

---

---

**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): June 4, 2018

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 that Processa Pharmaceuticals, Inc. (the “Company”) intends to use during presentations made before individuals and small groups in Bel Air, California at the LDMicro 8<sup>th</sup> Invitational on June 4-6, 2018 (the “Presentation Materials”) is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated by reference herein. The Presentation Materials speak as of the date of this Current Report on Form 8-K. While the Company 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, the Company specifically disclaims any obligation to do so. Additionally, the Company intends to post the Presentation Materials on the Investor Relations section of the Company’s website: [www.processapharma.com](http://www.processapharma.com).

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 if 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 June 4, 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 June 4, 2018.

**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**



Patrick Lin  
Chief Business and Strategy Officer  
&  
David Young, Pharm.D., Ph.D.  
CEO

*June 2018*

## 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. Any such offer or solicitation may be made only by means of a confidential Private Placement Memorandum ("Memorandum") and in accordance with the terms of all applicable securities and other laws. All information contained herein is subject to and qualified by the contents of the Memorandum. As more fully described therein, participation in any securities offering is limited to Accredited Investors. Please contact Processa Pharmaceuticals, Inc. (the "Company") to inquire about obtaining a copy of any such Memorandum. The information and any statistical data contained herein have been obtained from sources which we believe to be reliable, but we do not represent that they are accurate or complete, and they should not be relied upon as such. All opinions expressed and data provided herein are subject to change without notice.

This potential investment opportunity may not be suitable for all types of investors. All investments involve different degrees of risk. You should be aware of your risk tolerance level and financial situation at all times. The rights, duties, and obligations of all parties to the proposed transactions, including the Company, will be governed and limited by the operative documents, which will be available upon request to the extent not otherwise provided. The Company does not accept or assume any duties, responsibilities, or obligations except as specifically provided in the final transaction documents. Read any and all information presented carefully before making any investment decisions. All investments presented are subject to market risk and may result in the entire loss of investment.

The information contained herein should not be used in any actual transaction without the advice and guidance of legal counsel and a professional tax advisor who is familiar with all the relevant facts. 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 nor their members, directors, officers, employees and consultants assume any obligation to inform any person of any changes in the tax law 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.



Processa Pharmaceuticals

# Processa Pharmaceuticals (OTC:PCSA) Background

---

- **Clinical Stage Drug Development** Private Company (Promet Therapeutics, LLC) Formed in Dec 2015; Reverse Merger with a Dormant Non-Biotech OTC Company in Oct 2017
- Mission is to Develop Drugs to Treat Patients with High **Unmet Medical Need Conditions**
- **Decrease the Risk of Failure** by Selecting Drugs in the Portfolio that must
  - Have Some Evidence of Clinical Benefit prior to Being Acquired
  - Be able to Achieve a Major Milestone in 2-4 years
- Presently Negotiating to Acquire Drugs to **Expand the Processa Portfolio** in 2018 – 2019
- **Experienced Team** of Drug Developers, Pharma Executives, Biotech Investors that Collaborate and Negotiate with FDA Using a **Regulatory Science Approach**



## Key Milestones and Achievements

- ✓ Reverse Merged into Dormant Public OTC Company in Oct 2017 followed by 1:7 Reverse Split
- ✓ Raised \$4.27M as Promet in 2015 & \$6.88M in Private Placements, Including an Ongoing PIPE
- ✓ Met with the FDA on the Development of PCS499 for Necrobiosis Lipoidica (Billion Dollar Market) to Ensure Development ROI and Risk was Acceptable
- ✓ Licensed in PCS499 from Concert Pharmaceuticals (Discontinued in 2016 Even Though FDA Green Light for Phase 3 - Lower ROI and More Risky Indication), in Exchange for PCSA Equity
- ✓ Transferred Final Product Manufacturing to New Site (Old site Closed); Confirmed PK Profile & Higher Dose than Concert Used Clinically is Safe in Healthy Volunteers (FDA Agreed Dose)
- ✓ Additional Staff Being Hired to Meet our Drug Development and Corporate Needs





## Processa Pharmaceuticals Financial Overview

<b>Symbol-Share Price (5/30/18)</b>	PCSA - \$3.25
<b>Market Cap (5/30/18)</b>	\$115M
<b>Shares Outstanding</b>	35.3M Prior to Private Placements & ~38.8M Post Private Placements
<b>Private Placements</b>	\$6.88M (Last Closing on June 29, 2018)
<b>Cash (5/30/18)</b>	\$5.4M (Includes \$6.88M from Private Placements)
<b>Insider Ownership %</b>	> 70%
<b>Headquarters</b>	Hanover, MD



# Successful Drug Development



## 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 1<sup>st</sup> 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

### **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

### **Chief Financial Officer**

- Responsibilities Divided Amongst a Number of Part-Time Individuals who are Former CFOs in Private and Public Companies



