# 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 12, 2022**

# 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.**

On May 12, 2022, Processa Pharmaceuticals, Inc. (the "Company") issued a press release announcing the earnings and other financial results for the quarter ended March 31, 2022. The full text of the press release is furnished as Exhibit 99.1 along with a Product Development Clinical Update Presentation as Exhibit 99.2 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1 and 99.2) shall not be deemed "filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it 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 a filing.

**Item 9.01. Financial Statements and Exhibits.**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release issued on May 12, 2022 (furnished and not filed for purposes of Item 202) |
| 99.2 | Processa Product Development Clinical Update Presentation (furnished and not filed for purposes of Item 202) |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

**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 12, 2022

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

**Exhibit 99.1**

Processa Pharmaceuticals

**Processa Pharmaceuticals Announces First Quarter 2022 Financial Results and Provides Corporate Update**

- **Amended Next Generation Capecitabine study has restarted which will elucidate timelines for de novo formation of DPD**
- **Expanded efforts for enrollment in PCS499**
- **PCS12852 on target to complete enrollment by Q3**

HANOVER, Md., May 12, 2022 (GLOBE NEWSWIRE) — Processa Pharmaceuticals, Inc. (Nasdaq: PCSA) ("Processa" or the "Company"), a clinical stage company developing drugs for patients who have unmet medical conditions that require better treatment options to improve a patient's survival and/or quality of life, today announced financial results for the quarter ended March 31, 2022, and provided an update on its clinical programs.

Dr. David Young, CEO and chairman of Processa, commented, "We are on track to get important data from all our clinical programs over the remainder of this year that will elucidate the path to registration for these programs that each have a market that could exceed $1 billion.

- The amended protocol for Next Generation Capecitabine will provide insights into the de novo formation of DPD by mid-summer and allow us to get to the MTD by year-end;
- Our expanded outreach to find and enroll patients in the PCS499 uNL trial has identified new potential patients to complete enrollment for our interim analysis cohort mid-summer and interim results by year-end;
- Enrollment in PCS12852 is going well and is expected to fully enroll patients and provide top line results before the end of the year; and
- We expect to complete the initial development on the macromolecule assays that will be evaluated as potential biomarkers for PCS3117 and confirm our Regulatory Path with FDA by the end of the year."

**Financial Results for the Quarter Ended March 31, 2022**

We continue to manage our cash efficiently and had a cash balance of $14.4 million at March 31, 2022. We believe this will allow us to complete our three on-going clinical trials and fund our operations into the third quarter of 2023. During the three months ending on March 31, 2022 we spent cash of $1.8 million in our clinical trials and operations.

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For the three months ended March 31, 2022, we reported a net loss of $3.2 million, or $0.20 per share compared to a net loss of $2.1 million, or $0.14 per share for the same period of 2021. The increase in our net loss relates primarily to increased clinical trial costs we incurred.

During the three months ended March 31, 2022, we incurred research and development expenses totaling $2.0 million compared to $1.5 million for the same period in 2021. The increase in our R&D expenditures was primarily due to costs we incurred in our active clinical trials. Our general and administrative expenses totaled $1.2 million for the three months ended March 31, 2022 compared to $717 thousand for the same period in 2021. The increase related primarily to increases in non-cash stock-based compensation along with other operating and consulting costs. We allocated $829 thousand of non-cash compensation costs between our R&D and G&A expenses.

As of March 31, 2022, we had 15.8 million shares of common stock outstanding.

**Conference Call Information**

To participate in this event, please log-on or dial-in approximately 5 to 10 minutes before the beginning of the call.

Date: May 12, 2022
Time: 4:30 p.m. ET
Toll Free: 877-545-0320
International: 973-528-0002
Entry Code: 896576
Live Webcast: https://www.webcaster4.com/Webcast/Page/2572/45432

**Conference Call Replay Information**

Toll-free: 877-481-4010
International: 919-882-2331
Replay Passcode: 45432
Replay Webcast: https://www.webcaster4.com/Webcast/Page/2572/45432

**About Processa Pharmaceuticals, Inc.**

The mission of Processa is to develop products with existing clinical evidence of efficacy for patients with unmet or underserved medical conditions who need treatment options that improve survival and/or quality of life. The Company uses these criteria for selection to further develop its pipeline programs to achieve high-value milestones effectively and efficiently. Active clinical pipeline programs include: Next Generation Capecitabine (formerly identified as PCS6422) for metastatic colorectal cancer and breast cancer, PCS499 for ulcerative necrobiosis lipoidica and PCS12852 for gastroparesis. The members of the Processa development team have been involved with more than 30 drug approvals by the FDA (including drug products targeted to orphan disease conditions) and more than 100 FDA meetings throughout their careers. For more information, visit the company's website at www.processapharma.com.

