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): July 29, 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***") presented on July 29, 2021 at the LD Micro "Zooming with LD Micro" virtual investor event. The presentation is 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	July 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: July 29, 2021

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

Processa Pharmaceuticals

Zooming with LD Micro
July 29, 2021

David Young, PharmD, PhD
Chairman and CEO

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 Highlights

Increase Prob. of Approval
- Experienced Exec. Team & Staff
- Drug Development Regulatory Science Platform
- Pipeline Drugs Selected to Increase Prob of Success & Mitigate Risk

Capital Efficient
- $3.5 M/yr Overhead with 15 Staff
- $21 M Cash
- 15.5 M Outstanding Share, ~ 35% Insiders

•Regulatory Science Appproach
- 30 FDA Approvals, 100 FDA Meetings, 2 FDA Regulatory Science Contracts
- Programs Designed to Improve Benefit-Risk Profile as Viewed by FDA

Processa
Increasing ROI

Potential Markets
- Improved Efficacy/Safety Profile
- Each Drug Approximately $1.0 B U.S. Market

6-18 Month Clinical Milestones
- 499 Phase 2B uNL Interim Analysis, Study Completion
- 12852 Phase 2A Gastroparesis IND, Initiate Phase 2A
- 3117 Complete Biomarker Assay, Initiate Phase 2B
- 6422 Phase 1B GI Cancer Interim Analysis, MTD Identified

Processa Capital Structure and Share Information on March 31, 2021

- **Stock Listing:** PCSA – NASDAQ
- **52 Week Low-High:** $3.95 - $13.15
- **Price (July 23, 2021):** $7.00
- **Market Cap (July 23, 2021):** $108,651,312
- **Shares Outstanding:** 15,521,616
- **Fully Diluted Shares:** 16,511,147
- **Cash, Cash Equivalents:** $23,048,000
- **Expected 2021 Overhead Cash Burn, Including Salaries:** $3,500,000
- **Employees:** 15
- **Research Analyst Reports:**
  Robin Garner – Craig Hallum
  Aydin Huseynov MD, CFA - Benchmark
  Hogan Mullaly – Encode Ideas

Processa's Risk Abated Approach and Criteria for Drug Selection

Experience in Adding Value to Companies: > 30 FDA Approvals & Regulatory Science Contracts from FDA

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

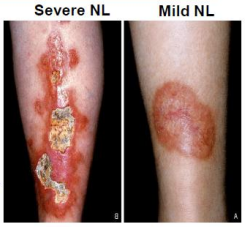
Pipeline of Drugs with Funding to Obtain Results for Key Milestones

Drug	Disease Target	Preclinical	Phase 1	Phase 2	Phase 3	Milestones
PCS499 Phase 2B	Ulcerative Necrobiosis Lipoidica			*		Interim Analysis 1H'22; Final Analysis 2H'22; FPI Phase 3 SPA 2023
PCS12852 Phase 2A	Gastroparesis, Constipation Disorders					Phase 2A IND Submission 3Q'21; FPI Phase 2A 1H'22; Final Analysis 2H'22 - 1H'23
PCS3117 Phase 2B	Pancreatic, Non-Small Cell Lung Cancer			*		Complete Biomarker Assays 1H'22; FPI Phase 2B 2H'22; FPI Phase 3 SPA 2023 - 2024
PCS6422 Phase 1B	Metastatic Colorectal, Breast Cancer		*			FPI 3Q'21; Interim Cohort Analysis 2H'21; MTD Determined 2022; FPI Phase 2B/3 2023 - 2024
PCS11T Pre-IND	Small Cell Lung, Colorectal Cancer					Complete IND Enabling Studies; Phase 1B IND Submission 1H'23

* Cleared by FDA for Patient Clinical Trial

FPI – First Patient In (i.e., randomized)
SPA – FDA Special Protocol Assessment
MTD – Maximum Tolerated Dose

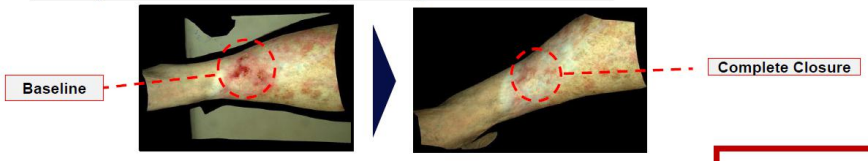
PCS499 to Be First to Market for the Treatment of Ulcerative Necrobiosis Lipoidica (uNL)



