

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) **December 5, 2017**

**PROCESSA PHARMACEUTICALS, INC.**

(Exact Name of Registrant as Specified in its Charter)

<b>Delaware</b>	<b>333-184948</b>	<b>45-1539785</b>
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

**7380 Coca Cola Drive, Suite 106,**  
**Hanover, Maryland 21076**  
(Address of Principal Executive Offices)

**(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
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act
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**Item 7.01 Regulation FD Disclosure.**

A copy of a slide presentation that Processa Pharmaceuticals, Inc. (the "Company") used during presentations made before individuals and small groups in Los Angeles at the LDMicro 10th Annual Main Event on December 5, 2017 (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 unless another date is specifically shown. 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 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.

**Item 9.01 Financial Statements and Exhibits.**

**Exhibit No. Description**

[99.1](#) Processa Pharmaceuticals, Inc., Corporate Presentation dated December 5, 2017

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**PROCESSA PHARMACEUTICALS, INC.**

Date: December 5, 2017

By /s/ David Young  
David Young  
Chief Executive Officer



**Processa Pharmaceuticals**  
(Formerly Promet Therapeutics, LLC)

**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 and Interim CFO

*December 2017*

## 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") or a licensed representative of Boustead Securities, LLC ("Boustead"), the FINRA Registered managing broker-dealer of this Offering, 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. Neither the Company nor Boustead, 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. Neither the Company nor Boustead assume any obligation to release updates or revisions to forward-looking statements contained herein.

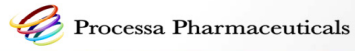


Processa Pharmaceuticals

## Processa Pharmaceuticals Highlights

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- **Clinical Stage** Drug Development Company – Our focus is Phase 2 on
- **Treat High Unmet Medical** Need – **Existing POC Clinical Data** for Structural Analog
- **Experienced Team** of Drug Developers, Pharma Executives, Biotech Investors
- **Collaborate and Negotiate** with FDA Using a FDA Regulatory Science Approach
- **2 - 4 Year Outcome** for Each Pipeline Product (Out-Licensing or Pivotal Study Completed)
- **Portfolio to be Expanded** in 2018



## Processa Pharmaceuticals Financial Overview

<b>Symbol-Share Price:</b>	PCSA - \$3.64*
<b>Headquarters</b>	Hanover, MD
<b>Market Cap</b> as of 11/27/17	\$128.4M
<b>Shares Outstanding</b>	35.3M*
<b>Cash</b> As of 11/27/17	\$3.0 M (Includes \$2.58 M Convertible Bridge Loan)
<b>Insider Ownership %</b>	76.1%

### Summary of Salient Points

> October 4, 2017: Promet Therapeutics, LLC signs Option & License Agreement with CoNCERT Pharmaceuticals (CNCE: \$22.93)

> October 4, 2017: Asset purchase of Promet closed to create Processa Pharmaceuticals, Inc.

> December 2017: Licensing Option to be exercised in exchange for \$8M of equity in Processa at market value, 15% of sublicensing fees, 4% - 10% backend royalties on net sales

> December 2017: PIPE financing currently underway at \$80M valuation

> 2018: Plan to uplist to NASDAQ CM or NYSE MKT

\* Post 1 for 7 Reverse Split



**Processa Pharmaceuticals**

## Summary of PIPE Offering

<b>Financing:</b>	PIPE
<b>Exemption:</b>	Reg D, 506c
<b>Security:</b>	Common Stock and Warrants
<b>Amount:</b>	1) \$4M (+\$3.0M Existing Cash) Covers One (1) Max. Tolerated Dose Phase 2 Trial, Some Tox for Second Asset 2) \$8M (+\$3.0M Existing Cash) Covers Two (2) Max Tolerated Dose Phase 2 Trials, Some Tox for Second Asset
<b>Price Per Share:</b>	\$2.26 (Total Shares of 35.3M after 1 for 7 Reverse Split)
<b>Pre-Money Valuation:</b>	\$80M Pre-Money Valuation Discounted from Total rNPV Valuation of \$120M - \$400M**
<b>Target Closing Date:</b>	1Q2018