**Forward-Looking Statements**

This release contains forward-looking statements. The statements in this press release that are not purely historical are forward-looking statements which involve risks and uncertainties. Actual future performance outcomes and results may differ materially from those expressed in forward-looking statements. 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.

For More Information:
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## 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 Pharmaceuticals, Inc (NASDAQ: PCSA) Highlights

- **Development Company** Focused on **Improving the Quality of Life (QOL) and/or Survival of Patients** with an Unmet Medical Need Condition
- Management & Development Team with **Track Record of Success**
- In-licensed Five Drugs Each with **Potential Sales of > $1.0B Plus Some Evidence of Efficacy** in the Targeted Population of Patients
- **Regulatory Science Approach** to Drug Development Initially Developed during FDA Collaborations 30 Years Ago and Refined over Time with Approvals in Almost Every Division of FDA



## 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**<br>• **Favorable competitive** dynamics | • **Evidence of clinical efficacy** in targeted medical condition<br>• **Higher** probability of **successful development** | • **Improve Benefit/Risk** profile that FDA evaluates for approval<br>• **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.)<br>• **Efficient development** program and clinical trial design | • **Intelligently monetize and partner assets** |



## Pipeline With High Value 2022 Milestones
## Five Drugs Each with $1B Market Opportunity

- 4 Drugs in Clinical Stage of Development and 1 in Pre-IND
  - 3 Drugs Targeting the Treatment of Cancer (Phase 1B, Phase 2B, Pre-IND Stage) (Blue Arrows)
  - 1 Drug in Phase 2B Targeting an Orphan Condition with no Approved Treatments and No Effective Standard of Care (Orange Arrow)
  - 1 Drug in Phase 2A Targeting an Unmet Medical Need Condition Where the Existing Treatment Options have Limited Use with Serious Adverse Events (Green Arrow)

| Drug | Disease Target | Non-clin | Phase 1 | Phase 2 | Phase 3 |
|---|---|---|---|---|---|
| Next Generation Capecitabine Phase 1B (PCS6422) | Metastatic Colorectal, Other Cancers | | | | |
| PCS499 Phase 2B | Ulcerative Necrobiosis Lipoidica | | | | |
| PCS12852 Phase 2A | Gastroparesis | | | | |
| PCS3117 Phase 2B | Pancreatic, Other Cancers | | | | |
| PCS11T Pre-IND | SC Lung, Other Cancers | | | | |

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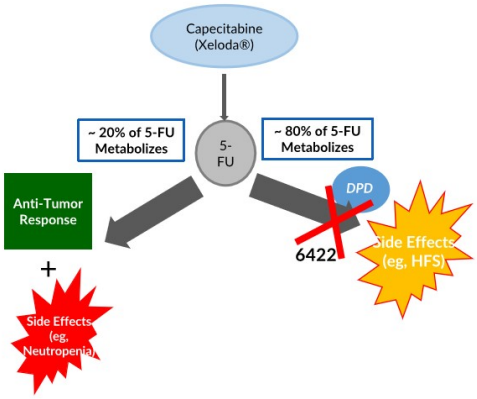
## Processa Pharmaceuticals, Inc (NASDAQ: PCSA) 1Q2022 Highlights

- In 1Q2022 each clinical development program has moved **closer to obtaining key findings** that are needed to design and initiate our pivotal trials and subsequent FDA submission
  - **Next Generation Capecitabine (Combination of PCS6422 and Capecitabine)**: Amended protocol to understand the timeline of DPD de novo formation while still determining the MTD of Next Generation Capecitabine
  - **PCS499**: Expanded our outreach to identify potential uNL patients in order to complete enrollment for our interim and final analysis in a more timely manner
  - **PCS12852**: Initiated recruitment of Phase 2A trial evaluating the effect on the gastric emptying rate and gastroparesis symptoms
  - **PCS3117**: Initiated development of assays to determine if biomarkers could be identified that would predict a patient's response to PCS3117 versus gemcitabine
- Continually Evaluate Approaches to **Increase the Probability of FDA Approval**, **Expedite Regulatory Development**, and **Decrease the Time to Approval**



## Next Generation Capecitabine Improves Safety/Efficacy Profile of Capecitabine (Combination of PCS6422 and Capecitabine)

### PCS6422 Irreversibly Inhibits Dihydropyrimidine Dehydrogenase (DPD) Enzyme




- Colorectal cancer: **> 145,000 new patients/yr** U.S., **> 45% of the new patients** with colorectal cancer presently receive capecitabine
- **U.S. market of capecitabine in colorectal cancer is ~ $1.0 B** and use in other cancers at least doubles the market potential
- Next Generation Capecitabine provides a combination drug product with
  - **A decrease in the formation of non-cancer killing metabolites** of capecitabine **which cause side effects,** potentially improving QOL & reducing treatment discontinuations
  - The same cancer-killing mechanism of action as capecitabine but with **higher potency and potentially better response rate**