- Skin, tissue below the skin becomes necrotic, last from months to years with complications such as infections, amputation; **Histopathology ≠ diabetic ulcers**
- **30% of NL patients have painful ulcers occurring naturally or from contact trauma;**
- **Natural complete healing of moderate to severe ulcers in less than 5% of these patients** during the first 1-2 years after onset
- **No FDA approved treatment for uNL or NL**, no standard of care, all treatments are inadequate; **Drugs have been used off-label with mixed success** (e.g., **pentoxifylline (PTX)**) - side effect profile, limited efficacy
- **Economic Value: Initial Market**
  - 75,000 – 185,000 NL patients in U.S.
  - **22,000 – 55,000 uNL patients in U.S.**
  - **499 has orphan designation for NL (7-year market exclusivity)** and patent exclusivity until 2030
  - **U.S. market potential in uNL is ~ $1 B annual gross sales**

Unmet Medical Need, Evidence of Clinical Efficacy, PCS499 Improves Benefit-Risk

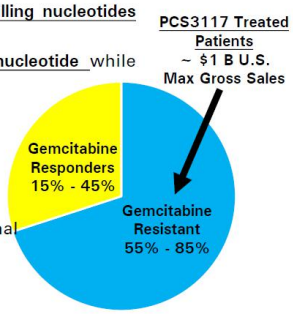
- **PCS499 is the deuterated analog of a major metabolite of PTX**; has identical metabolites and pharmacological targets but **PK of 499 + metabolites is different than PTX + metabolites resulting in a better 499 safety profile and allowing the administration of a higher, more efficacious dose of 499**
- **499 + metabolites target pharmacology that directly affect 6 of the 7 NL pathophysiological changes**
- **1.8 gm/d of 499 has better safety profile than 1.2 gm of PTX** in animal tox studies and Phase 1 healthy human volunteer studies
- In the Phase 2A study of 10 NL and 2 ulcerative NL patients, **all ulcers closed** in the 2 ulcerative NL patients, **including new contact trauma ulcers, and 1.8 gm/d was well tolerated**



Drug	Disease Target	Preclinical	Phase 1	Phase 2	Phase 3	Milestones
PCS499 Phase 2B	Ulcerative Necrobiosis Lipoidica			*		Interim Analysis 1H'22; Final Analysis 2H'22; FPI Phase 3 SPA 2023

PCS3117 to Treat Gemcitabine Resistant Pancreatic and Lung Cancer Patients

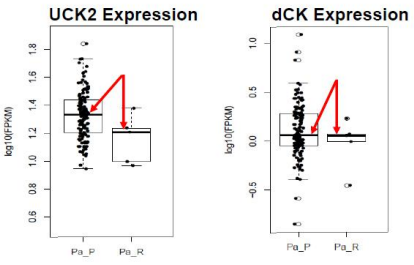
- **Gemcitabine is the most widely used** chemotherapeutic agent used to treat pancreatic and non-small cell lung cancer
- **55% - 85% of patients are inherently resistant to gemcitabine or acquire resistance**; inherent or acquired resistance caused by
  - Increase in CDA enzyme activity breaking down gemcitabine but is less important for PCS3117
  - Deficiency in hENT1 decreases gemcitabine and PCS3117 transport through the cell membrane
  - **Down-regulation of rate-limiting dCK enzyme decreases formation of cancer killing nucleotides** but does not affect PCS3117 which is activated by UCK2 enzyme
  - **Up-regulation of RRM1/RRM2 increases formation of endogenous cytidine nucleotide** while increases production of cancer killing PCS3117 nucleotides



- **PCS3117 has similar structure to gemcitabine** but is activated through a different pathway and causes cancer cell apoptosis in more ways than gemcitabine
- **PCS3117 has been shown in gemcitabine resistant** cancer patients and tumor animal models **to alter cancer progression**

Target Population: More Likely to Respond to or Activate PCS3117 than Gemcitabine

- **Biomarker assays are being developed and evaluated** to potentially define a targeted, personalized medicine approach to identifying patients who will respond to 3117 better than gemcitabine
- **Patients more likely to respond to or activate 3117 than gemcitabine**
  - Patients with high UCK2 levels
  - Patients who catabolize (breakdown) 3117 less than gemcitabine
  - Patients who have inherent or acquired resistance to gemcitabine but not 3117
- **3117 has FDA Orphan Designation for pancreatic cancer and patents to 2036**

