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): May 20, 2021

PROCESSA PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	001-39531	45-1539785
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

7380 Coca Cola Drive, Suite 106, Hanover, Maryland, 27106

(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (443) 776-3133

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 Stock, $0.0001 par value per share	PCSA	The Nasdaq Stock Market LLC

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 FD Disclosure.

Processa Pharmaceuticals, Inc. ("***Processa***") will present and participate in virtual meetings with analysts and investors on May 21, 2021 at the Oppenheimer Rare & Orphan Disease Summit. During these virtual meetings, Processa's presentation will be uploaded into a portal, which is furnished as Exhibit 99.1 and is incorporated herein by reference. The presentation will also be made available in the "Investors" section on Processa's website, located at processapharmaceuticals.com.

Processa undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time through the filing of other reports or documents with the Securities Exchange Commission, through press releases, or through other public disclosure, including in the "Investors" section of Processa's website. Processa routinely uses its website as a means of disclosing material non-public information and for complying with its disclosure obligations under Regulation FD.

The information in this Item 7.01 and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	May 2021 Corporate Presentation

SIGNATURES

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.

PROCESSA PHARMACEUTICALS, INC.

Date: May 20, 2021

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

Rare & Orphan Disease Summit
May 21, 2021

Necrobiosis Lipoidica
A Rare Disease Affecting Many

David Young, PharmD, PhD
Chairman and CEO

OPPENHEIMER

Processa Pharmaceuticals

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 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. 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 which could cause actual results to differ from those contained in the forward-looking statements. The Company does not assume any obligation to release updates or revisions to forward-looking statements contained herein.

Processa's Differentiated Approach

Experience in Adding Value to Companies with Over 30 FDA Approvals

DEVELOP NOT **DISCOVER** — REGULATORY SCIENCE PLATFORM

Unmet Medical Need +	Efficacy Evidence +	Regulatory Science +	Capital Efficiency +	Potentially High ROI
• Clear and obvious **patient need** • **Favorable competitive** dynamics	• **Evidence of clinical efficacy** in targeted medical condition • **Higher** probability of **successful development**	• **Improve Benefit/Risk** profile that FDA evaluates for approval • **Optimize trial design** and **anticipate** what **FDA** requires for approval (Trifecta: decreasing risk, time to approval & cost)	• **Leverage** considerable **prior investments** before licensing (tox, CMC, etc.) • **Efficient development** program and clinical trial design	• **Intelligently monetize and partner assets**

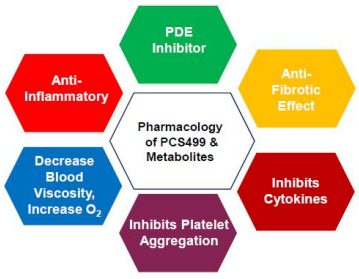
Processa Pipeline – Multiple Opportunities For Success

Pipeline of Drugs to Treat Patients who Need Better Treatment Options

Drug	Disease Target	Preclinical	Phase 1	Phase 2	Phase 3	Market Size
PCS499	Ulcerative Necrobiosis Lipoidica					> $1 B
PCS6422	Metastatic Colorectal, Breast Cancer					> $1 B
PCS12852	Gastroparesis, Functional Constipation					> $1 B
PCS11T	Small Cell Lung, Colorectal Cancer					> $1 B

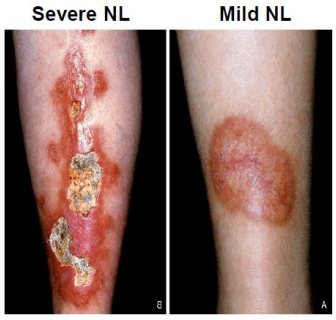
PCS499: Diverse Pharmacological Properties

- Deuterated analog of the major metabolite of Pentoxifylline (PTX) (PTX FDA approved for claudication in the 80s)
- Metabolizes qualitatively to the same PTX metabolites but the amount of key active moieties after 1.2 gm of 499 or PTX is administered, is more than twice as much after 499 compared to PTX because of the deuteration on 499
- PCS499 and its metabolites have diverse pharmacological properties (see diagram)
- The diverse pharmacology of PCS499 could be beneficial in a number of orphan and non-orphan medical conditions
- PCS499 originally developed by CoNCERT Pharmaceuticals in Diabetic Nephropathy; discontinued development after FDA end of Phase 2 meeting



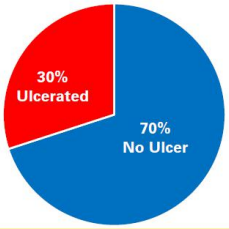
What is Necrobiosis Lipoidica (NL)?

