# 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): August 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** | **21076** |
| | **(Address of Principal Executive Offices)** | **(Zip Code)** |

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

**Not Applicable**
**(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))

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 2.02. Results of Operations and Financial Condition.**

On August 12, 2022, we issued a press release announcing earnings and other financial results for the quarter ended June 30, 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, or the Exchange Act, 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 August 12, 2022 (furnished and not filed for purposes of Item 2.02) |

| | |
|---|---|
| 99.2 | Processa Product Development Clinical Update Presentation (furnished and not filed for purposes of Item 2.02) |
| 104 | Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL documents) |

**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: August 12, 2022

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

Processa Pharmaceuticals

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

- **PCS12852 on target to complete enrollment by September**
- **Expanded efforts to increase enrollment in PCS499 and PCS6422 showing results**

HANOVER, Md., August 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 and/or require better treatment options to improve a patient's survival and/or quality of life, today announced financial results for the quarter ended June 30, 2022, and provided an update on its clinical programs.

Dr. David Young, President and CEO of Processa, commented, "Our efforts to enhance enrollment through adding new sites, extensive marketing campaigns and working with our CRO partners are showing results:

- We expect to close out enrollment for PCS12852 for Gastroparesis within the next month and present top-line data from the trial before the end of the year.
- We now have a sufficient number of patients in the screening queue for PCS6422 to complete our interim cohorts which we believe will provide valuable insights on de novo formation of DPD. We anticipate we will determine the maximum tolerated dose by early 2023.
- Patients are beginning to show a willingness to travel, and we are seeing increased patient activity in our PCS499 ulcerative necrobiosis lipoidica (uNL) trial. We are optimistic that we will enroll our interim analysis cohort before the end of the year.
- As part of our efforts to increase enrollment on our PCS499 trial, we recently launched a website to increase awareness of uNL and to inform patients of the ongoing Phase 2B Study of PCS499.

Advancing these 3 drugs in their respective clinical trial allows us to obtain the clinical data to better define each pivotal trial as well as provide us with more insight into how FDA will review each of these products when we submit the New Drug Applications to FDA."

**Financial Results for the Six Months Ended June 30, 2022**

Our cash balance on June 30, 2022, was $12.1 million, which should be sufficient to complete our three on-going clinical trials and fund our operations into the third quarter of 2023. During the six months ended June 30, 2022, we spent $4.1 million in cash for these three clinical trials and our operations. This is significantly less than our GAAP net loss of $8.4 million due to the effect of non-cash items like amortization and stock-based compensation, and the application of amounts we had prepaid to our CROs last year.

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Our net loss for the six months ending on June 30, 2022, was $8.4 million or $0.53 per share compared to a net loss of $5.3 million, or $0.35 per share for the same period of 2021. The increase in our net loss relates primarily to increased clinical trial costs we incurred in our three ongoing trials. For the six months ended June 30, 2022, we incurred $5.2 million in research and development costs, an increase of $2.1 million when compared to the same period of 2021. We anticipate clinical trial costs will continue to increase for the rest of the year as our trials continue to progress and we fund development activities for the other drugs in our pipeline.

During the six months ending June 30, 2022, our general and administrative expenses totaled $3.2 million compared to $2.1 million for the same period in 2021. The increase related primarily to increases in non-cash or stock-based compensation costs, along with other operating and consulting costs. We allocated $2.8 million of non-cash compensation costs between our R&D and G&A costs, with the majority recorded as G&A.

Our net cash used in operating activities during the six months ended June 30, 2022, decreased by $300,000 to $4.1 million, compared to $4.4 million for the same period in 2021. While we experienced increased GAAP costs related to our clinical trials and operations, we continued to make use of equity incentives to compensate our executive and development team, thereby reducing our cash outflow, and we were able to apply previously made advanced payments to our CROs against current trial costs.