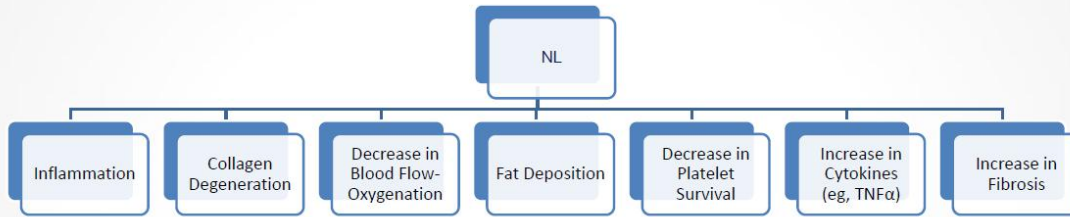
**Necrobiosis Lipoidica (NL)**  
**74,000-185,000 in US & 200,000 – 500,000 Worldwide**  
**(Includes Non-Diabetic Patients & 0.3% of All Diabetic Patients)**



Processa Pharmaceuticals

## Necrobiosis Lipoidica (NL)

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



## 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 Current FDA Approved Treatment, No Known Biotech or Pharma Companies Developing a Drug for NL
  - Dermatologists Mainly Use Topical Steroids and Other Drugs with Poor Response and Undesired Toxicity Profiles
  - Pentoxifylline (PTX) is Used Off-Label: Response can Start after 1 Month with Significant Improvement 3-12 Months (Case Studies)
  - PTX Does Not Have Widespread Use: Small Percentage of Patients Respond at the FDA Labelled Dose of PTX and Increasing the Dose Results in PTX Dose Limiting Toxicities





# PCS499 Diverse Pharmacology Useful for Multiple Indications

---

## **PCS499 is the Deuterated Form of the Major Metabolite of Pentoxifylline (PTX)**

- Pharmacology Slightly Different from PTX
- Greater Exposure to PCS499 after PCS499 Administered than the Non-Deuterated Form of PCS499 after PTX Administered

## **Previous Evaluation of PCS499 in Diabetic Nephropathy (Processa Not Pursuing This Indication at This Time)**

- Safe in Humans and Ready to Be Administered to Patients with Other Conditions
- FDA Approved IND, Phase 1 and 2 Studies Complete, at End of Phase 2 Meeting FDA Would Allow Concert to Move into Phase 3
- FDA Strongly Recommended a Higher Dose and Required Different Endpoints for Phase 3 Study



**Processa Pharmaceuticals**

# PCS499 Diverse Pharmacology Useful for Multiple Indications

---

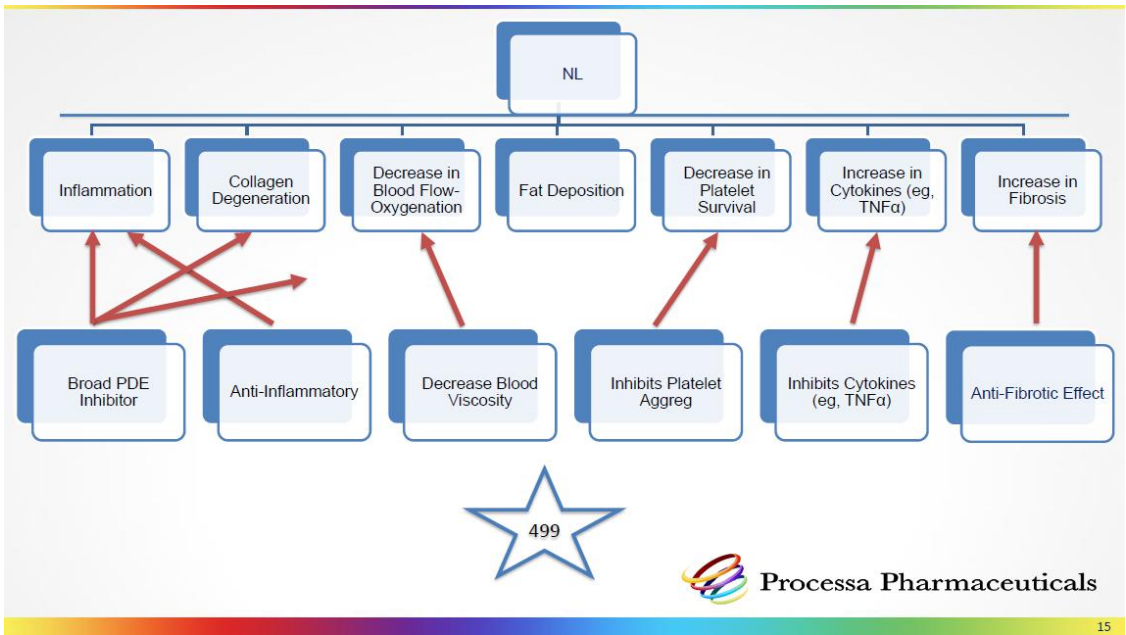
## Evidence of PCS499 Efficacy in Patients with Necrobiosis Lipoidica (NL)