- Skin and tissue below the skin becomes necrotic, can last from months to years with complications such as infections, amputation, and squamous cell cancer
- 70% of the patients are women between 20 – 60 years old; 60% of NL patients are diabetic but NL is not dependent on glucose control
- 30% of NL patients have painful ulcers occurring naturally or from contact trauma to the lesion
- Natural complete healing of moderate to severe ulcers during the first 1-2 years after onset occurs in less than 5% of these patients
- 7 pathophysiological changes have been reported in NL
  - Decrease in blood flow & oxygenation
  - Decrease in platelet survival
  - Increase inflammation
  - Increase fibrosis
  - Increase cytokines
  - Degeneration collagen
  - Alters fat deposition



Is Necrobiosis Lipoidica (NL) or Ulcerative NL (uNL) Rare or Ultra Rare?

75,000 – 185,000 NL Patients in the US



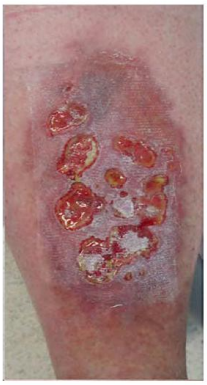
- **22,000 – 55,000 uNL Patients in US**
- **150,000 – 400,000 uNL Patients Worldwide**

- Patients seen by numerous physicians including primary care, endocrinologist, dermatologist
- Often misdiagnosed for diabetic ulcer unless a biopsy is obtained
- Diagnosis requires a biopsy to demonstrate histopathology of these lesions shows a characteristic granulomatous inflammatory reaction surrounding destroyed collagen, thickened blood vessel walls and endothelial swelling

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

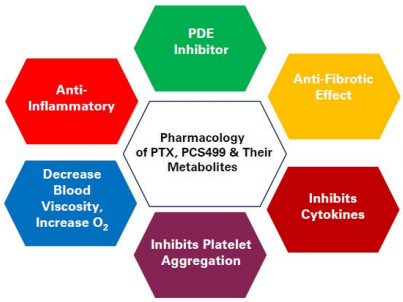
What Treatment Options Exist for Ulcerative NL or NL?

- There is no FDA approved treatment for NL or UNL and there is no standard of care; all are inadequate
- Drugs have been used off-label with mixed success (for example; pentoxifyline (PTX), immunomodulating drugs) but all are inadequate given their side effect profile and/or limited efficacy
- Topical steroids are typically prescribed because they can slow the progression of early active non-ulcerated lesions, but careful monitoring is necessary as steroids can increase atrophy and the risk of ulceration



Why PCS499 for the Treatment of uNL?

- PTX is not approved for NL, but it is used off-label and, in a small percentage of patients, PTX treatment will completely close ulcers for patients who can tolerate the highest labelled dose, supporting the hypothesis that PTX and its metabolites may be targeting the correct pharmacological pathways
- PCS499 has similar, but not identical pharmacology properties of PTX, and the metabolite profile of PCS499 results in a better adverse event profile based on toxicology, Phase 1 and Phase 2 studies



Pathophysiological Changes in NL

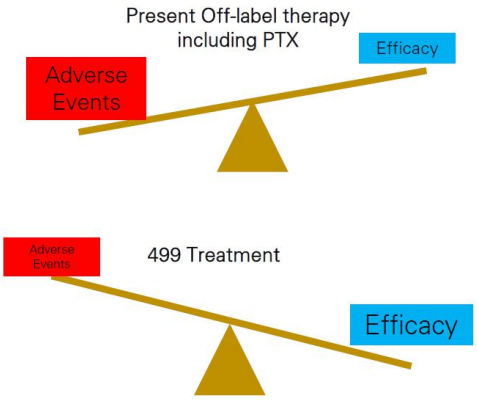
- ☑ Decrease in blood flow & Oxygenation
- ☑ Decrease in platelet survival
- ☑ Increase inflammation
- ☑ Increase fibrosis
- ☑ Increase cytokines
- ☑ Degeneration collagen
- ☐ Alters fat deposition

PCS499 Target Profile for Ulcerative Necrobiosis Lipoidica (uNL)

- **Target Indication:**
  - Treatment of ulcerative necrobiosis lipoidica ("uNL")
  - PCS499 has FDA orphan designation for NL
- **Target Claims:**
  - Completely closes open necrobiosis lipoidica ulcers; improves non-ulcerated NL lesions
  - Well tolerated
  - Natural healing of more severe ulcers occurs in less than 5% of the patients 1-2 years after ulcer forms

PCS499 FDA Designated Orphan Drug - Ulcerative Necrobiosis Lipoidica (uNL)