\*\$80M Pre-Money Valuation = High rNPV for NL in US = Low rNPV for NL in SDI = 70% Discount on the Average Total rNPV  
^Source: Company





# We Know How to Succeed in 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 in 2007 to \$5.6B Market Cap in 2014 in Mallinckrodt acquisition (370x increase in 7 years)
- **Development Team Knows the Process to Obtain Drug Approvals with Proven Track Record**
  - 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

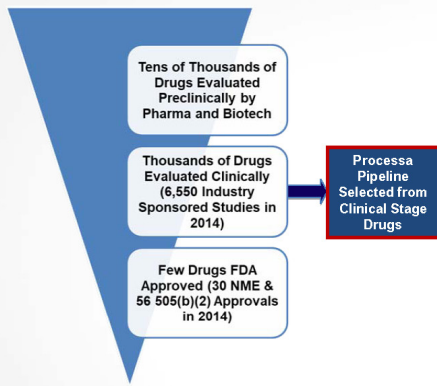
 **Processa Pharmaceuticals**

## OUR LEADERSHIP

- **David Young, Pharm.D., Ph.D., CEO and Interim CFO**
  - 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 and 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
- **Sian Bigora, Pharm.D., Chief Development Officer**
  - Former VP of Regulatory Affairs at Mallinckrodt, Questcor Pharmaceuticals, AGI Therapeutics, ICON, GloboMax
  - Former Instructor of FDA Reviewers
- **Helen Pentikis, Ph.D., Interim Chief Scientific Officer**
  - Founder of Symbiomix Therapeutics, a venture backed, late stage company acquired by Lupin Pharmaceuticals
  - Former Head of Clinical Pharmacology at AkaRx; Global VP of PK-PD at ICON; VP of PK at GloboMax.
  - Fellow in PK and Clinical Pharmacology at the FDA
- **Wendy Guy, Chief Administrative Officer**
  - Former Senior Manager in Business Operations at Questcor, AGI Therapeutics, ICON, GloboMax with 20 Years Experience in Corporate Management, HR and Finance



## Major Criteria for Selecting Pipeline Products for Development



- ✓ **Pharmacology Aligns** with Pathophysiology
- ✓ **Clinical POC Data Exists** for Drug or Analog
- ✓ **Minimal Risk in FDA Acceptance of IND and Development Program** (Often Already Evaluated Clinically in Different Target Population; If CMC/Tox Work Required, Not Extensive)
- ✓ Products Requiring a NDA Program  $\geq$  \$100M &  $\geq$  7 Yrs, **Out-License 2-4 Years After Acquiring (After Dose Ranging, Before Pivotal Study)**
- ✓ Products Requiring a NDA Program  $\leq$  \$75M &  $\leq$  6 Yrs, **Pivotal Completed in 3-4 Yrs, Possibly Develop to NDA**
- ✓ **Attractive ROI** (e.g., In-Licensing, Development Cost, Timeline, rNPV)



Processa Pharmaceuticals

## PCS499 Diverse Pharmacology Useful for Two Indications

### PCS499 has Multiple Pharmacological Targets and is the Analog of a Major Metabolite of an Approved Drug

- Modulates Immune Cells (e.g., Neutrophils) and Cytokines (e.g.,  $\text{TNF } \alpha$ )
- Effects on Blood Viscosity & Oxygenation, Platelet Aggregation
- Anti-Fibrotic Effect

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

- FDA Approved IND, Phase 1 and 2 Studies Complete, FDA Recommended a Higher Dose
- Safe in Humans and Ready to Be Administered to Patients with Other Conditions

### Processa Pipeline for PCS499 Includes Two Unmet Medical Need Conditions

- Necrobiosis Lipoidica (NL)
- Radiation Therapy Adverse Effects in Oncology (RTAE)



