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**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 23, 2019**

Commission file number 333-184948

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**PROCESSA PHARMACEUTICALS, INC.**

(Exact name of Registrant as Specified in its Charter)

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**Delaware**

(State or Other Jurisdiction of  
Incorporation or Organization)

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**45-1539785**

(I.R.S. Employer  
Identification Number)

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**7380 Coca Cola Drive, Suite 106, Hanover, Maryland 21076**

(Address of Principal Executive Offices, Including Zip Code)

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**(443) 776-3133**

(Registrant's Telephone Number, Including Area Code)

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(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.

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**Item 7.01. Regulation Disclosure.**

A copy of a slide presentation (Presentation Materials”) that Processa Pharmaceuticals, Inc. (“Processa Pharmaceuticals”) intends to publish to its website, 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**

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

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**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 23, 2019.

**PROCESSA PHARMACEUTICALS, INC.**  
Registrant

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

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# Processa Pharmaceuticals

CORPORATE PRESENTATION  
OCTOBER 2019

## Disclaimer: Forward Looking Statements

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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 and its directors, officers, employees and consultants do not 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.



## Company Overview

### Focused on Acquiring and Developing Drug Products for Patients Needing Treatments to Extend Survival and/or Significantly Improve Quality of Life

- Building a portfolio of high value drugs for patients with unmet medical need conditions
- Experienced management, development team with a track record of successful FDA approvals and value creation
- Present portfolio of two drugs with addressable markets > \$1.5 B
  - Clinical evidence of efficacy for both drugs decreasing the risks associated with development
  - Expanding each drug to additional indications could potentially occur in the future
  - Additional drug acquisitions for the portfolio are being negotiated
- Non-study R&D and G&A burn rate is < \$2.5 M in 2019
- Several value inflection points over the next 12 – 18 months



Processa Pharmaceuticals

**Our People Are a Competitive Advantage**



**Processa Pharmaceuticals**



## Our People Lead to Success

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- Established and proven Executive Team with 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 a proven record of success and has worked together in other companies
  - > 30 years of experience developing drugs
  - Trained FDA reviewers, conducted FDA sponsored research to support 4 FDA Guidances, helped in the writing of 3 FDA Guidances
  - FDA Advisory Committee involvement as Committee Member & Sponsor
  - Involved with > 30 FDA approvals & > 100 FDA meetings, the most recent approval was for Acthar which was a key value creation event for Questcor Pharmaceuticals
  - Agnostic to therapeutic area having worked with every FDA Drug Review Division



## Our Leadership

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### **David Young, Pharm.D., Ph.D., CEO, Chairman of the Board**

- 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 and Director, Board of Directors**

- 20 Years Financing and Investing Experience in Biopharma Sector;
- 25 years on Wall Street involved with over 500 IPOs and Follow on Offerings
- Principal/Founder Primarius Capital, Focused on Small Cap with Numerous \$3B+ Mkt Cap Winners
- Former E\*Offering Co-Founding Partner Growing Company to 200 Employees & \$80M Rev. During 1<sup>st</sup> Year; Former Principal at Robertson Stephens & Co.



## Our Leadership

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**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**

- 30 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



## Our Strategy and Competitive Advantage

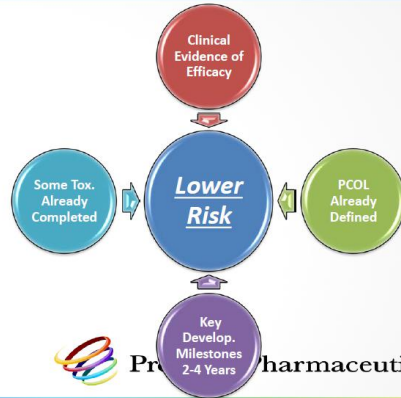
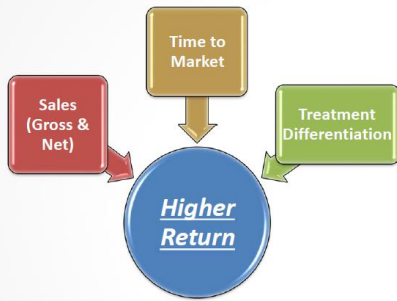