As of June 30, 2022, we had 15.8 million common shares 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: August 11, 2022
Time: 4:30 p.m. ET
Toll Free: 877-545-0320
International: 973-528-0002
Entry Code: 623559
Live Webcast: https://www.webcaster4.com/Webcast/Page/2572/46205

**Conference Call Replay Information**

Toll-free: 877-481-4010
International: 919-882-2331
Replay Passcode: 46205
Replay Webcast: https://www.webcaster4.com/Webcast/Page/2572/46205

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**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 includes Next Generation Capecitabine (formerly identified as PCS6422) for metastatic colorectal cancer and breast cancer, PCS499 (ulcerative necrobiosis lipoidica) and PCS12852 (GI motility/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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**mfloyd@processapharma.com**
(301)651-4256

Patrick Lin
(925) 683-3218
**plin@processapharma.com**

**Exhibit 99.2**


## 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.

# Our People Lead to Success

## Management Team

**David Young, PharmD. PhD**
President and Chief Executive Officer

**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

**Justin Yorke**
Chairman of the Board
Manager of the San Gabriel Fund, JMW Fund and the Richland Fund

**David Young, PharmD. PhD**
President and CEO, Processa Pharmaceuticals
Former CSO and Director, Questcor Pharmaceuticals

**Khoso Baluch**
Independent Director
Former CEO of CorMedix, Inc.
Independent Director, Poxel SA

**James Neal**
Independent Director
CEO and Chairman of the Board, XOMA Corp

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

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



# 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**
- **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
- In-licensed Five Drugs Each with **Potential Sales of > $1.0B Plus Some Evidence of Efficacy** in the Targeted Population of Patients
- 4 of the 5 drugs have INDs, **3 of the 4 drugs are presently in clinical trials**, and the development strategy for 1 of the 4 drugs is being refined prior to putting it into a clinical study
- The **6422 clinical trial is now up and running with sites recruiting** as they were prior to the protocol changes (based on our interim analysis) resulted in regulatory delays at FDA and the sites
- Although enrollment in the **PCS499** studies has been slower than hoped, **our supplemental patient enrollment programs** (e.g., travel reimbursement, study-specific website) **have recently resulted in an increase in the number of patients inquiring about their eligibility** for screening in these trials
- **Patient enrollment for the PCS12852 gastroparesis trial has done very well** and we expect to complete the study by the end of the year

# 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 of 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 Box, Blue Arrows)
  - 1 Drug in Phase 2B Targeting an Orphan Condition with no Approved Treatments and No Effective Standard of Care and 1 Drug in Phase 2A Targeting an Unmet Medical Need Condition Where the Existing Treatment Options have Limited Use with Serious Adverse Events (Orange Box, Yellow 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 | | | | |

## Pipeline Milestones During the Next 12 Months

| Drug | Disease Target | Status and Milestones |
|---|---|---|
| **Next Generation Capecitabine Phase 1B (PCS6422)** | **Metastatic Colorectal, Other Cancers** | • Cohort 1 and 2A Completed, 1 Pt in Cohort 2B completed, 1 Site being Added (Total of 6 Sites)<br>• Complete Enrollment and Interim Analysis of Cohort 2A, 2B, 2C to Better Understand the Timeline of Inhibition & De Novo Formation of the DPD Enzyme<br>• Complete 1B Trial & Identify MTD<br>• Finalize Potential Paths to Approval & Meet with FDA to Define Path Forward |
| **PCS499 Phase 2B** | **Ulcerative Necrobiosis Lipoidica** | • 3 Pts Completed Trial, Supplemental Patient Enrollment Programs are now having an Effect on Enrollment<br>• Complete Interim Cohort Enrollment and Analysis of Primary Endpoint<br>• Complete Trial Enrollment & Analysis, Finalize Potential Paths to FDA Approval, & Meet with FDA to Define Path Forward |
| **PCS12852 Phase 2A** | **Gastroparesis** | • Enrolled 20 out of 24 patients<br>• Complete Enrollment & Obtain Final Results<br>• Initiate Phase 2B Trial |
| **PCS3117 Phase 2B** | **Pancreatic, Other Cancers** | • Finalize Potential Paths to FDA Approval & Meet with FDA to Define Path Forward |
| **PCS11T Pre-IND** | **SC Lung, Other Cancers** | • Select Manufacturing Sites & Design Initial Clinical Program |



## Questions and Answers

- What is Management doing to deal with the progress of the programs, especially enrollment in 499 and 6422?
  - Has Processa considered that the eligibility requirements to enroll in their trials may be too stringent?
  - Is it possible that Processa is splitting resources across the drugs in the pipeline too much causing delays? Does the company need more resources?

- What is your plan for each asset?
  - Do you plan to partner or out-license each asset and, if you do, when?
  - How do you plan to fund the next studies?

