

**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): January 9, 2023

Commission file number 001-39531

**PROCESSA PHARMACEUTICALS, INC.**

(Exact name of Registrant as Specified in its Charter)

Delaware  
(State or Other Jurisdiction of  
Incorporation or Organization)

45-1539785  
(I.R.S. Employer  
Identification Number)

7380 Coca Cola Drive, Suite 106, Hanover, Maryland 21076  
(Address of Principal Executive Offices, Including Zip Code)

(443) 776-3133  
(Registrant's Telephone Number, Including Area Code)

(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: Par value \$.0001	PCSA	Nasdaq Capital Market

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 Disclosure.**

Processa Pharmaceuticals, Inc. (“*Processa*”) will be presenting at the Biotech Showcase and meeting with analysts and investors at the 41<sup>st</sup> Annual J.P. Morgan Healthcare Conference. During these meetings, Processa’s presentation will be uploaded into a portal, which is furnished as Exhibit 99.1 and is incorporated herein by reference. The presentation will also be made available in the “Investors” section on Processa’s website, located at processapharmaceuticals.com.

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

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

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

Exhibit No.	Exhibit Description
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**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized, on January 9, 2023.

PROCESSA PHARMACEUTICALS, INC.  
Registrant

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

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Processa Pharmaceuticals

## **Next Generation Chemotherapy**

**David Young, PharmD, PhD**  
**President and CEO**

**Biotech Showcase**  
**January 11, 2023**

## Disclaimer: Forward Looking Statements

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The following summary is provided for informational purposes only and does not constitute an offer or solicitation to acquire interests in the investment or any related or associated company.

The information contained here is general in nature and is not intended as legal, tax or investment advice. Furthermore, the information contained herein may not be applicable to or suitable for an individual's specific circumstances or needs and may require consideration of other matters. The Company and its directors, officers, employees and consultants do not assume any obligation to inform any person of any changes or other factors that could affect the information contained herein.

These materials may include forward-looking statements including financial projections, plans, target and schedules on the basis of currently available information and are intended only as illustrations of potential future performance, and all have been prepared internally.

Forward-looking statements, by their very nature, are subject to uncertainties and contingencies and assume certain known and unknown risks. Since the impact of these risks, uncertainties and other factors is unpredictable, actual results and financial performance may substantially differ from the details expressed or implied herein. 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.



# Investment Opportunity with De-Risked Next Generation Chemotherapy

## *Successful, Experienced Team*

- Leaders of the Development Team were involved with 2 FDA contracts where Regulatory Science was conceived
- Development Team was involved with > 30 FDA approvals for indications across FDA
- Management Team was involved with Billion-Dollar exits (Questcor - \$5.7 B & Gentium - \$1.0 B)

## *Processa Regulatory Science Approach Capitalizing on Project Optimus Oncology Initiative*

- Regulatory Science became the foundation of the Processa Development Team to obtain > 30 FDA approvals for multiple types of indications over the last 32 years
- Processa capitalizes on using its Regulatory Science Approach to implement the Project Optimus Oncology Initiative in order to define the "optimal" regimen to improve the safety/efficacy profile

## *Next Generation Chemotherapy*

- Next Generation Chemotherapy drugs were designed from the three most widely used chemotherapy drugs
- Next Generation drugs use Project Optimus to demonstrate improved safety/efficacy over existing drugs

## *Substantial Market Opportunities*

- The safety/efficacy profile of each drug differentiates it from existing on-label and off-label therapy
- The market for each Next Generation Chemotherapy asset is greater than \$1B

## *Capital Efficient strategy*

- Processa will be advancing multiple assets to Phase 3-readiness within 24 months after funding with a low SG&A
- Known safety/efficacy profile with existing therapy leads to efficient clinical development

## *Significant inflection points over the next 24 months after funding*

- Next Generation Capecitabine Phase 2B trial to define safer/more efficacious regimens will be initiated 2H2023
- Pancreatic cancer PCS3117 Phase 2 trial will be initiated in 2H2023 & Lung Cancer PCS11T Phase 1B trial in 2H2024
- Partner or out-license non-oncology assets

# Processa Senior Management

Management Team Involved With Billion-Dollar Exits (Questcor - \$5.7 B & Gentium - \$1.0 B) & Two FDA Contracts Where Regulatory Science Was Conceived



David Young, Pharm.D, Ph.D.

President & CEO

**Joined Processa 2018**

#### Former Roles

- ✓ CSO & Independent Director, **Questcor**
- ✓ U.S. President, **AGI Therapeutics**
- ✓ CEO, **GloboMax**
- ✓ Associate Professor, **University of Maryland**
- ✓ Pharm.D., PhD, **University of S. California**



Sian Bigora, Pharm.D.

Chief Development Officer

**Joined Processa 2018**

#### Former Roles

- ✓ VP Regulatory, **Questcor**
- ✓ VP Clinical Research, **AGI Therapeutics**
- ✓ VP Regulatory, **ICON Plc, GloboMax**
- ✓ Clinical Research Assoc., **Univ. of Maryland**
- ✓ Pharm.D., **University of Maryland**



Michael Floyd

Chief Operating Officer

**Joined Processa 2020**

#### Former Roles

- ✓ President & CEO, **Elion Oncology**
- ✓ U.S. Project Lead, **Gentium**
- ✓ President, **Arpida**
- ✓ BSBA, **Georgetown University**



Patrick Lin

Chief Business & Strategy Officer

**Joined Processa 2018**

#### Former Roles

- ✓ Founder and Managing Partner, **Primarius Capital**
- ✓ Robertson Stephens & Co.
- ✓ Co-Founding Partner, **E\*Offering**
- ✓ MBA, **Kellogg Graduate School**; BS, **University of S. California**



James Stanker, CPA

Chief Financial Officer

**Joined Processa 2019**

#### Former Roles

- ✓ Audit Partner, **Grant Thornton**
- ✓ CFO, **NASDAQ listed company and a privately-held life science company**
- ✓ Director/Audit Committee Chairman, **Hersperos**
- ✓ MBA, **California State University**; BS, **San Jose University**