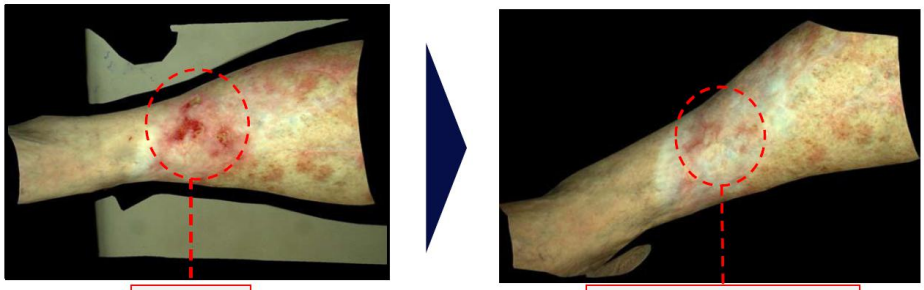
- **Differentiation of PCS499 from Existing Therapy**
  - No approved NL or uNL treatment in U.S. or worldwide; Off-label drugs are prescribed to treat NL with mixed results
- **Why Does 499 Work Better than PTX and Other Drugs**
  - Metabolizes qualitatively to the same PTX active metabolites but the amount of key active moieties after 1.2 gm of 499 or PTX is administered, is greater than twice as much after 499 compared to PTX
  - PCS499 is tolerated much better than PTX even at 50% higher dose of 1.8gm/d of 499 vs the 1.2 gm/d maximum labelled dose of PTX
  - The 1.8 gm/d of 499 is exposing the patient to much greater active moieties which shifts the balance of safety vs efficacy to higher efficacy



Phase 2A Trial of 1.8 gm/d of PCS4999 in NL Patients

Less Than 5% of uNL Patients Have Ulcers Naturally Heal During First 1-2 Years After Occurrence

- PCS499 was well tolerated at 1.8 gm/d
- In the only two NL patients with open ulcers, all ulcers completely closed
- Ulcers occurring from contact trauma to the NL lesion during the study also completely closed



Baseline | Complete Closure

PCS499 FDA Designated Orphan Drug - Ulcerative Necrobiosis Lipoidica (uNL)

- **Phase 2B to Better Define Variables for Phase 3:**
  - **General Design:** Randomized, double-blind placebo-controlled trial of 1.8 gm/d of 499 in 20 uNL patients with primary efficacy evaluation at 6 months
  - **Objective:** To determine complete closure response rate of ulcers in patients on placebo vs 499
  - **Inclusion Criteria Examples:** Biopsy-confirmed diagnosis of ulcerated NL; at least one (1) ulcer with a minimum surface area of 1 cm2, total ulcer area of a minimum of 2 cm2, and no more than 6 ulcers
  - **Exclusion Criteria Examples:** In the last 6 weeks took other drugs such as oral corticosteroids, topical drugs, systemic pentoxifylline, theophylline, immunosuppressant or immunomodulatory drugs

- Selected clinical sites for Phase 2B trial in patients with ulcerative necrobiosis lipoidica (uNL), Adding more sites
- Begun screening patients for uNL trial last week
- Interim Analysis 1Q22
- Final Analysis 2H22

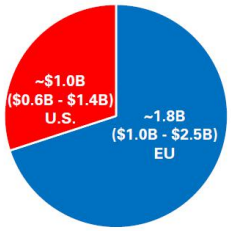
In 2023

Begin Phase 3 after End of Phase 2 meeting and Special Protocol Assessment agreement from FDA

PCS499 uNL Potential Gross Sales of $600M - $1.4 B

- **Economic Value: Initial Markets**
  - 22,000 – 55,000 patients in U.S. have uNL
  - Presently no approved treatment and off-labeled drugs not proven to be significantly effective/safe in patients with NL or uNL
  - 499 has orphan designation for NL
  - 499 would be the first approved drug to treat patients with uNL or NL
  - U.S. market potential in uNL is ~$600 M - $1.4 B

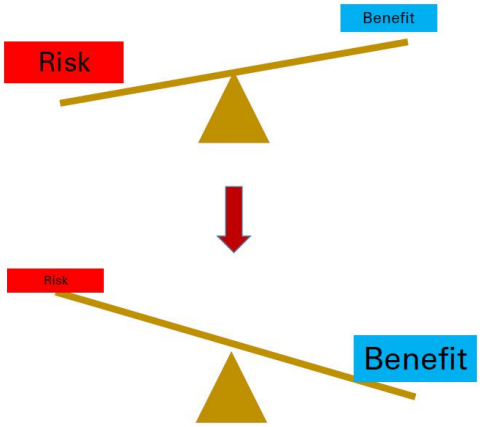
Ulcerative Necrobiosis Lipoidica (uNL)
Max Gross Sales



- **22,000 – 55,000 uNL Patients in US**
- **150,000 – 400,000 uNL Patients Worldwide**

Processa Corporate and Regulatory Science Approach

Pipeline Criteria	
Unmet Medical Need	✓
Efficacy Evidence	✓
Regulatory Science	✓
Capital Efficiency	✓
Potentially High ROI	✓



Processa Capital Structure and Share Information May 14, 2021

- **Stock Listing**: PCSA – NASDAQ
- **52 Week Low-High**: $3.95 - $13.15
- **Price (May 14, 2021)**: $6.15
- **Market Cap (May 14, 2021)**: $95,457,938
- **Shares Outstanding**: 15,521,616
- **Fully Diluted Shares**: 16,511,147
- **Cash, Cash Equivalents**: $21,404,094.82
- **Expected 2021 Overhead Cash Burn**: $3,500,000
- **Employees**: 15
- **Research Analysts**:
  Robin Garner – Craig Hallum;
  Aydin Huseynov MD, CFA - Benchmark
  Hogan Mullaly – Encode Ideas