## Next Generation Capecitabine (Combination of PCS6422 and Capecitabine)


**Phase 1B Next Generation Capecitabine Cohort 1 and 2 Interim Results**

- No DLTs, no drug-related adverse events greater than Grade 1, and no hand-foot syndrome side effects were observed in Cohort 1 and 2
- 24-48 hours after 6422 administration, 5-FU potency (systemic exposure per mg of capecitabine) was **approx. 50 x greater** than reported for FDA approved capecitabine
- The 6422 dosage regimen has been modified in the amended Phase 1B protocol because the improved metabolism profile and increased **potency of Next Generation Capecitabine were not maintained during the 7 days of chemotherapy dosing**
- In order to identify a 6422 regimen that provides minimum exposure to 6422 while maintaining the high potency of capecitabine, **the timeline of DPD inhibition and de novo formation is being evaluated in the amended Phase 1B trial**



## Next Generation Capecitabine (Combination of PCS6422 and Capecitabine) Q1 Achievements and Future Milestones

**Achievements in 1Q2022**

- Amended Phase 1B protocol to determine the 6422 regimens that would increase the cancer-killing potency of Next Generation Capecitabine for all 7 days of capecitabine dosing while decreasing metabolites that only cause AEs
- Enrolled 1 patient in the amended protocol with some sites still waiting for their IRB approval
- Hope to add more sites to the amended protocol

**Milestones Mid-2022**

- Determine the PCS6422 regimen needed to increase the potency of capecitabine
- Initially evaluate an individualized/personalized treatment approach to treating patients with Next Generation Capecitabine

**Milestones 2H2022**

- Complete enrollment of Phase 1B trial
- Preliminarily identify the Maximum Tolerated Dose (MTD) of Next Generation Capecitabine

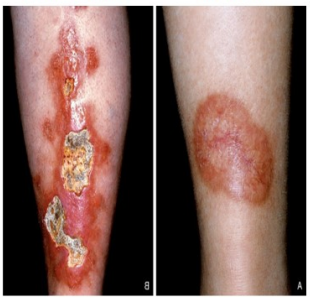
**2023**

- Meet with FDA to define the remaining studies in the development program
- Initiate Phase 2B or adaptive designed Phase 3 trial depending on FDA meeting and Phase 1B trial



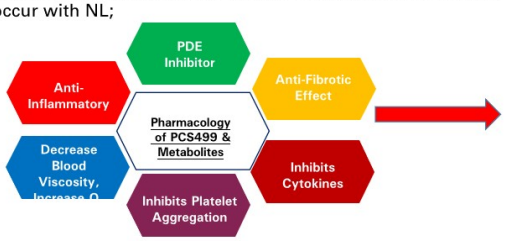
## PCS499: Would be the First Drug Approved to Treat Ulcerative Necrobiosis Lipoidica (uNL) or Any Form of NL

- Skin, tissue below the skin become necrotic forming open ulcers; can last from months to years with complications such as infections, amputation, and cancer
- Literature reports approximately 22,000 – 55,000 uNL patients in the U.S. will have painful ulcers occurring naturally or from contact trauma to the lesion
- Natural **complete healing or wound closure of moderate to severe ulcers during the first 1-2 years after onset occurs in less than 5% of uNL patients**
- 60% of NL patients are diabetic resulting in the Phase 2B trial being significantly affected by COVID.
- **Market potential of > $1B** given the unmet medical need in this serious condition



## Unmet Medical Need, Evidence of Clinical Efficacy

- No FDA approved treatment for uNL or NL, no standard of care, all treatments inadequate (eg, pentoxifylline (PTX) used off-label providing limited efficacy given the safety profile)
- PCS499 is the deuterated analog of a major metabolite of PTX; has identical metabolites and pharmacological targets but PK of 499 and its metabolites is different than PTX and its metabolites, resulting in a better 499 safety profile and allowing for the administration of a higher, more efficacious dose of 499 (1.8 gm/d of 499 has a better safety profile than 1.2 gm of PTX in animal tox studies and Phase 1 healthy human volunteer studies)
- Determined 1.8 gm/d of 499 was safe in 12 NL patients and effective in closing the open ulcers of the 2 patients with uNL in an open-labeled Phase 2A trial
- Pharmacological targets of 499 and its metabolites positively affect 6 of the 7 pathophysiological changes that can occur with NL;




**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: Phase 2B Trial for the Treatment of Ulcerative Necrobiosis Lipoidica Q1 Achievements and Future Milestones

**Achievements in 1Q2022**

- 3 patients completed trial; Closed EU sites that were not enrolling
- COVID has had an impact on enrollment – Potential patients who have been identified have not come in for screening; a couple of patients identified for the trial died from COVID before being screened
- Expanded the remedial patient identification and enrollment efforts put in place 4Q'21:
  - 1 patient in screening, 1 patient completed pre-screen and scheduled for screening, 5 patients identified that need to go through pre-screening
  - Continued evaluation of additional sites