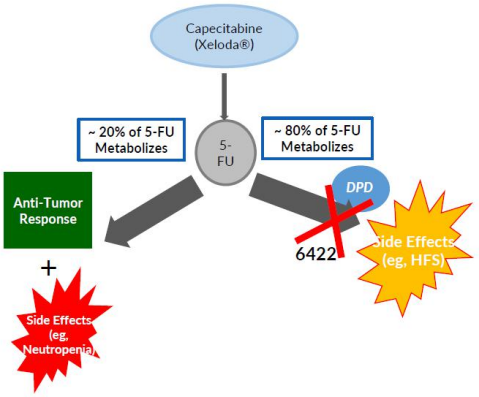


Pa_P : Pancreatic Tumor, N=134
Pa_R : Normal pancreas, N=5
(Data from Univ. of Toronto)

Drug	Disease Target	Preclinical	Phase 1	Phase 2	Phase 3	Milestones
PCS3117 Phase 2B	Pancreatic, Non-Small Cell Lung Cancer			*		Complete Biomarker Assays 1H'22; FPI Phase 2B 2H'22; FPI Phase 3 SPA 2023 - 2024

PCS6422 Combined with Capecitabine To Provide Better Safety/Efficacy Profile

PCS6422 Irreversibly Inhibits Dihydropyrimidine Dehydrogenase (DPD) Enzyme



6422 Inhibits DPD Allowing Two Ways to Win

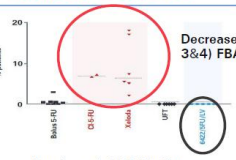
- **Lower Side Effects** by Lowering 5-FU Metabolite FBAL– Potentially Improve QOL & Reduce Treatment Discontinuations
- **Improve Capecitabine Efficacy** – Potentially Increase Response Rate by Increasing Tumor Exposure to Cancer Killing 5-FU Metabolites

Economic Value: Initial Markets

- 6422 + Capecitabine combination potentially 1st line therapy for a number of cancers (e.g., metastatic colorectal and breast cancer)
- Colorectal cancer; > 145,000 new patients/yr U.S., > 1.8 M total colorectal cancer patients worldwide; > 45% of the new patients with colorectal cancer presently receive capecitabine
- **U.S. market potential in colorectal cancer is ~ $1.0 B**

Unmet Medical Need and Evidence of Clinical Benefit

- **Safety Differentiation of 6422 + Capecitabine vs Existing Chemotherapy**
  - 50-70% of capecitabine patients have adverse events from FBAL resulting in decreasing capecitabine dose or stopping therapy
  - Clinical trial of the 6422 + capecitabine provides preliminary evidence that the combination will **decrease FBAL adverse events**
- **Efficacy Differentiation of 6422 + Capecitabine vs Existing Cancer Chemotherapy**
  - ~30% of patients do not respond at all to capecitabine and ~30% are partial responders
  - Clinical trial of the 6422 + capecitabine combination provides preliminary evidence that the combination may **extend progression free survival (PFS) in patients who do not respond to capecitabine as well as increase PFS in those patients who do respond**

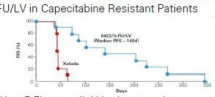


Decrease Incidence of HFS (Grade 3&4) FBAL Side Effects

Revollo et al. 2008 Clin Cancer Res; Masuda et al. 2017. NEJM

Improve Capecitabine Efficacy with 6422:

Lower Dose of 6422 Administered Hours Before 5-FU/LV in Capecitabine Resistant Patients



5-FU = 5-Fluorouracil; LV = Leucovorin; PFS = Progression Free Survival, SD = Stable Disease; PR = Partial Response; PD = Progressive Disease

Drug	Disease Target	Preclinical	Phase 1	Phase 2	Phase 3	Milestones
PCS6422 Phase 1B	Metastatic Colorectal, Breast Cancer	→	→ *			FPI 3Q'21; Interim Cohort Analysis 2H'21; MTD Determined 2022; FPI Phase 2B/3 2023 - 2024

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SPA – FDA Special Protocol Assessment
MTD – Maximum Tolerated Dose

Our People Lead to Success

Management Team

David Young, PharmD. PhD
Chief Executive Officer, Chairman of the Board

Sian Bigora, PharmD.
Chief Development Officer

Michael Floyd
Chief Operating Officer

Patrick Lin
Chief Business – Strategy Officer

James Stanker, CPA
Chief Financial Officer

Wendy Guy
Chief Administrative Officer

Board of Directors

David Young, PharmD. PhD
Chairman of the Board, CEO

Justin Yorke
Independent Director
Manager of the San Gabriel Fund, JMW Fund and the Richland Fund

Virgil Thompson
Independent Director
Former Chairman of the Board, Questcor Pharmaceuticals

Geraldine Pannu
Independent Director
Founding and Managing Partner of GLTJ Pioneer Capital

Khalid Islam, PhD
Director
Former CEO of Gentium
Chairman of the Board of Fennec Pharm.