Wendy Guy

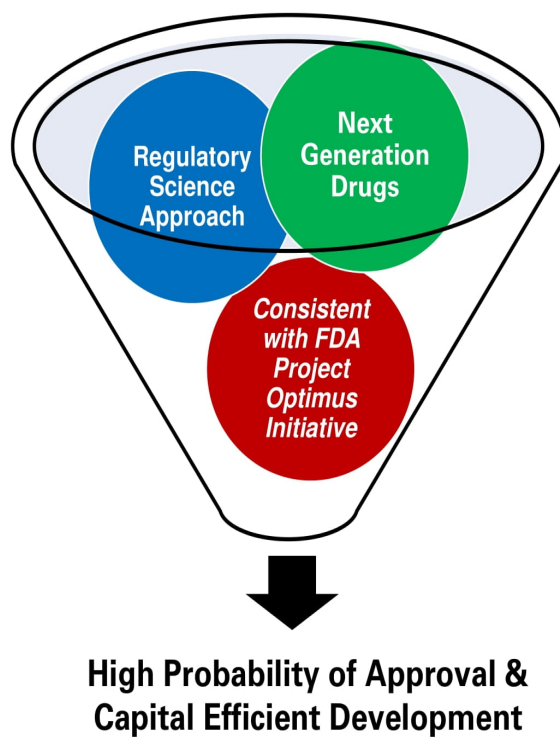
Chief Administrative Officer

**Joined Processa 2018**

#### Former Roles

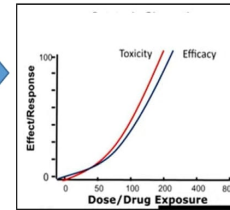
- ✓ Senior Manager, Business Operations, **Questcor**
- ✓ Senior Manager, **AGI Therapeutics**
- ✓ Senior Manager, Administration, **ICON Plc, GloboMax**
- ✓ AA, **MWCC**

## Three Next Generation Chemotherapy Drugs with Routes to Approval



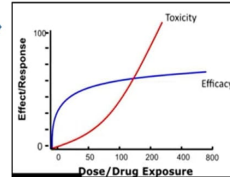
# FDA Project Optimus: Evaluate Safety & Efficacy as a Function of Drug Exposure

- **Maximum Tolerated Dose (MTD):** Historically, Used to determine efficacious dose while assuming toxicity & efficacy follow a parallel path.



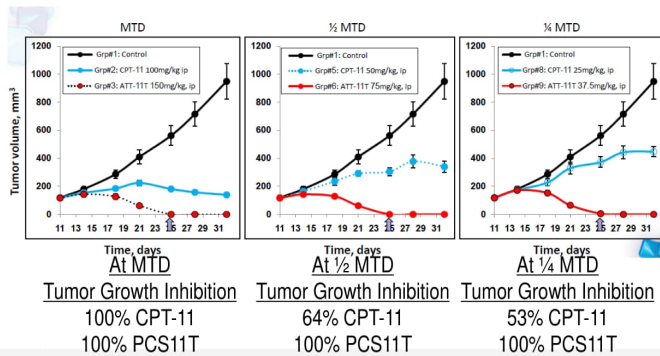
Assumption with MTD Approach

- **FDA Project Optimus Oncology Initiative:** Evaluation of safety & efficacy in Relationship to Drug Exposure & Dosage Regimen may show toxicity and efficacy do not show a parallel path.



Possibility with Project Optimus

- **Example Irinotecan vs PCS11T, Next Generation Irinotecan, in a colorectal xenograft animal model**