**Milestones Mid-2022**

- Complete enrollment of 5-10 patients in Phase 2B trial to be used in the interim analysis

**Milestones 2H2022**

- Obtain top-line interim analysis results
- Complete enrollment of Phase 2B trial

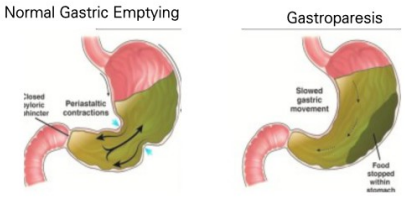
**2023**

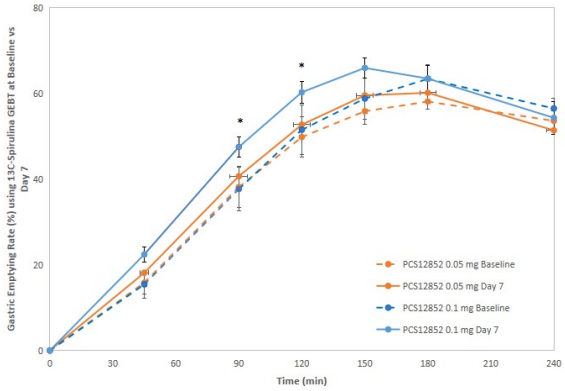
- Complete Phase 2B trial
- Meet with FDA to define the next trial which we expect to be a pivotal trial; Initiate Phase 3 trial

## PCS12852: Treatment of Gastroparesis

### PCS12852 is a More Potent and More Selective 5HT4 Agonist than Previous 5HT4 Agonists

- Target Indication:
  - Treatment of moderate to severe gastroparesis
- Target Claims:
  - Improves gastric emptying rate and the symptoms associated with moderate to severe gastroparesis (e.g., bloating, pain, nausea, vomiting)






## PCS12852: Treatment of Gastroparesis (> $1.5B Market)

- Existing FDA approved drugs and off-labeled prescribed drugs are mainly used for the treatment of diabetic gastroparesis and not for idiopathic or post-surgical gastroparesis
- All these drugs have a poor side effect profile limiting their use
- Present market size for gastroparesis is estimated to be over $1.5B

| | PCS12852 | Other 5HT4 Drug (e.g., Cisapride, Prucalopride, Mosapride) | Dopamine D2 Antagonist (.e.g,, Metoclopramide) |
|---|---|---|---|
| Target Population | • Potentially all gastroparesis patients (e.g., diabetic, idiopathic) | • Diabetic gastroparesis patients | • Diabetic gastroparesis patients |
| Binding | • Specific & potent 5HT4 receptor binding | • Less specific binding to 5HT4 than 12852<br>• Less potent than 12852 | • Binds to Dopamine D2 receptors |
| Side Effects | • No serious side effects in clinical studies to date | • Serious cardiovascular side effects (e.g., cisapride removed from market)<br>• Suicidal ideation (e.g., prucalopride) | • Black Box Warning serious neurological side effects, Side effects require limited use |
| Efficacy | • Increase gastric emptying rate in patients with constipation | • Increase gastric emptying rate<br>• Successful treatment demonstrated | • Only drug FDA approved for treatment of gastroparesis |



## PCS12852: Treatment of Gastroparesis
## Q1 Achievements and Future Milestones

**Achievements in 1Q2022**

- 5 patients enrolled out of 24 to be enrolled; 5 in screening; > 50% screening failure rate expected

**Milestones Mid-2022**

- None at this time

**Milestones 2H2022**

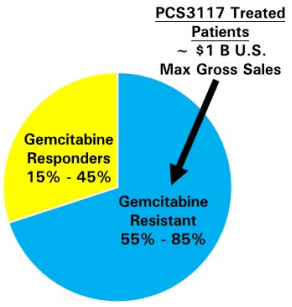
- Completion of enrollment expected with top-line results of gastric emptying rate available at the end of 2022
- Final analysis of Phase 2A expected Dec 2022-Jan 2023 which includes evaluating the improvement in gastric emptying rate and gastroparesis symptoms, the primary endpoint in pivotal trials

**2023**

- Evaluating alternative regulatory paths to expedite approval with plans to discuss approaches with the FDA in 2023
- Phase 2B trial to begin in 2023

## PCS3117 for Cancer Patients Resistant to Gemcitabine

- PCS3117 has a 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
- Gemcitabine is the most widely used chemotherapeutic agent used to treat pancreatic, non-small cell lung, and biliary cancer
- 55% - 85% of patients are inherently resistant to gemcitabine or acquire resistance; inherent or acquired resistance is 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 the formation of cancer-killing nucleotides but does not affect PCS3117 which is activated by UCK2 enzyme