Processa Pharmaceuticals

# Pipeline Background Slides

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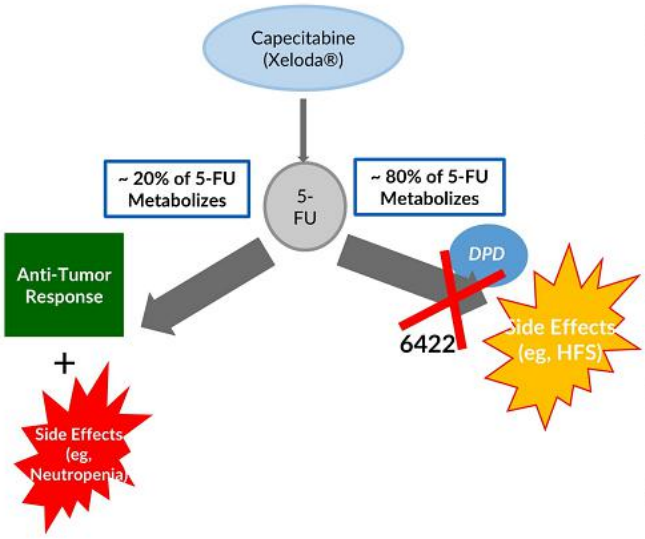
# Next Generation Capecitabine (Combination of PCS6422 and Capecitabine)

## 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

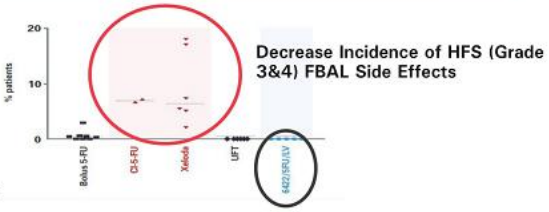
**Economic Value: Initial Markets**

- 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

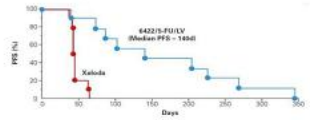



*Revollo et al. 2008 Clin Cancer Res;* Masuda et al. 2017. NEJM

- **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



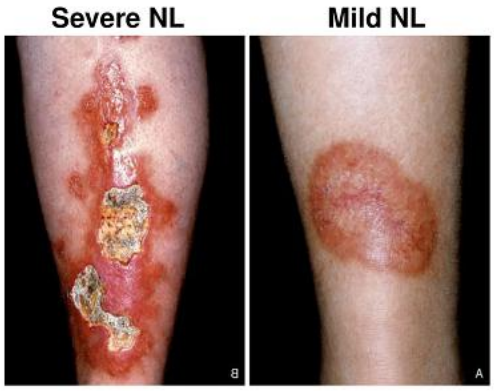
Processa Pharmaceuticals

# PCS499

## Ulcerative Necrobiosis Lipoidica (uNL)

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

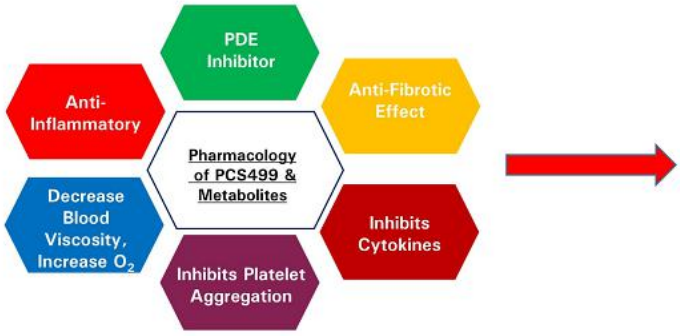
- Skin and tissue below the skin become necrotic forming open ulcers; can last from months to years with complications such as infections, amputation, and cancer
- Literature reports approximately 22,000 – 55,000 uNL patients in the U.S. will have painful ulcers occurring naturally or from contact trauma 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