- PTX Case Studies and Experience of NL KOLs
- PCS499 Exposure After PCS499 Administration Significantly Different than Non-Deuterated Metabolite Exposure after PTX Administration
- PCS499 Pharmacology is a Little Different than PTX and Probably More Beneficial
- PCS499 Diverse Pharmacology Matches the Mixed Pathophysiological Changes of NL

## PCS499 has Multiple Pharmacological Targets

- Broad Spectrum Phosphodiesterase (PDE) Inhibitor
- Modulates Immune Cells (e.g., Neutrophils) and Cytokines (e.g., TNF $\alpha$ )
- Effects Blood Viscosity & Oxygenation, Platelet Aggregation
- Anti-Fibrotic Effect

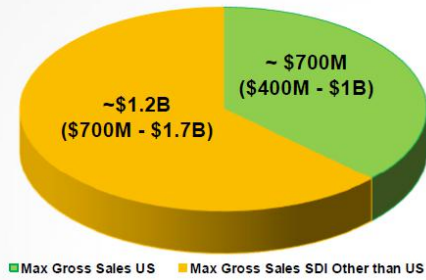




## Market Opportunity

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

#### Necrobiosis Lipoidica (NL) Max Gross Sales



- 200,000 – 500,000 Patients Worldwide
- 74,000-185,000 in US
- Max Gross Annual Sales Based on Prevalence Range:
  - \$1.1B - \$2.7B Worldwide
  - \$400M – \$1.0B in US

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



## Negotiations Underway for Additional Assets

---

- **Presently Negotiating with 3 Companies to License/Develop Drugs in the Oncology, Cardiovascular and CNS Space**
- **Two Types of Agreements Being Negotiated**
  - Option to Purchase or In-License Drug
  - Development Team Collaboration (DTC) Partnership where the Drug Ownership Remains in the Present Company but Development Performed by Processa in Exchange for Expenses at Cost, Milestone Payments and Royalties.



# Plan and Timeline

	2H2018	1H2019	2H2019	2020 - 2022
PCS499 NL	<ul style="list-style-type: none"> <li>• Submit IND</li> <li>• Begin Phase 2 Max Dose Safety Study, Prelim Eff</li> </ul>	<ul style="list-style-type: none"> <li>• Readout on Max Dose Acceptable to Patients, FDA</li> </ul>	<ul style="list-style-type: none"> <li>• Begin Phase 2b/3 Pivotal</li> <li>• Begin Last Phase 1 &amp; Tox Studies</li> </ul>	<ul style="list-style-type: none"> <li>• Phase 2b/3 Readout; if FDA Acceptable, Single Pivotal Study</li> <li>• NDA Submission in NL</li> </ul>
Portfolio	<ul style="list-style-type: none"> <li>• Finalize Options to Acquire New Assets</li> </ul>	<ul style="list-style-type: none"> <li>• Meet with FDA on New Assets to Evaluate ROI/Timeline</li> </ul>	<ul style="list-style-type: none"> <li>• Exercise Options on New Assets</li> </ul>	<ul style="list-style-type: none"> <li>• Develop All Drugs in Portfolio</li> </ul>
Corp.	<ul style="list-style-type: none"> <li>• Complete Requirements for NASDAQ/NYSE Uplist</li> </ul>	<ul style="list-style-type: none"> <li>• Uplist to NASDAQ or NYSE</li> <li>• Raise \$15-40M</li> </ul>	<ul style="list-style-type: none"> <li>• Possible Out-License Drug(s) in Portfolio</li> </ul>	<ul style="list-style-type: none"> <li>• Possible Out-License Drug(s) in Portfolio</li> </ul>

# Summary

---

## **The Challenge:**

- To Maximize ROI by Efficiently Developing Drugs in High Unmet Medical Need Conditions

## **The Solution:**

- Assemble a Team Experienced in Navigating Through Development and FDA Approval
- Follow Processa Pipeline Selection Criteria (e.g., Clinical Evidence of Efficacy Exists, Minimal Risk in FDA Acceptance of IND and Development Program)
- Raise Capital to Support Cost Effective Regulatory Science, Not Scientific Knowledge
- Develop our New Development Team Collaboration (DTC) Business Model to Increase Value and Obtain Non-Diluting Cash
- Define and Achieve Value Added Milestones to Increase Likelihood of Out-Licensing or Selling Assets
- Increase Shareholder Value Through Development, Out-Licensing/Selling Assets, Merger and/or Acquisition



**Processa Pharmaceuticals**