## PCS3117 Clinical Status

- PCS3117 presently has an orphan designation for the treatment of Pancreatic Cancer
- PCS3117 presently has an IND for the treatment of Pancreatic Cancer
- Previous Trials
  - PCS3117 monotherapy Phase 2A trial as second or third-line therapy in patients with progressive metastatic pancreatic cancer after 1-5 previous therapies of chemotherapy (93% (40/43) refractory to gemcitabine); PCS3117 shown to be more effective (31% for 2 months PFS and 12% for 4 months) than gemcitabine monotherapy
  - PCS3117 + Abraxane Phase 2A trial as first-line therapy in chemotherapy naïve patients with metastatic pancreatic cancer had results similar to gemcitabine + Abraxane

## PCS3117: Treatment of Pancreatic Cancer or Other Cancers
## Q1 Achievements and Future Milestones

**Achievements in 1Q2022**

- Initiated development of assays to determine if biomarkers could be identified that would predict a patient's response to PCS3117 versus gemcitabine

**Milestones Mid-2022**

- Preliminary assay to be completed but not qualified or validated as a biomarker

**Milestones 2H2022**

- Although 3117 already has FDA Orphan Designation for the treatment of pancreatic cancer, drug development "roadmaps" to be defined for
  - 2nd or 3rd line therapy in metastatic pancreatic cancer,
  - 1st line therapy for recurrent pancreatic cancer after surgery with Adjuvant Chemotherapy of FOLFIRINOX (folinic acid, fluorouracil, irinotecan, and oxaliplatin), and
  - 1st or 2nd line therapy in the treatment of biliary tract cancer
- FDA meeting to better define development program and target population of patients

**2023**

- Initiate Phase 2B or Phase 3 trial depending on FDA meeting in 2022



## Processa Pipeline Achievements and Future Milestones

- **Near Term Milestones (March-August)**
  - **Next Generation Capecitabine**: Expect interim results on the dosing regimen of PCS6422 (one component of Next Generation Capecitabine) and determine how much the cancer-killing potency of capecitabine will be increased throughout capecitabine treatment
  - **PCS499**: Complete enrollment of patients for interim analysis
  - **PCS12852**: Initiate all sites for Phase 2A gastroparesis trial
  - **PCS3117**: Complete initial development of assays to be evaluated as potential biomarkers
- **End of Year Milestones (September–December)**
  - **Next Generation Capecitabine**: Complete enrollment of Phase 1B trial, obtain preliminary Maximum Tolerated Dose (MTD), evaluate the possibility of a personalized treatment approach
  - **PCS499**: Complete enrollment of patients for trial and obtain top-line results on interim analysis
  - **PCS12852**: Complete enrollment of patients in Phase 2A trial and obtain top-line results
  - **PCS3117 & PCS11T**: Define potential development programs for approval in multiple cancers
- **2023 Milestones U.S.**
  - Obtain final results from 3 clinical trials, 3 different indications
  - **Initiate at least 2 new trials (pivotal registration and/or Phase 2B trials)**



## 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

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

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

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

Processa Pharmaceuticals

## Pipeline Background Slides

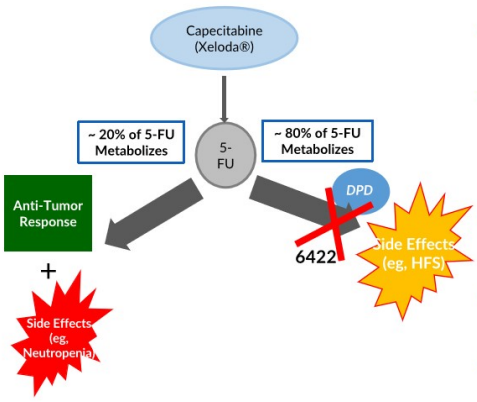
Processa Pharmaceuticals

## Next Generation Capecitabine
## (Combination of PCS6422 and Capecitabine)

## Metastatic Colorectal Cancer, Breast Cancer, Pancreatic Cancer, Other Cancers

# Next Generation Capecitabine Improves Safety/Efficacy Profile of Capecitabine (Combination of PCS6422 and Capecitabine)

## 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

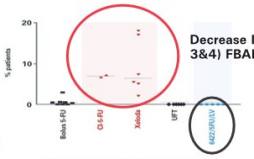
**Economic Value: Initial Markets**

- Potential for Next Generation Capecitabine to replace capecitabine in the treatment of colorectal cancer and other cancers
- 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