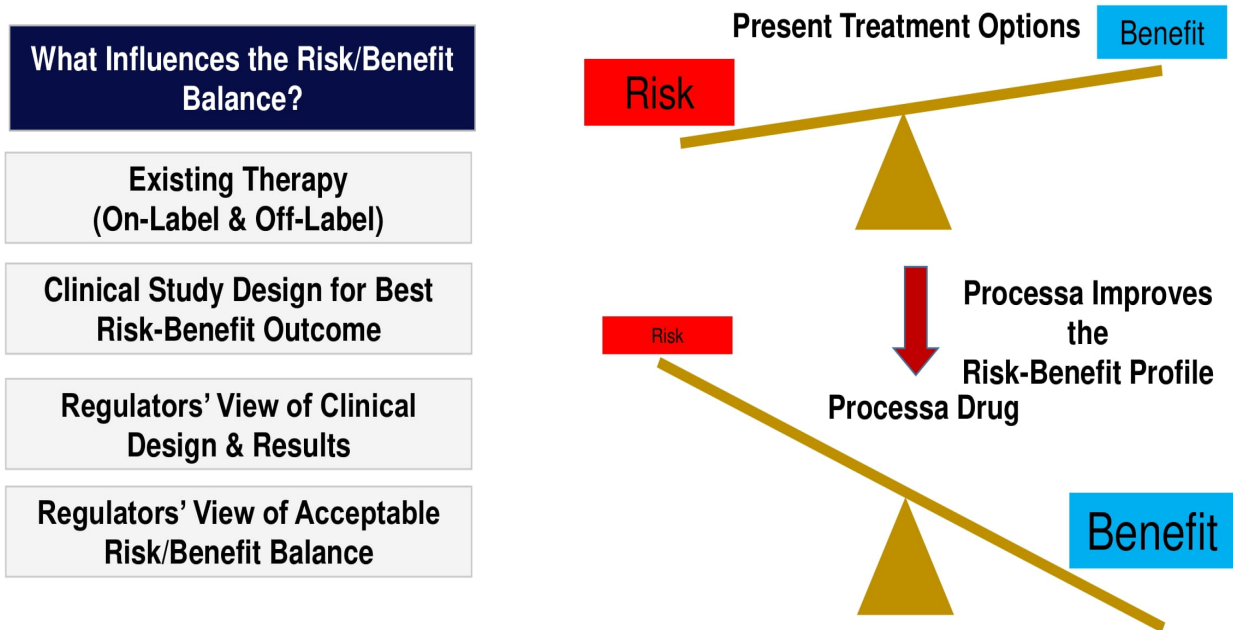


Evaluate Safety and Efficacy as a Function of Drug Exposure/Drug Regimens

# Regulatory Science Approach

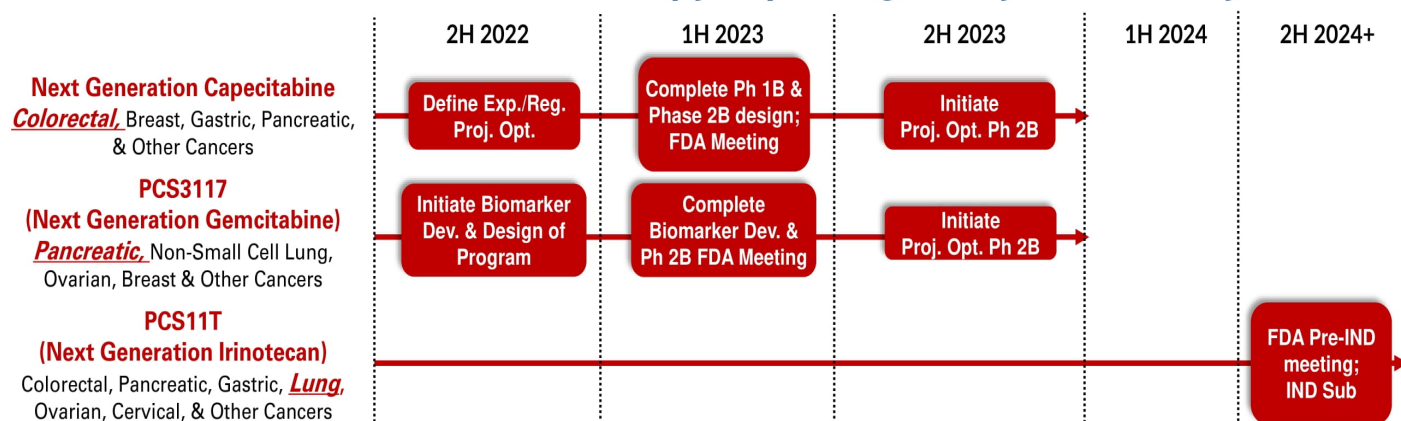
Conceived from 2 FDA Contracts with the Approach Resulting In > 30 FDA Approvals For Indications Across FDA

Risk And Benefit Are More Than Adverse Event And Efficacy Response

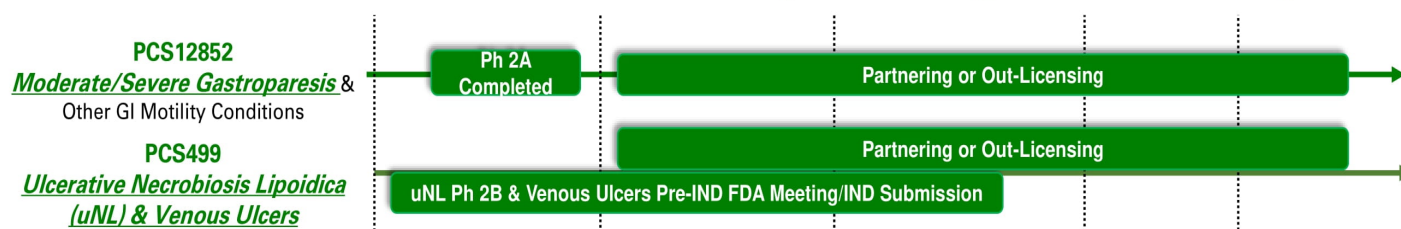


# Processa Pipeline of Drugs, Each with > \$1B Market

## Next Generation Chemotherapy Improving Safety and Efficacy



## Candidates for Monetization by Partnering or Out-Licensing







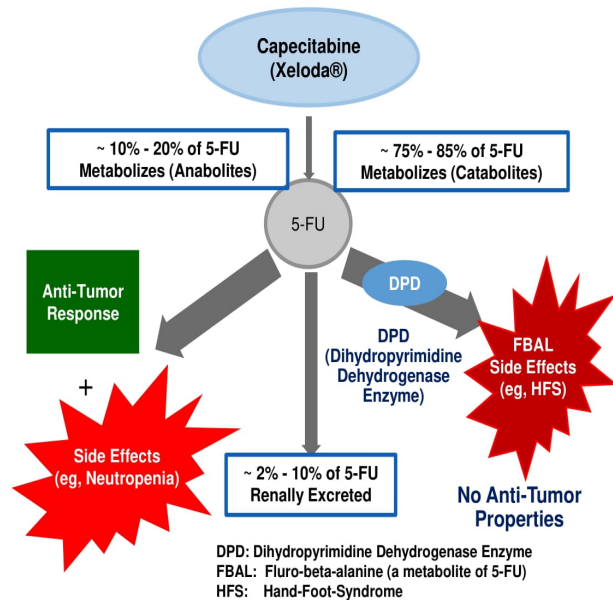
Processa Pharmaceuticals

**Next Generation Capecitabine (NGC)  
(Combination Regimens of PCS6422 and  
Capecitabine)**

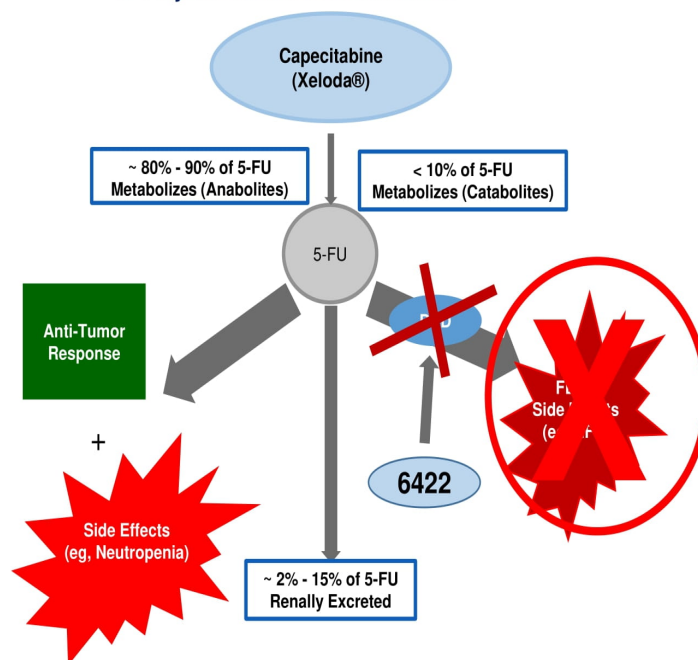
**Colorectal Cancer, Gastric, Breast Cancer,  
Pancreatic Cancer, and Other Cancers**