Processa Pharmaceuticals

# Our Strategy: Obtain Drugs with High Potential Value, Lower Risk of Failure during Development

Increase return on investment (ROI) by selecting drugs and indications with higher potential gross sales, faster time to market, & differentiation from existing treatments

Decrease risk of failure by selecting drugs with some clinical evidence of efficacy/safety, pharmacology-tox understood, & value added milestones in 2-4 years



 ProPharmaceuticals

## Competitive Advantage: Processa Approach to Obtaining Drug Approval



We Know The Way  
To The FDA

Over the Last 25+ Years, Our Team Has Refined a Regulatory Science Platform or Approach for the Development of Drugs for FDA Approval

- The Regulatory Science Platform is based on our experience teaching FDA reviewers, conducting research funded by FDA for FDA Guidances, writing FDA Guidances, developing drugs for FDA approval, and meeting with FDA as a colleague and as a sponsor
- R&D studies are conducted to provide the scientific foundation upon which FDA will make regulatory decisions, not for scientific knowledge
- Processa does not focus on one therapeutic area but has the knowledge and expertise to obtain drug approvals across therapeutic areas having successfully interacted with almost every FDA division

 Processa Pharmaceuticals

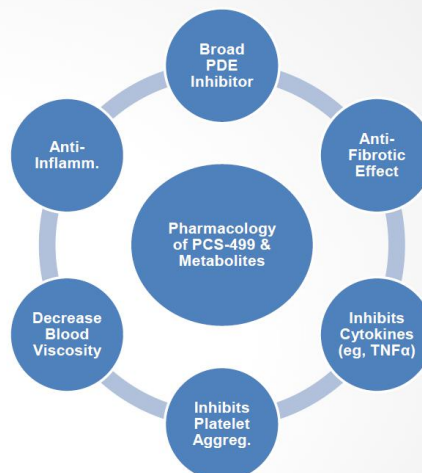
**Processa Present Portfolio:  
PCS-499 & HT-100**



**Processa Pharmaceuticals**

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

- PCS-499 metabolizes to same active moieties as PTX (including reversibly metabolized to PTX itself) but the metabolite profile is different after PCS-499 administration than PTX (i.e., the % exposure to various active metabolites and administered drug is different)
- PCS-499 and active metabolites have a diverse pharmacology profile →
- Originally developed by Concert Pharmaceuticals in Diabetic Nephropathy, taken to an end of Phase 2 meeting





## Patient Need: No Approved Treatment for Necrobiosis Lipoidica (NL)

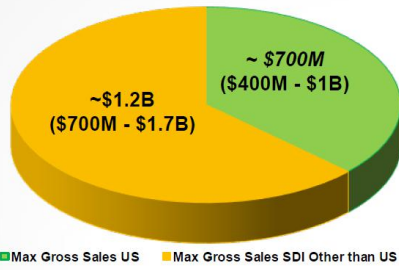
- Occurs in women/men 20 – 60 y/o
- Potential to last for months or years
- Skin becomes necrotic; 30% of patients have painful ulcerations; complications - infections, amputation, squamous cell cancer
- No standard of care or FDA approved treatment; no known biotech or pharma company developing a drug for NL; Dermatologists mainly use topical steroids and other drugs with poor response; Pentoxifylline (PTX) is not approved for NL but has been used off-label successfully in a small percentage of NL patients



# High Value: NL Market Opportunity

## Max Annual Gross Sales > \$1.0 B

Necrobiosis Lipoidica (NL)  
Max Gross Sales



- 74,000 – 185,000 Patients in US
- 200,000 – 500,000 Patients in High Sociodemographic Index (SDI) Countries



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

## High Value: Faster Time to Market

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- Development of PCS-499 can be expedited given many of the NDA required chemistry, manufacturing, pre-clinical and Phase 1 studies have already been conducted by Concert Pharmaceuticals.
- In our NL pre-IND (Investigation New Drug) meeting with the FDA, FDA agreed to the possibility of 1 pivotal trial given the orphan designation, seriousness of NL and no approved treatment.