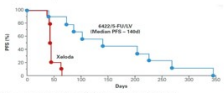

**Decrease Incidence of HFS (Grade 3&4) FBAL Side Effects**

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

- **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

**Improve Capecitabine Efficacy with 6422:**

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




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



# Next Generation Capecitabine (Combination of PCS6422 and Capecitabine)


**Phase 1B Next Generation Capecitabine Cohort 1 and 2 Interim Results**

- No DLTs, no drug-related adverse events greater than Grade 1, and no hand-foot syndrome side effects were observed in Cohort 1 and 2
- Next Generation Capecitabine with 1 dose of 6422 inhibited DPD activity 24-48 hours after 6422 administration to < 10% of 5-FU metabolized to FBAL compared to 80% reported for FDA approved capecitabine
- 24-48 hours after 6422 administration, 5-FU potency (systemic exposure per mg of capecitabine) was **approx. 50 x greater** than reported for FDA approved capecitabine
- The improved metabolism profile and increased **potency did not exist 7 days after a single dose of 6422**; the 6422 dosage regimen has been modified in amended Phase 1B protocol
- Need to identify a 6422 regimen that provides minimum exposure to 6422 while still inhibiting 5-FU metabolism such that < 10% of 5-FU is metabolized to FBAL
- The timeline of DPD inhibition and de novo formation needs to be evaluated in order to identify 6422 regimens that will inhibit DPD throughout capecitabine dosing

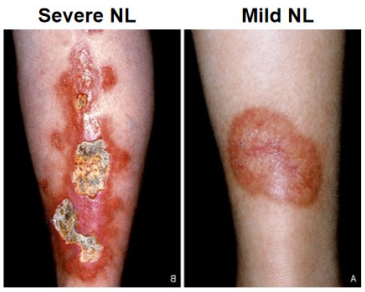
Processa Pharmaceuticals

# PCS499

## Ulcerative Necrobiosis Lipoidica (uNL)

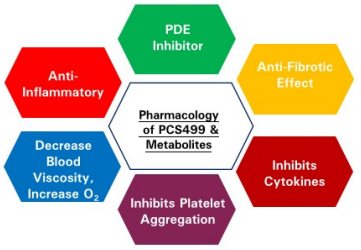
## PCS499: Would be the First Drug Approved to Treat Ulcerative Necrobiosis Lipoidica (uNL) or Any Form of NL

- Skin and tissue below the skin become necrotic forming open ulcers; can last from months to years with complications such as infections, amputation, and cancer
- Literature reports approximately 22,000 – 55,000 uNL patients in the U.S. will have painful ulcers occurring naturally or from contact trauma to the lesion
- Prevalence at any given time is probably significantly less
- Natural complete healing or wound closure of moderate to severe ulcers during the first 1-2 years after onset occurs in less than 5% of uNL patients
- No FDA approved treatment for uNL or NL, no standard of care, all treatments are inadequate
- Market potential of > $1B given the unmet medical need in this serious condition



## Unmet Medical Need, Evidence of Clinical Efficacy

- 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)); provide poor safety profile given their limited efficacy
- PCS499 is the deuterated analog of a major metabolite of PTX; has identical metabolites and pharmacological targets but PK of 499 and its metabolites is different than PTX and its metabolites, resulting in a better 499 safety profile and allowing for the administration of a higher, more efficacious dose of 499
- Pharmacological targets of 499 and its metabolites positively affect 6 of the 7 pathophysiological changes that can occur with NL



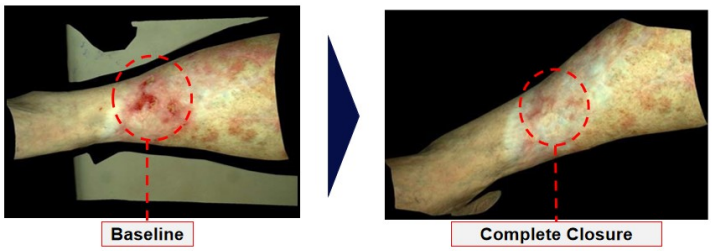

**Pathophysiological Changes in NL**

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



## PCS499 in 2020 - 2021

- 1.8 gm/d of 499 has a better safety profile than 1.2 gm of PTX in animal tox studies and Phase 1 healthy human volunteer studies
- Determined 1.8 gm/d of 499 was safe in 12 NL patients and effective in closing the open ulcers of the 2 patients with uNL in an open-labeled Phase 2A trial



Baseline | Complete Closure

- FDA has defined uNL as a serious condition based on communications with Processa
- Collaborated with FDA to define the information needed from a Phase 2B trial to guide us in the design of a single pivotal Phase 3 trial in 2023



Processa Pharmaceuticals

# PCS12852

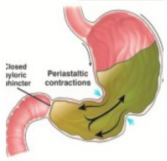
# Gastroparesis

## Gastroparesis

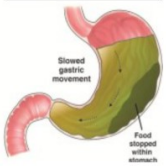
### PCS12852 is a More Potent and More Selective 5HT4 Agonist than Previous 5HT4 Agonists