# 5-FU & Capecitabine - Most Widely Used Cancer Chemotherapy Agents

- 50% - 70% of Patients on Capecitabine Have Dose-Limiting Side Effects Requiring Change in Therapy;
- Approximately 60% Of Patients Do Not Respond Or Are Partial Responders



- Combining PCS6422 Regimen (Irreversibly Inhibiting DPD) With Capecitabine Regimen, The 5-FU Formed Is Only Metabolized To Anabolites

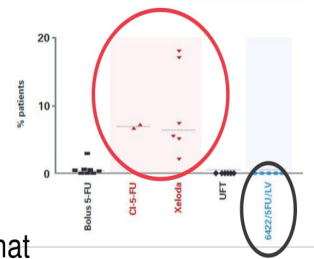




## Why Believe in NGC (PCS6422+Capecitabine): Evidence of Clinical Benefit

### ➤ PCS6422 + 5-FU Safety is Better than Existing Chemotherapy

- 50-70% of Capecitabine patients have adverse events from FBAL resulting in decreasing Capecitabine dose or stopping therapy.
- Clinical trial of the PCS6422 + 5-FU provided initial evidence that NGC will decrease FBAL adverse events.



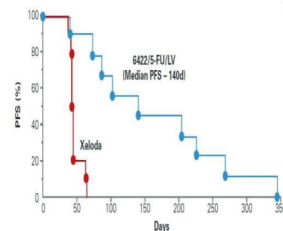
Decrease Incidence of HFS (Grade 3&4) FBAL Side Effects

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

### ➤ PCS6422 + 5-FU Efficacy Occurred in Patients Not Responding to Capecitabine

- ~60% of patients do not respond or are partial responders to Capecitabine.
- Clinical trial evidence in 9 patients that NGC (when 6422 is administered before 5-FU) extends progression free survival (PFS) in patients who do not respond to Capecitabine and increases PFS in those patients who do respond.

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



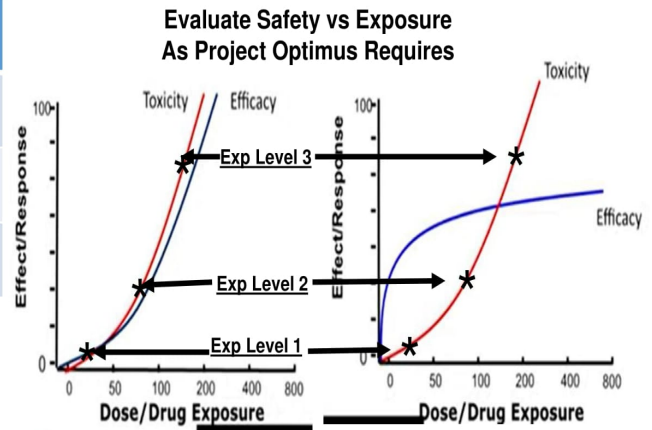
Kaplan-Meier Plot Shows PCS6422 + 5-FU Efficacy Occurred in Patients not Responding to Capecitabine

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

## NGC Project Optimus: Evaluate Safety as a Function of Drug Exposure and 6422 Regimens in Phase 1B Trial

Phase 1B Trial	DLTs from Anabolites (e.g., Neutropenia)	AEs, DLTs from FBAL (e.g., HFS)**
5-FU <b>Exposure Level 1</b> (NGC Regimen A)	0/1	0/1
5-FU <b>Exposure Level 2</b> (NGC Regimen B)	0/5	0/5
5-FU <b>Exposure Level 3</b> (NGC Regimen C)	2/5 (Exposure Limiting)	0/5

\*\*50%-70% of patients on approved Capecitabine have adverse events from FBAL



- Evaluated timeline of maintaining the potency of NGC to ~ 50-times greater than approved Capecitabine.
- Evaluated relationship between dose-limiting toxicities (DLTs)/adverse events and 5-FU exposure; <10% of approved Capecitabine dose administered with PCS6422 causes DLTs.
- **Safe 5-FU exposure levels (and NGC regimens) identified for evaluation in the Phase 2B safety/efficacy study; exposure levels and NGC regimens that cause DLTs have also been identified.**

# NGC Project Optimus Objectives in 2023

## Need To Evaluate Safety And Efficacy As A Function Of Drug Exposure & NGC Regimens In Phase 2B Trial

- 5-FU exposure and NGC regimens have been identified for a Phase 2B trial which will provide the exposure range required for FDA's Project Optimus Oncology Initiative
- Discuss with FDA the development program and Phase 2B trial design in relation to Project Optimus in 1H2023
- Evaluate additional regulatory approaches to expedite the development program
- Evaluate current studies to determine the potential for new intellectual property and life extension

Initiate Phase 2B trial in 2H2023



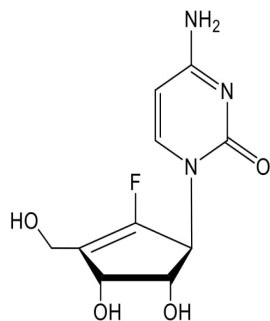
Processa Pharmaceuticals

PCS3117

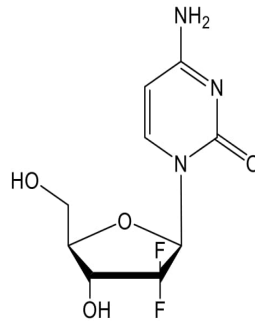
**Pancreatic Cancer**, Adjuvant Therapy for Pancreatic  
Cancer, Biliary Cancer, Non-Small Cell Lung, and  
Other Cancers

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## PCS3117: Next Generation Gemcitabine



PCS3117  
Oral Administration  
(Cytosine + Ribose Analog)



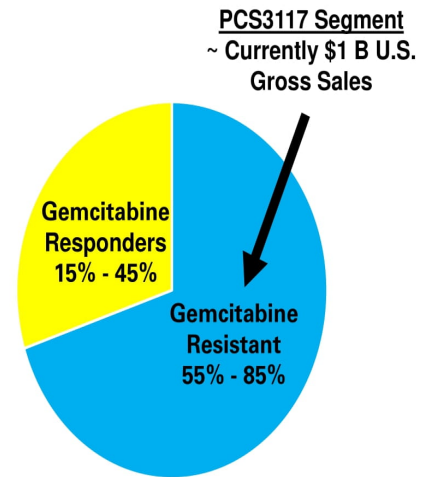
Gemcitabine (dFdC)  
IV Administration  
(Cytosine + F,F-Deoxyribose)

➤ **PCS3117 is the "Next Generation" of FDA-approved Gemcitabine.**

- PCS3117 is more efficacious than Gemcitabine with a similar safety profile.
  - 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 already has FDA Orphan Designation for the treatment of pancreatic cancer and the drug development "roadmaps" have been defined.