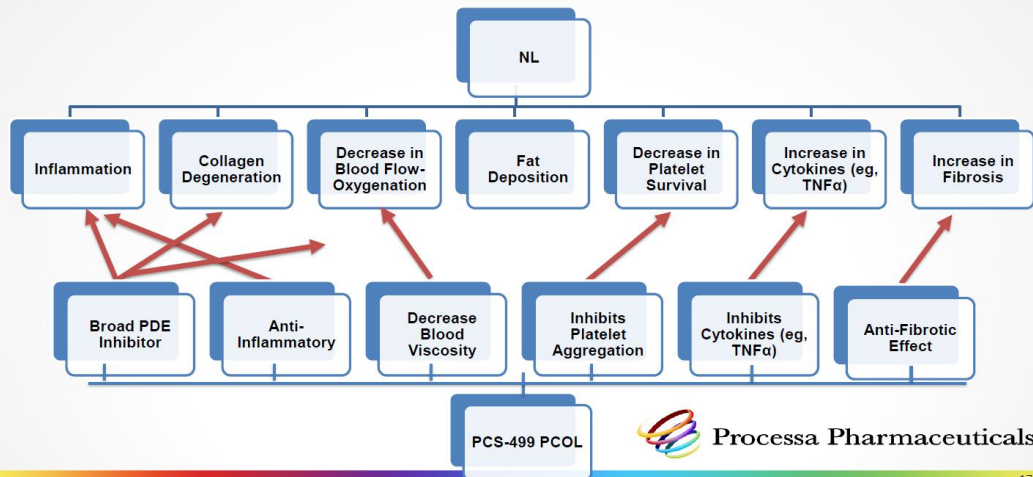
## High Value: Differentiation from other Treatments

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- Since there is no standard of care for NL and the treatment options presently used result in minimal efficacy (even off-label use of PTX, the non-deuterated parent drug of PCS-499), a new efficacious-safe drug would have the opportunity to differentiate itself from existing therapy
- In pre-clinical toxicology studies, the maximum tolerated dose for PCS-499 > PTX
- In Phase 1 and Phase 2 studies, 1.8 gm/day (900 mg b.i.d.) of PCS-499 administered orally was well tolerated while PTX is not well tolerated at doses > 1.2 gm/day (400 mg t.i.d.) and not tolerated even at 1.2 gm/day for some patients (1.2 gm/day is the max FDA recommended dose)
- After PCS-499 administration, the same active moieties exist systemically as in PTX but the amounts of key active moieties after the same dose of PCS-499 and PTX are more than 2 times greater after PCS-499 administration



## Lower Risk: PCS-499 is the Only Drug Other than PTX to Target the Many NL Pathophysiological Changes



## Lower Risk: Clinical Evidence Exists Supporting the Use of PTX and PCS-499 in NL

- PTX is used OFF-LABEL and response can start after 1 month with significant improvement within 3-12 months (published case studies and clinical experience)
- PTX does not have widespread use; a small percentage of patients respond at the maximum tolerated dose of PTX while many patients cannot tolerate the highest dose of PTX
- Increasing PTX dose beyond 1.2 gm/day (400 mg t.i.d.) to achieve higher response rate results in dose limiting side effects (nausea, vomiting, headaches)
- The PCS-499 Phase 2 NL trial has demonstrated that 1.8 gm/day (900 mg b.i.d.) is well tolerated and efficacy has been observed in patients with severe NL



## Lower Risk: PCS-499 Pharmacology, Toxicology, PK Already Evaluated

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- Pharmacology of PCS-499 and PTX has been evaluated
- The toxicology in animals and safety in humans for PCS-499 and PTX has been evaluated
- The CMC for PCS-499 has been defined and already being refined for NDA submission
- The single and multiple dose PK for the final PCS-499 product has been completed
- All pre-clinical and Phase 1 studies required prior to Phase 3 trial have been completed
- Other toxicology (eg, carcinogenicity) and Phase 1 (eg, drug interaction studies) requirements for NDA approval are to be discussed at our next meeting with FDA