## PCS499 For Treatment of Necrobiosis Lipoidica (NL) - No Approved Treatment

- Inflammatory Site Disorder With Pathophysiology Involving the Immune System and Blood Flow
- Skin Becomes Necrotic; 30% of Patients Have Painful Ulcerations
- Potential to Last for Month or Years
- Complications: Infections, Amputation, Squamous Cell Cancer
- No Current FDA Approved Treatment; Dermatologists Are Mainly Using Topical Steroids with Poor Long Term Response; Some Dermatologists Use Other Products with Mixed Results



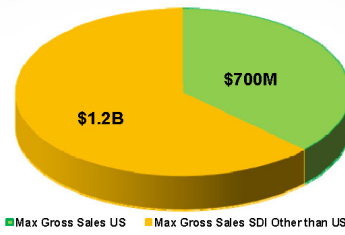
## PCS499 For Treatment of Necrobiosis Lipoidica (NL) - No Approved Treatment

- Evidence of PCS499 Efficacy in Patients with NL
  - Diverse Pharmacology Targets Mixed Pathophysiological Changes Associated with NL
  - Some Dermatologists Use a Drug with Similar Pharmacology but Have Mixed Results (Dose Probably Too Low But Unable to Give Higher Doses Because of Adverse Events)
  - PCS499 and PCS499 Metabolite Profile Likely to Improve Efficacy/Safety over Drugs Presently Used
- **Target Population 200,000 – 500,000** Patients in High Sociodemographic Index (SDI) Countries (74,000-185,000 in US)
- Anticipate Orphan Drug Designation



## Market Opportunity Based on Average Prevalence

Necrobiosis Lipoidica (NL)  
\$1.9B Max Gross Sales Based on Average Prevalence in All SDI Countries



Target Population 200,000 – 500,000 Patients in  
High Sociodemographic Index (SDI) Countries (74,000-185,000 in US)  
(Range of Max Gross Sales Based on Prevalence Range:  
\$1.1B - \$2.7B SDI Countries, \$400M – \$1.0B in US)

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

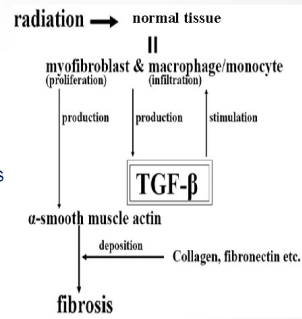


Processa Pharmaceuticals



## PCS499 To Treat Radiation Therapy Adverse Effects (RTAE) in Head/Neck Cancer – No Approved Treatment

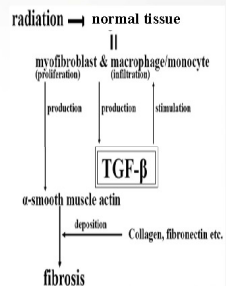
- Patients with Head/Neck Cancer Receiving Radiation Therapy (RT) Often Have Progressive Fibrotic Tissue Sclerosis and/or Xerostomia from Normal Tissue Being Exposed to Radiation
- Normal Tissue Continues to Change from Months - Years after RT
- No FDA Approved Treatment; Radiation Oncologists Do Not Have a Standard of Care and Use a Variety of Drug Products to Treat Various Symptoms



Processa Pharmaceuticals

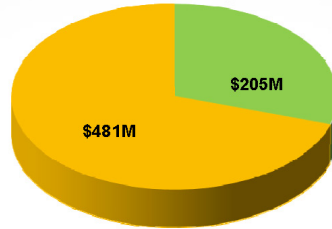
## PCS499 To Treat Radiation Therapy Adverse Effects (RTAE) in Head/Neck Cancer – No Approved Treatment

- Evidence of PCS499 Efficacy In Patients with RTAE
  - Diverse Pharmacology Targets Mixed Pathophysiological Changes Associated with RTAE
  - Some Radiation Oncologists Use a Drug with Similar Pharmacology but Have Mixed Results (Dose Probably Too Low But Unable to Give Higher Doses Because of Adverse Events)
  - PCS499 and PCS499 Metabolite Profile Likely to Improve Efficacy/Safety over Drugs Presently Used
- **Target Population 76,000 – 184,000** Patients in High Sociodemographic Index (SDI) Countries (26,000 – 52,000 in US)
- PCS499 Efficacy in Treating RTAE in Head/Neck Cancer Opens Up More Opportunities to Treat Other Types of Radiation Treated Cancer
- Anticipate Orphan Drug Designation