## PCS3117 Opportunity

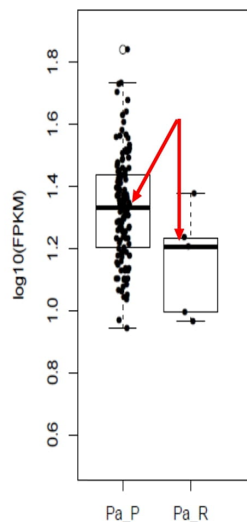
- Gemcitabine is the most widely used chemotherapeutic agent used to treat pancreatic, non-small cell lung, and biliary cancer.
- U.S. pancreatic cancer Gemcitabine sales: ~ \$1 B; U.S. market for all cancer/indications is > \$1.5 B .
- 55% - 85% of patients are inherently resistant to Gemcitabine or acquire resistance.
- **Initial target indications are:**
  - **First-line therapy for post-surgical recurrent pancreatic cancer after FOLFIRINOX adjuvant chemotherapy.**
  - **First-line treatment in pancreatic cancer patients where biomarkers identify resistance to Gemcitabine.**
  - **Second-line treatment of pancreatic cancer with or without biomarkers.**



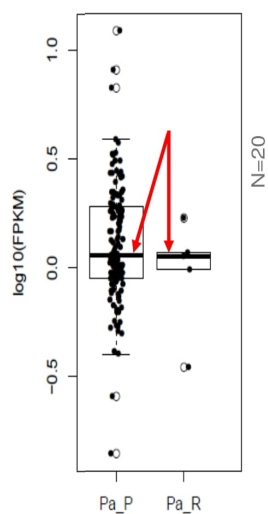
## PCS3117 - UCK2 Level as a Predictive Biomarker

### Higher UCK2 Expressions In Human Pancreatic Tumors Compared To Normal Tissue

UCK2 Expression  
(Enzyme Activating PCS3117)



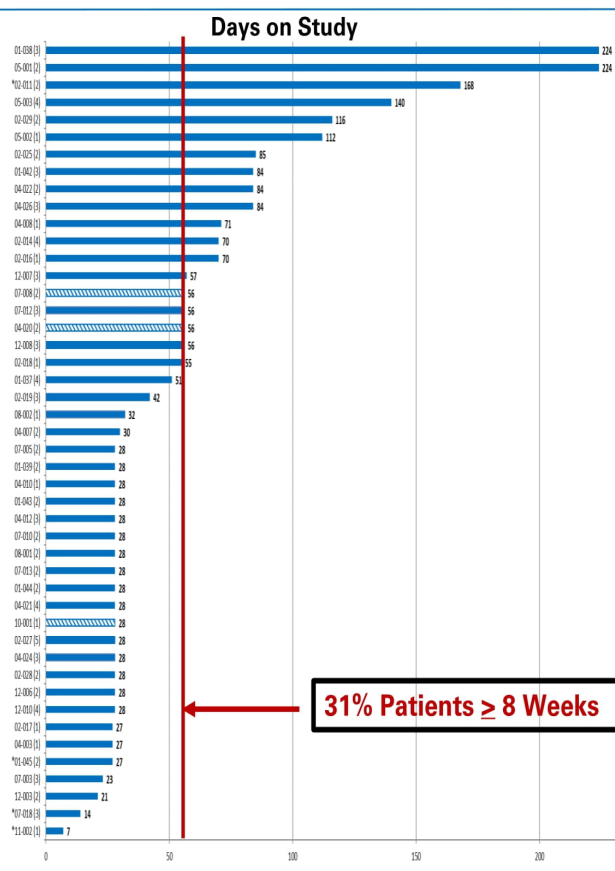
dCK Expression  
(Enzyme Activating Gemcitabine)



N=20

Pa\_P : Pancreatic Tumor, N=134  
Pa\_R : Normal pancreas, N=5  
(Data from Univ. of Toronto)

## PCS3117 Prior Evidence of Clinical Safety and Efficacy in Pancreatic 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 8 weeks or more.**
- 12% (5 patients) had stable disease for more than 4 months.
- One patient had a tumor reduction of 40% after 28 days of treatment.
- Mild to moderate adverse events were reported with a better overall safety profile than Gemcitabine.



## PCS3117 Milestones in 2023

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- Complete the evaluation of potential biomarkers in pancreatic cancer patients to identify potential responders to PCS3117 as 1st line therapy prior to treatment using a Precision Medicine approach in 1H2023.
- Complete the evaluation of potential biomarkers in pancreatic cancer patients to identify potential non-responders to Gemcitabine.
- Meet with FDA to discuss pancreatic cancer development program in 1H2023.
- Submit Phase 2B protocol to existing IND mid-2023.