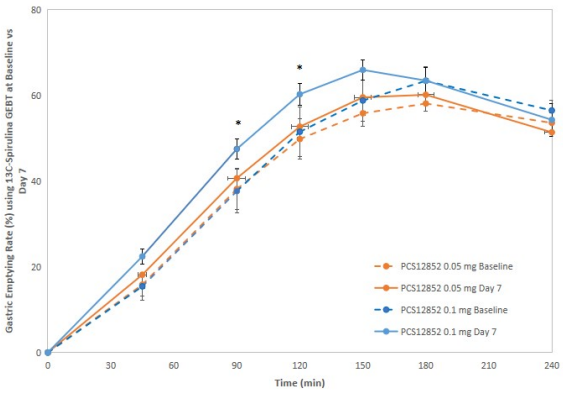
- Target Indication:
  - Treatment of moderate to severe gastroparesis
- Target Claims:
  - Improves gastric emptying rate and the symptoms associated with moderate to severe gastroparesis (e.g., bloating, pain, nausea, vomiting)

Normal Gastric Emptying




Gastroparesis






## Treatment of Gastroparesis (> $1.5B Market)

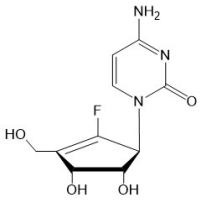
- Existing FDA approved drugs and off-labeled prescribed drugs are mainly used for the treatment of diabetic gastroparesis
- All these drugs have a poor side effect profile limiting their use
- Present market size for gastroparesis is estimated to be over $1.5B

| | PCS12852 | Other 5HT4 Drug (e.g., Cisapride, Prucalopride, Mosapride) | Dopamine D2 Antagonist (.e.g,, Metoclopramide) |
|---|---|---|---|
| Target Population | • Potentially all gastroparesis patients (e.g., diabetic, idiopathic) | • Diabetic gastroparesis patients | • Diabetic gastroparesis patients |
| Binding | • Specific & potent 5HT4 receptor binding | • Less specific binding to 5HT4 than 12852<br>• Less potent than 12852 | • Binds to Dopamine D2 receptors |
| Side Effects | • No serious side effects in clinical studies to date | • Serious cardiovascular side effects (e.g., cisapride removed from market)<br>• Suicidal ideation (e.g., prucalopride) | • Black Box Warning serious neurological side effects, Side effects require limited use |
| Efficacy | • Increase gastric emptying rate in patients with constipation | • Increase gastric emptying rate<br>• Successful treatment demonstrated | • Only drug FDA approved for treatment of gastroparesis |

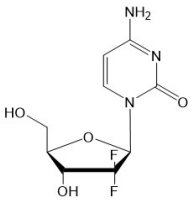
Processa Pharmaceuticals

# PCS3117
## Metastatic Pancreatic Cancer, Biliary Cancer, Other Cancers

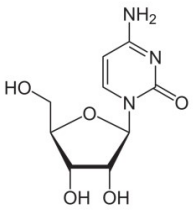
## 1H'22 - PCS3117 Biomarker Assay Development Completed




RX-3117
Oral Administration
(Cytosine + Ribose Analog)




Gemcitabine (dFdC)
IV Administration
(Cytosine + F,F-Deoxyribose)



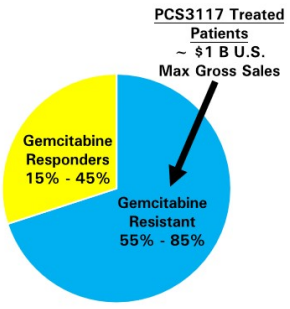

Cytidine
(Cytosine + Ribose Ring)

- Gemcitabine Market
  - First-line treatment for locally advanced or metastatic pancreatic cancer; inoperable, locally advanced or metastatic non-small cell lung
  - Second-line and third-line treatment for ovarian cancer and other types of cancer
  - Gross Sales: $815 M U.S., $1.7 B worldwide



## PCS3117 for Cancer Patients Resistant to Gemcitabine

- PCS3117 has a 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
- Gemcitabine is the most widely used chemotherapeutic agent used to treat pancreatic, non-small cell lung, and biliary cancer
- 55% - 85% of patients are inherently resistant to gemcitabine or acquire resistance; inherent or acquired resistance is 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 the formation of cancer-killing nucleotides but does not affect PCS3117 which is activated by UCK2 enzyme



