy
- First patient dosed January 2019
- In 2019
 - Complete enrollment of 12 patients before June 2019 and obtain all tolerance and efficacy data before end of 2019
 - Request FDA meeting at end of 2019 to define larger randomized trial (Phase 2b or Phase 3) and SPA



Processa Pharmaceuticals

Our People Lead to Success



**We Know The Way
To The FDA**

- **Established and Proven Executive Team with Over 20+ Years of Biotech Management Experience**
 - Most Recently Helped Transform Questcor Pharmaceuticals from \$15M Market Cap in 2007 to \$5.6B in 2014 when acquired by Mallinckrodt
- **Development Team has Worked Together in other Companies and has a Proven Record of Success**
 - Over 25 Years of Experience Developing Drugs
 - Over 30+ FDA Approvals
 - 100+ FDA Meetings
 - Trained FDA Reviewers
 - Worked on 3 FDA Guidance's with FDA
 - FDA Advisory Committee Involvement as a Committee Member and Sponsor



Processa Pharmaceuticals

OUR LEADERSHIP

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

- Former Board Member, CSO of Questcor Pharmaceuticals ~\$15M Market Cap to \$5.6B in 7 years
- Former President, AGI Therapeutics; Founder & CEO, GloboMax
- Former Instructor of FDA Reviewers; Former FDA Advisory Committee Member

Patrick Lin, Chief Business and Strategy Officer

- 20 Years Financing and Investing Experience in Biopharma Sector; Principal/Founder Primarius Capital, Focused on Small Cap with Numerous \$3B+ Mkt Cap Winners
- Former E*Offering Co-Founder Growing Company to 200 Employees & \$80M Rev. During 1st Year
- Former Robertson Stephens & Co. Principal with >500 Successful IPO & Follow-On Offerings



OUR LEADERSHIP

- **Sian Bigora, Pharm.D., Chief Development Officer**
 - Former VP, Regulatory Affairs at Mallinckrodt, Questcor Pharmaceuticals, AGI Therapeutics, GloboMax
 - Former Instructor of FDA Reviewers
- **James Stanker, CPA, Chief Financial Officer**
 - 25 years of Financial and Executive Leadership Experience
 - Former Audit Partner at Grant Thornton and Global Head of Audit Quality for Grant Thornton International; Former CFO at NASDAQ Listed Company and a Privately Held Company
 - Currently on the Board of Directors and Chairman of the Audit Committee of GSE Systems, Inc. (NYSE MKT: GVP)
- **Wendy Guy, Chief Administrative Officer**
 - Former Senior Manager in Business Operations at Questcor, AGI Therapeutics, GloboMax with 20 Years Experience in Corporate Management, HR and Finance



Processa Pharmaceuticals

Additional Efforts

Increase Probability of Company Success

Decrease Company Risk

Increase Shareholder Value

Additional Efforts

- Evaluating PCS-499 in Other Indications Where Preliminary Clinical Evidence Exists for PTX Efficacy and PTX Dose Limiting Adverse Events
- Evaluating and Negotiating Acquisition of Drugs with Existing Evidence of Clinical Efficacy (e.g., Women's Health, Oncology, CNS)
- Income Generating Efforts
 - Exploring the out-licensing of PCS-499 for ex-US development
 - Negotiating Development Team Collaborations (DTCs) where drug ownership remains in existing company but development (including FDA interactions) is performed by Processa in exchange for SGA, milestone payments, bio-bucks



Processa Pharmaceuticals

✓ **Achievements Over Last 15 Months**
 • **Key Future Milestones**

Milestone	Achievement
Obtain Listing on Public Market	<ul style="list-style-type: none"> ✓ Listing on OTCQB - Dec 2018 • Listing on Nasdaq or NYSE – Working Toward This****
Raise Funds	<ul style="list-style-type: none"> ✓ \$6.88M Private Placement – June 2018 • Raise Additional Funds – Working Toward This****
Generate Revenue	<ul style="list-style-type: none"> • Development Team Collaboration (DTC) Drugs - In Discussion with Companies**** • Out-licensing of PCS-499 ex-US - Identifying Individuals who Could Assist****

✓ **Achievements Over Last 15 Months**
 • **Key Future Milestones**

Milestone	Achievement
PCS-499 Development in Necrobiosis Lipoidica (NL); Multi- Billion Dollar Worldwide Market	<ul style="list-style-type: none"> ✓ Pre-IND FDA Meeting on the Development Program – Oct 2017 ✓ In-licensed PCS-499 – March 2018 ✓ Orphan Designation – June 2018 ✓ FDA IND Clearance – October 2018 ✓ First Patient Dosed in Phase 2 Safety-Tolerance Trial – Jan 2019 • Complete Phase 2 Enrollment – 1H2019**** • Obtain Enough Safety-Efficacy Data to Define Dosage Regimen for Randomized Phase 2b or 3 Trial – 4Q2019**** • Request FDA Meeting on Phase 2b or 3 Trial and SPA – 4Q2019**** • Initiate Randomized Trial (Phase 2b or 3) – 1H2020****
Expand Pipeline	<ul style="list-style-type: none"> • Drug Development & Commercial Evaluation of Additional PCS-499 Indications – Ongoing**** • Drug Development & Commercial Evaluation of Drugs for In-Licensing – Ongoing****

Plan and Timeline

	1H2019	2H2019	2020 - 2022
PCS-499 NL	<ul style="list-style-type: none"> • Complete Enrollment of Phase 2a Dose Tolerance Trial • Partial Readout on Dose Tolerance for Patients 	<ul style="list-style-type: none"> • Complete 6 Month 1⁰ Endpoint of Trial for All Patients • Request Meeting with FDA on Phase 2b or 3 Trial and SPA 	<ul style="list-style-type: none"> • SPA Submission • Phase 2b/3 Initiated and Completed • Complete FDA Required Phase 1 & Tox Studies • NDA Submission in NL
PCSA Portfolio	<ul style="list-style-type: none"> • Evaluate Other Indications for PCS-499 • Obtain 1-3 Additional Assets • Meet with FDA on New Assets to Evaluate ROI & Timeline 	<ul style="list-style-type: none"> • Prioritize Portfolio and Develop Drugs 	<ul style="list-style-type: none"> • Develop Drugs
Non-Diluting Income Generation	<ul style="list-style-type: none"> • Add DTC Drugs • Explore ex-US Out-licensing of PCS-499 	<ul style="list-style-type: none"> • Develop DTC Drugs 	<ul style="list-style-type: none"> • Develop DTC Drugs • Out-License PCS-499 in US

als

Summary

- **Developing Drugs to Treat Patients with High Unmet Medical Need Conditions that Could Provide a ROI to Achieve the Processa Vision of Becoming a Multi-Billion Dollar Company**
- **Experienced Team to Navigate: 1) Drug Development & FDA Using PCSA Regulatory Science Approach & 2) SEC/Financial Req. of a Public Company**
- **Expand Portfolio with Drugs Already Having Clinical Evidence of Efficacy**
- **Obtain Income Through DTCs and/or ex-US Out-Licensing of PCS-499**