Initiate Phase 2B trial in 2H2023



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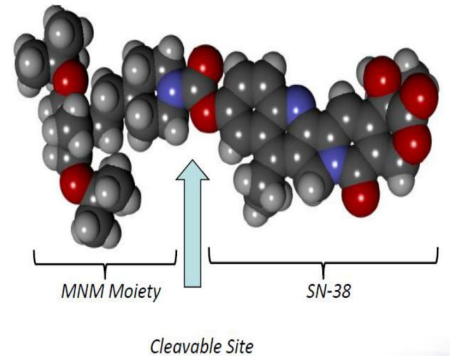
**PCS11T**

**Colorectal, Lung, Pancreatic, Cervical and  
Other Cancers**

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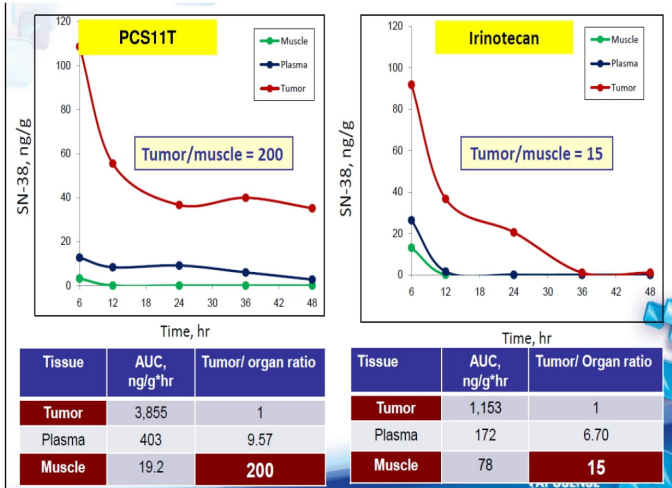
## PCS11T (Next Generation Irinotecan): Lipophilic Prodrug of SN-38 (Irinotecan Active Metabolite)

- 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.**
- Given the PCS11T specificity for cancer cells, upon approval it is **unlikely that PCS11T will have the BlackBox diarrhea warning that Irinotecan has.**
- **Irinotecan sales prior to generics was > \$1B.**

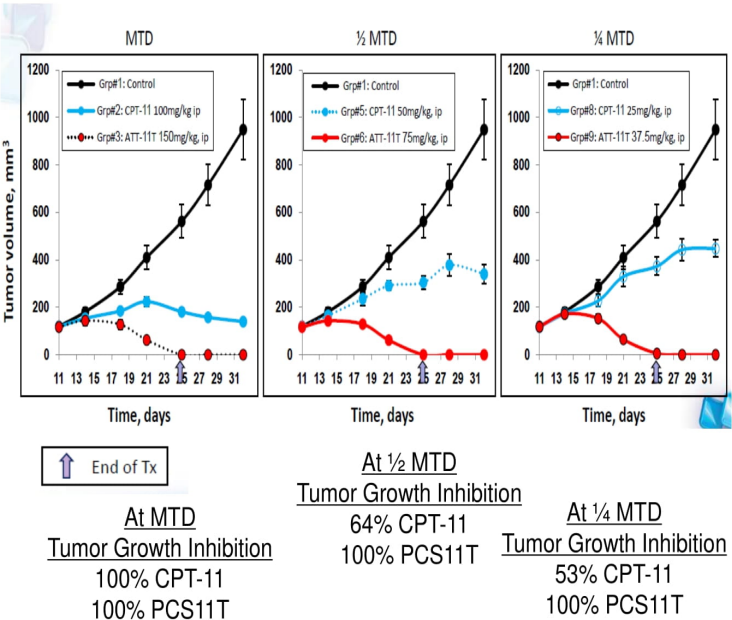


# Importance of Regulatory Science and Project Optimus for PCS11T, Next Generation Irinotecan

Tumor-Bearing Mice Had 200x Higher Drug In Tumor vs Muscle Compared To 15x With Irinotecan



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



## PCS11T Milestones in 2023

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- Drug Substance manufacturing site has been selected and Drug Product manufacturing sites are being evaluated.
- Drug development “roadmaps” are being developed for lung, pancreatic, colorectal, and other potential cancers.
- Complete manufacturing of Drug Substance and Drug Product.

Initiate IND Enabling Toxicology Studies in 2H2023

## 2022 Key Accomplishments and 2023 Anticipated Key Events

Next Generation Treatment	2022 Key Accomplishments	2023 Anticipated Key Events
Next Generation Capecitabine (NGC)	<ul style="list-style-type: none"> <li>✓ Identified DPD inhibition and de novo formation timeline.</li> <li>✓ Identified safe and dose limiting 5-FU exposure levels and NGC dosage regimens.</li> </ul>	<ul style="list-style-type: none"> <li>• Meet with FDA on NGC Project Optimus plan.</li> <li>• Initiate Phase 2B trial with multiple NGC regimens to evaluate relationship of 5-FU exposure to efficacy.</li> </ul>
PCS3117	<ul style="list-style-type: none"> <li>✓ Identified clinical development program.</li> </ul>	<ul style="list-style-type: none"> <li>• Complete biomarker analysis.</li> <li>• Meet with FDA on programs.</li> <li>• Initiate Phase 2B trial.</li> </ul>
PCS11T	<ul style="list-style-type: none"> <li>✓ Identified sites for pre-IND CMC, tox studies.</li> </ul>	<ul style="list-style-type: none"> <li>• Initiate IND enabling studies.</li> </ul>
PCS12852	<ul style="list-style-type: none"> <li>✓ Completed Phase 2A study.</li> <li>✓ Determined safe dose in gastroparesis that improves symptoms associated with gastroparesis.</li> </ul>	<ul style="list-style-type: none"> <li>• Submit Phase 2B protocol to IND.</li> <li>• Partner or out-license.</li> </ul>
PCS499	<ul style="list-style-type: none"> <li>✓ Enrolled additional patients for uNL</li> <li>✓ Initiated development strategy in Venous Ulcers.</li> </ul>	<ul style="list-style-type: none"> <li>• Complete interim analysis.</li> <li>• Meet with FDA on Phase 2B venous ulcers IND</li> <li>• Partner or out-license.</li> </ul>

## Intellectual Property and Market Exclusivity

Program	Description of IP	Overview of Patent Expiration Dates and Market Exclusivity
PCS6422	Existing Patents, Provisional Patents To Be Submitted Patents Potential FDA Market Exclusivity	2042 2043 7 Years after approval
PCS3117	Existing Patents, Provisional Patents To Be Submitted Patents Potential FDA Market Exclusivity	2034 2043 7 Years after approval
PCS11T	Existing Patents, Provisional Patents To Be Submitted Patents Potential FDA Market Exclusivity	2031 2043 7 Years after approval
PCS12852	Existing Patents, Provisional Patents To Be Submitted Patents Potential FDA Market Exclusivity	2037 N/A 5 Years
PCS499	Existing Patents, Provisional Patents To Be Submitted Patents Potential FDA Market Exclusivity	2034 N/A 5-7 Years after approval