## Market Opportunity Based on Average Prevalence

Radiation Related Adverse Effects in Head/Neck Cancer  
\$686M Max Gross Sales Based on Average Prevalence in All SDI Countries



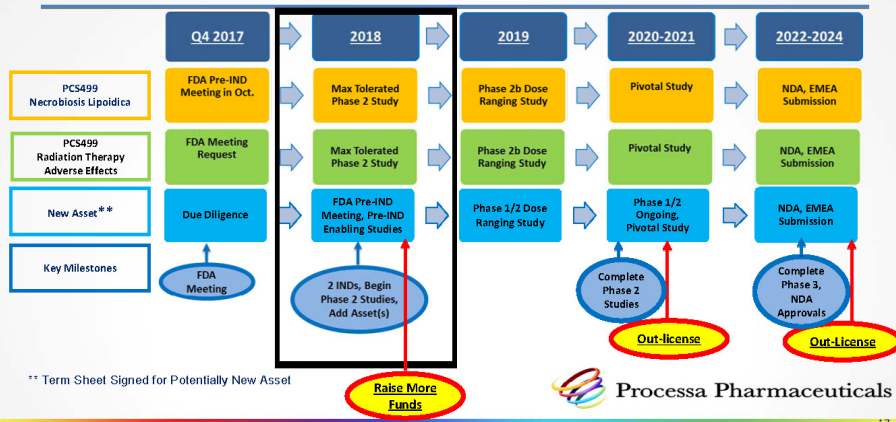
■ Max Gross Sales US ■ Max Gross Sales SDI Other than US  
Target Population 76,000 – 184,000 Patients in  
High Sociodemographic Index (SDI) Countries (26,000 – 52,000 in US)  
(Range of Max Gross Sales Based on Prevalence Range :  
\$400M – \$972M SDI Countries, \$137M – \$274M in US)

Source: Siegel, et al. CA Cancer J Clin. 2017; Global Burden of Disease Cancer  
Collaboration. JAMA Oncol. 2017; Company



Processa Pharmaceuticals

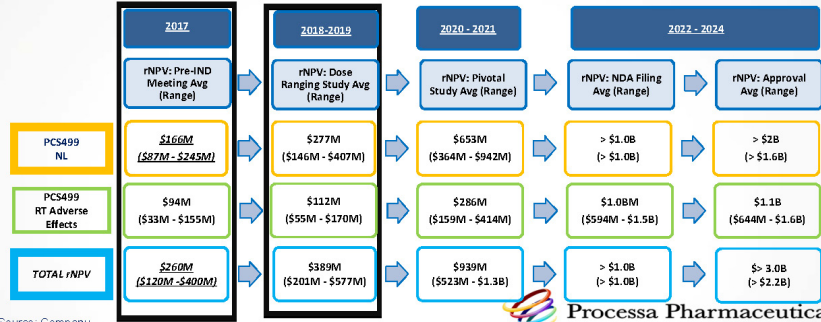
# Portfolio and Anticipated Pipeline Timeline with Key Milestones



# Processa rNPV for Only NL and RTAE by Clinical Milestone

**Valuation Based on:**

- Team Experience and Past Successes
- PCS499 in Clinical Stage of Development for 2 Indications
- Risk Adjusted Net Present Value (rNPV) of PCS499 in High SDI Countries (See Below, See Appendix)\*



\*Source: Company

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 ^Source: Company



## Summary

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### **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 or Pre-Clinical POC Data Exists, Minimal Risk in FDA Acceptance of IND and Development Program)
- Define and Achieve Value Added Milestones Including Out-licensing Products at Various Stages of Development to Further Increase Value and Obtain Non-Diluting Cash
- Raise Capital to Support Cost Effective Programs, Not Scientific Knowledge
- Increase Shareholder Value Through Development, Out-Licensing/Selling Assets, Merger and/or Acquisition