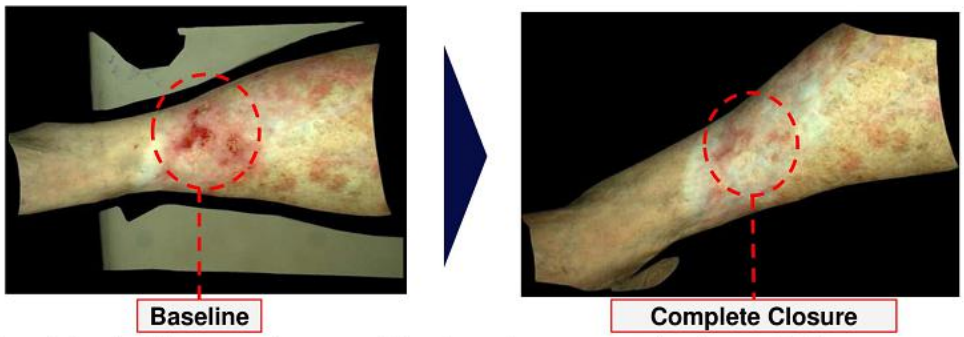



**Pathophysiological Changes in NL**

- 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




- 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

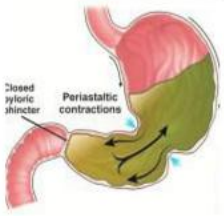
## Gastroparesis

# Gastroparesis

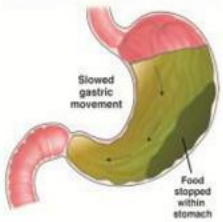
## PCS12852 is a More Potent and More Selective 5HT4 Agonist than Previous 5HT4 Agonists

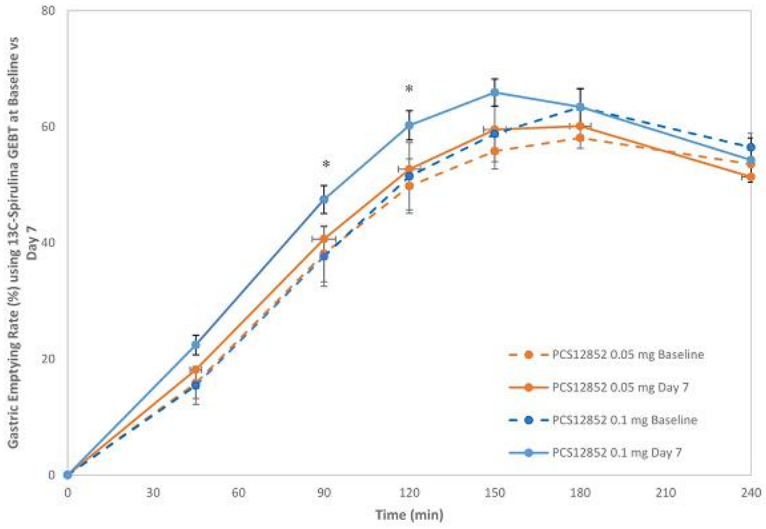
- Target Indication:
  - Treatment of moderate to severe gastroparesis
- Target Claims:
  - Improves gastric emptying rate and the symptoms associated with moderate to severe gastroparesis (e.g., bloating, pain, nausea, vomiting)

Normal Gastric Emptying




Gastroparesis






# Treatment of Gastroparesis (> $1.5B Market)

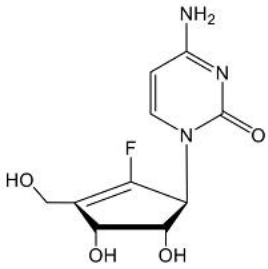
- Existing FDA approved drugs and off-labeled prescribed drugs are mainly used for the treatment of diabetic gastroparesis
- All these drugs have a poor side effect profile limiting their use
- Present market size for gastroparesis is estimated to be over $1.5B

| | 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 |

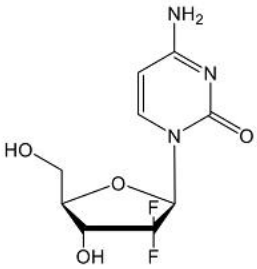
Processa Pharmaceuticals

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

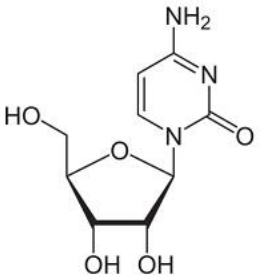
## 1H'22 - PCS3117 Biomarker Assay Development Completed




RX-3117
Oral Administration
(Cytosine + Ribose Analog)




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

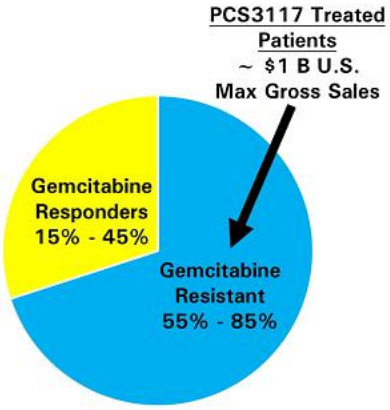



Cytidine
(Cytosine + Ribose Ring)