## Financial Highlights and Capital Structure

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- Cash on September 30, 2022, of \$9.1 million provides a cash runway into the third quarter of 2023.
- Overhead only cash burn, including salaries, is expected to be less than \$4.5 million in 2022.
- Shares Outstanding on September 30 , 2022 was 15,895,087, fully diluted shares totaled 19,225,006.
- 24% of our outstanding common stock (32% of our fully diluted common stock) is held by officers and directors.
- Currently have 15 employees.
- Research Analyst Reports:
  - Francois Brisebois, Oppenheimer; Robert Wasserman, Benchmark;
  - Naz Rahman, Maxim; Hogan Mullaly, Encode Ideas



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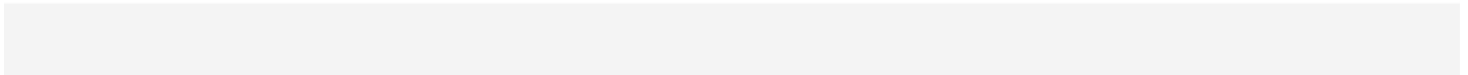
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- Partner or out-license non-oncology assets



Processa Pharmaceuticals

**Backup Slides**

**PCS12852 & PCS499**





Processa Pharmaceuticals

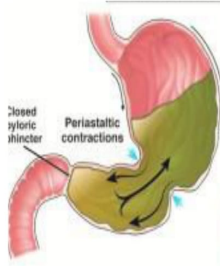
PCS12852

**Gastroparesis, Other GI Motility Conditions**

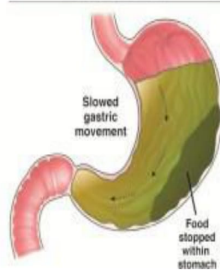
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# Gastroparesis

Normal Gastric Emptying



Gastroparesis



## Gastroparesis Symptoms

Mild – Severe:

➤ Heartburn, too much bloating, belching

Moderate – Severe:

➤ Feeling full soon after starting a meal or long after eating a meal

➤ Nausea

➤ Vomiting

➤ Upper abdominal pain

➤ Early satiety

➤ Target Indication:

- Treatment of moderate to severe gastroparesis

➤ Target Claims:

- Improves gastric emptying rate and the symptoms associated with moderate to severe gastroparesis

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

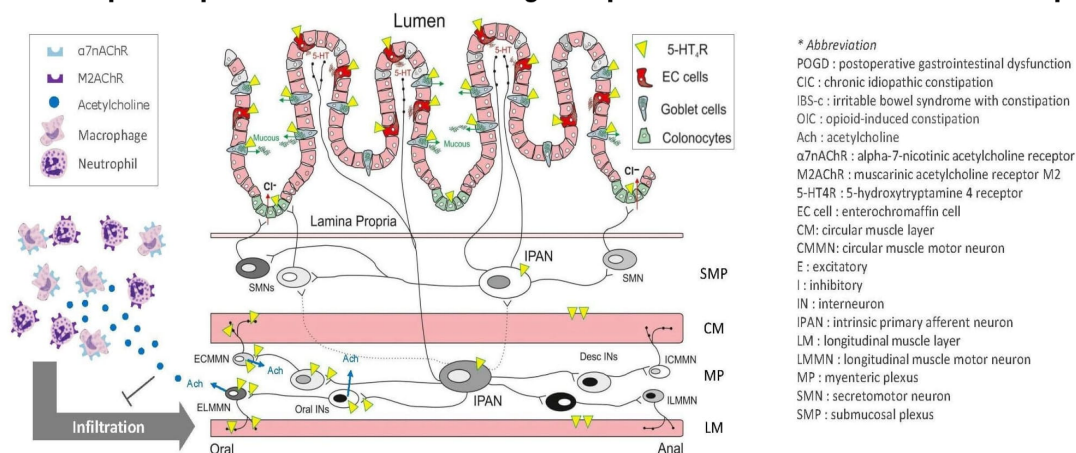
- Existing FDA approved drugs and off-labeled prescribed drugs are mainly used for the treatment of diabetic gastroparesis
- All these drugs have a poor side effect profile limiting their use
- Present market size for gastroparesis is estimated to be over \$1.5B

	PCS12852	Other 5HT4 Drug (e.g., Cisapride, Prucalopride, Mosapride)	Dopamine D2 Antagonist (e.g., Metoclopramide)
Target Population	<ul style="list-style-type: none"> <li>Potentially all gastroparesis patients (e.g., diabetic, idiopathic)</li> </ul>	<ul style="list-style-type: none"> <li>Diabetic gastroparesis patients</li> </ul>	<ul style="list-style-type: none"> <li>Diabetic gastroparesis patients</li> </ul>
Binding	<ul style="list-style-type: none"> <li>Specific &amp; potent 5HT4 receptor binding</li> </ul>	<ul style="list-style-type: none"> <li>Less specific binding to 5HT4 than 12852</li> <li>Less potent than 12852</li> </ul>	<ul style="list-style-type: none"> <li>Binds to Dopamine D2 receptors</li> </ul>
Side Effects	<ul style="list-style-type: none"> <li>No serious side effects in clinical studies to date</li> </ul>	<ul style="list-style-type: none"> <li>Serious cardiovascular side effects (e.g., cisapride removed from market)</li> <li>Suicidal ideation (e.g., prucalopride)</li> </ul>	<ul style="list-style-type: none"> <li>Black Box Warning serious neurological side effects, Side effects require limited use</li> </ul>
Efficacy	<ul style="list-style-type: none"> <li>Increase gastric emptying rate in patients with constipation</li> </ul>	<ul style="list-style-type: none"> <li>Increase gastric emptying rate</li> <li>Successful treatment demonstrated</li> </ul>	<ul style="list-style-type: none"> <li>Only drug FDA approved for treatment of gastroparesis</li> </ul>