## Status of PCS-499 NL Program

- Defined development program in pre-IND collaborative meeting with FDA; FDA stated that 1 pivotal study may be acceptable for NL
- Received Orphan Designation (7 years of Market Exclusivity upon approval)
- PCS-499 IND cleared by FDA for PCS-499 Phase 2a safety/tolerability trial in 12 NL patients
- Enrollment complete in Phase 2a trial; PCS-499 well tolerated at 1.8 gm/d; ulcers have completely closed in some NL patients; 6 month efficacy results for 9 patients available in December 2019; trial to be completed March 2020
- Plan to request FDA meeting at end of 2019 to define Special Protocol Assessment (SPA) for larger randomized pivotal trial (Phase 2b/3)
- Phase 2b/3 trial anticipated to start 2020 and complete in 2023





## HT-100 Anti-fibrotic and Anti-inflammatory Drug

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- Affects collagen expression and TGF- $\beta$  pathway
- History
  - Incomplete tox package but FDA cleared IND for Duchenne Muscular Dystrophy (DMD)
  - Efficacy observed in pediatric DMD patients
  - Previous company mismanaged DMD trial resulting in a Serious Adverse Event
  - Placed on clinical hold, later removed off clinical hold
- Potential Indications (Processa plans to first develop HT-100 in an adult indication, then move back to pediatric indications after more is known about therapeutic window)
  - Idiopathic Pulmonary Fibrosis, Scleroderma, other fibrotic related conditions in adults
  - DMD or other fibrotic related conditions in pediatric patients
- Plan to meet with FDA in 2020 to define the development in an adult fibrotic condition where there is existing clinical evidence that a drug with ant-fibrotic properties would be efficacious



**Financial Metrics  
&  
12 - 18 Month Catalysts**



**Processa Pharmaceuticals**

## Processa Financial Overview

OTCQB (10/11/19)	PCSA - \$2.50/share
Market Cap (10/11/19)	\$97 M
Shares Outstanding	~ 38.7 M Shares
Prior Cash Investment in Processa	~ \$7.5 M
Present Cash Balance (10/11/19)	~ \$1.26 M
Convertible Line-of-Credit (September 2019)	\$1.4 M (full \$1.4 M still available to PCSA)
Total 2019 Remaining Expenses	~ \$600 K (other than Phase 2 Trial)
Remaining Phase 2 Trial Expenses	~ \$500 K to be paid through 1H2020
PCSA Insider Ownership %	> 70%
Nasdaq Listing	Presently working on Nasdaq listing



## Catalysts Over the Next 12 – 18 Months

- Obtain Nasdaq listing, raise funds to support the catalysts briefly described below
- Development of PCS-499
  - Complete Phase 2 trial (safety, tolerability, efficacy trial) in NL patients (1H2020)
  - Meet with FDA to discuss remaining requirements for NDA submission(1Q2020)
  - Submit Special Protocol Assessment (SPA) for Phase 2/3 pivotal trial; initiate trial (2H2020)
  - Out-license PCS-499 for development and commercialization outside the U.S.
- Development of HT-100
  - Meet with FDA on first IND indication for adults (1H2020)
  - Submit IND for safety/tolerability trial in healthy volunteers in order to better define therapeutic window in adults; initiate trial (2H2020)
- Development of new drug asset(s)
  - Acquire at least one other drug asset that fits the Processa model (2020)
  - Meet with FDA on the development program for the drug and indication (2020)
  - Depending on previous clinical trials, design the next trial; obtain FDA approval to conduct next clinical trial



## Summary

### **Focused on Acquiring and Developing Drug Products for Patients Needing Treatments to Extend Survival and/or Significantly Improve Quality of Life**

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