- 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

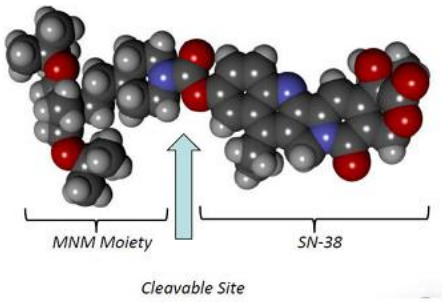
Processa Pharmaceuticals

# PCS11T

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

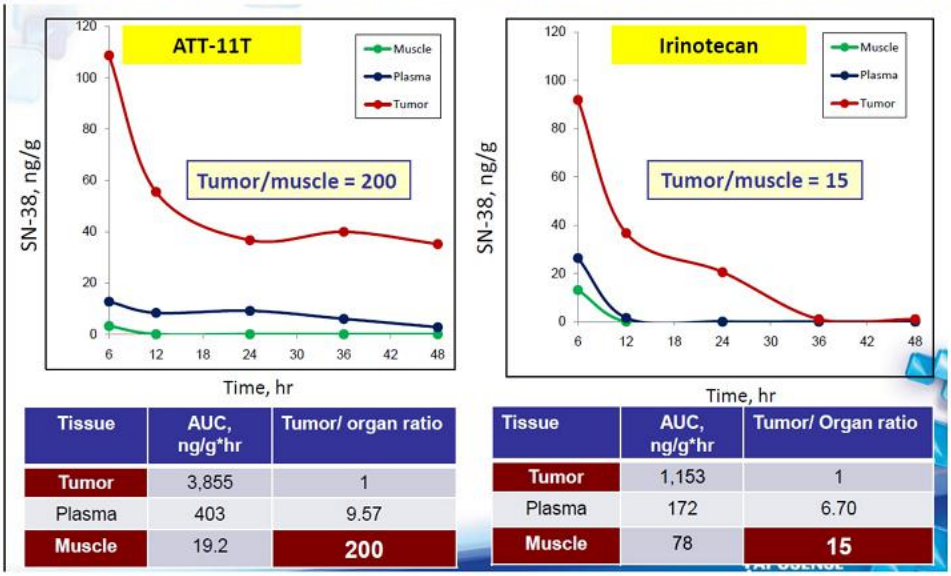
## PCS11T: Lipophilic Prodrug of SN-38 (Irinotecan Active Metabolite)

- 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**

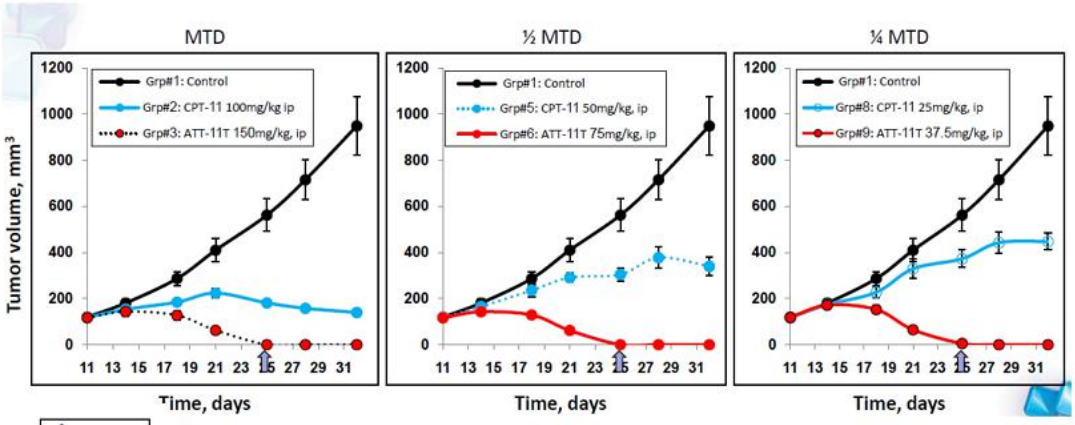



| Tissue | AUC, ng/g*hr | Tumor/ organ ratio |
|---|---|---|
| **Tumor** | 3,855 | 1 |
| Plasma | 403 | 9.57 |
| **Muscle** | 19.2 | **200** |

| 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 | At ½ MTD | At ¼ MTD |
|---|---|---|
| Tumor Growth Inhibition | Tumor Growth Inhibition | Tumor Growth Inhibition |
| 100% ATT11-T | 100% ATT11-T | 100% ATT11-T |
| 100% CPT-11 | 64% CPT-11 | 53% CPT-11 |