## PCS3117 Prior Evidence of Clinical Efficacy and Safety in Cancer Patients

- PCS3117 monotherapy Phase 2A trial as second or third-line therapy in patients with progressive metastatic pancreatic cancer after 1-5 previous therapies of chemotherapy (93% (40/43) refractory to gemcitabine)
  - 31 % (14 patients) had progression-free survival (PFS) for 2 months
  - 12% (5 patients) had stable disease for more than 4 months
  - One patient had a tumor reduction of 40% after 28 days of treatment
  - A previous report of gemcitabine as 2nd line therapy had only 17% disease-free progression
  - Mild to moderate adverse events reported with a better overall safety profile than gemcitabine
- PCS3117 + Abraxane Phase 2A trial as first-line therapy in chemotherapy naïve patients with metastatic pancreatic cancer
  - Overall response rate of 23% observed in patients (9/40)
  - Median progression-free survival of 5.4 months
  - Overall response rate was better than previous reports with only Abraxane
  - Overall response rate was no better than previous reports with gemcitabine + Abraxane



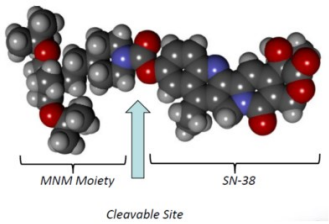
Processa Pharmaceuticals

# PCS11T

## Small Cell Lung, Pancreatic, Colorectal, Other Cancers

## PCS11T: Lipophilic Prodrug of SN-38 (Irinotecan Active Metabolite)

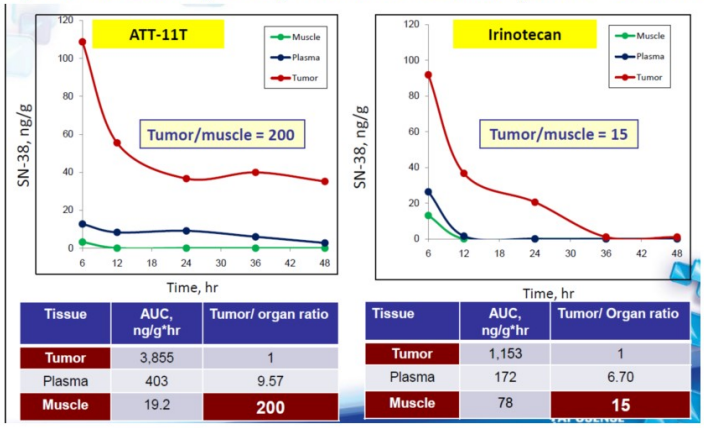
- Pro-drug of SN-38 linking SN-38 to a molecular nano-motor (MNM), a proprietary compound, which interacts with cell membranes preferentially accumulating in the membrane of tumor cells and the tumor core more than normal cells
- Creates an albumin/drug complex (similar conceptually to the albumin-paclitaxel complex in Abraxane) that extends the half-life of SN-38 by 5x compared to irinotecan in pre-clinical studies and likely decrease the side effects
- Given the MNM-SN38 specificity for cancer cells, upon approval it is unlikely that PCS11T will have the BlackBox diarrhea warning which irinotecan has
- Irinotecan sales prior to generics was > $1B






## Higher and More Selective Tumor Exposure to SN38 with PCS11T (formerly ATT-11T) versus Irinotecan

**Tumor-bearing mice had 200x higher drug in tumor vs muscle compared to 15x with Irinotecan**

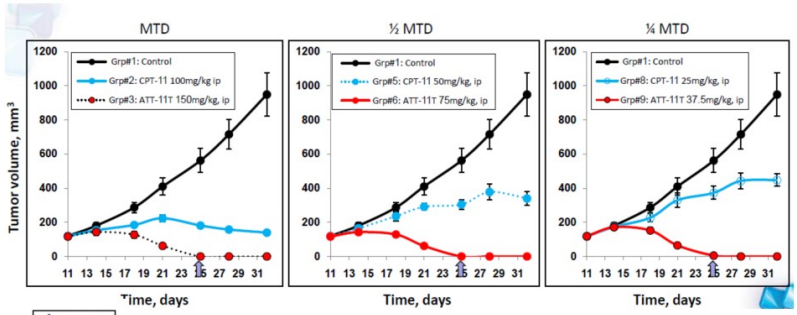



| Tissue | AUC, ng/g*hr | Tumor/ organ ratio |
|---|---|---|
| Tumor | 3,855 | 1 |
| Plasma | 403 | 9.57 |
| Muscle | 19.2 | 200 |

| Tissue | AUC, ng/g*hr | Tumor/ Organ ratio |
|---|---|---|
| Tumor | 1,153 | 1 |
| Plasma | 172 | 6.70 |
| Muscle | 78 | 15 |



## Efficacy Maintained at Lower Doses of PCS11T When Compared to Irinotecan in SW620 Colorectal Cancer Xenograft Model




At MTD
Tumor Growth Inhibition
100% ATT11-T
100% CPT-11

At ½ MTD
Tumor Growth Inhibition
100% ATT11-T
64% CPT-11

At ¼ MTD
Tumor Growth Inhibition
100% ATT11-T
53% CPT-11