# PCS12852: 5-HT<sub>4</sub> Receptor Agonist - Wide Range of GI Motility Disorders

## Clinically Proven Mechanism of Action

- Enhancement of both GI motility & secretion via increased Ach, 5-HT, Cl- and mucus release.
- Neural anti-inflammatory effects on post-operative ileus by inhibiting macrophage and neutrophil infiltration.
- **Wide development potential to treat POGD, gastroparesis, CIC, IBS-c, OIC, and overlap syndrome.**



Adopted from Gwynne, R.M(2019), *Neurogastroenterology & Motility* 31(10) and Tsuchida, Y. (2011), *Gut* 60, 638–647

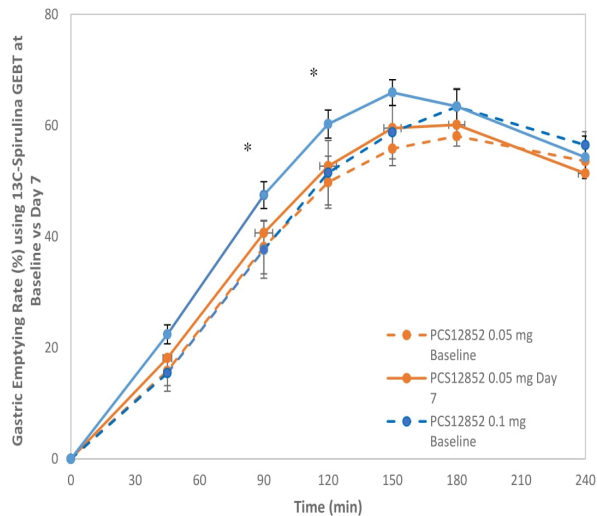
# PCS12852 Increase Gastric Emptying

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

### Phased 2A Trial in Healthy Volunteers & Constipation Patients

7 – 8 patients per group

Healthy Volunteers (< 3 Bowel Movements per Wk) or Functional Constipation Patients

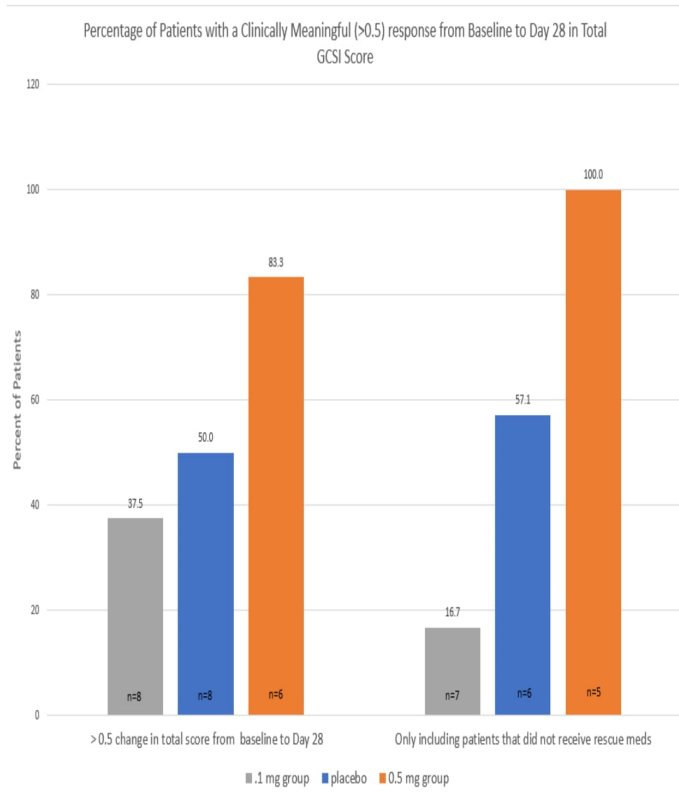


### U.S. Phase 2A Proof-of-Concept Trial in Gastroparesis Patients

- Gastric Emptying Breath Test (GEBT) results demonstrated that a daily dose of 0.5 mg of PCS12852 over 28 days in 6 patients improved the gastric emptying rate compared to baseline more than a daily dose of placebo
- GEBT for 0.1 mg of PCS12852 was not significantly different from the placebo
- Adverse events were mild to moderate with no clinically significant cardiovascular, unexpected, or serious adverse events



# PCS12852 Clinically Improves Gastroparesis Symptoms



- A 0.5 mg PCS12852 daily dose over 28 days resulted in a clinically meaningful improvement in gastroparesis symptoms as defined by greater than a 0.5 reduction in the ANMS GCSI-DD score compared to baseline.
- **83.3% of the patients receiving a 0.5 mg PCS12852 daily dose had a clinically meaningful reduction in gastroparesis symptoms, greater than the 50% response rate on placebo.**
- **100% of the patients on a 0.5 mg PCS12852 daily dose who did not receive rescue medication the last week of treatment had a clinically meaningful reduction in gastroparesis symptoms, greater than the 57.1% response on placebo.**
- Over 28 days the mean gastroparesis symptoms score continually improved more for the 0.5 mg PCS12852 group than the placebo group suggesting that longer treatment than 28 days may result in greater differences in gastroparesis symptoms for a 0.5 mg daily dose of PCS12852 than for placebo.



## PCS12852 Milestones in 2023

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- Meet with the FDA the 1H2023 to define the next steps of the gastroparesis development program and to agree on the design of the Phase 2B trial.
- Evaluate additional regulatory approaches to expedite the development program.
- Evaluate current studies to determine the potential for new intellectual property or life extension.
- Initiate Phase 2B trial in 2023 depending on priorities, funding, and licensing/partnering opportunities.

Candidate for Monetization by Partnering or Out-Licensing in 2023



Processa Pharmaceuticals

**PCS499**

**Ulcerative Necrobiosis Lipoidica (uNL),**  
**Venous Ulcers, Other Indications**

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

- Skin, tissue below the skin becomes necrotic forming open ulcers; can last from months to years with complications such as infections, amputation, and cancer.
- Literature reports a **prevalence of approximately 22,000 – 55,000 uNL** patients in the U.S. will have painful ulcers occurring naturally or from contact trauma to the lesion (**Probably closer to 5,000 to 10,000 patients in U.S.**).
- 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.

Severe NL



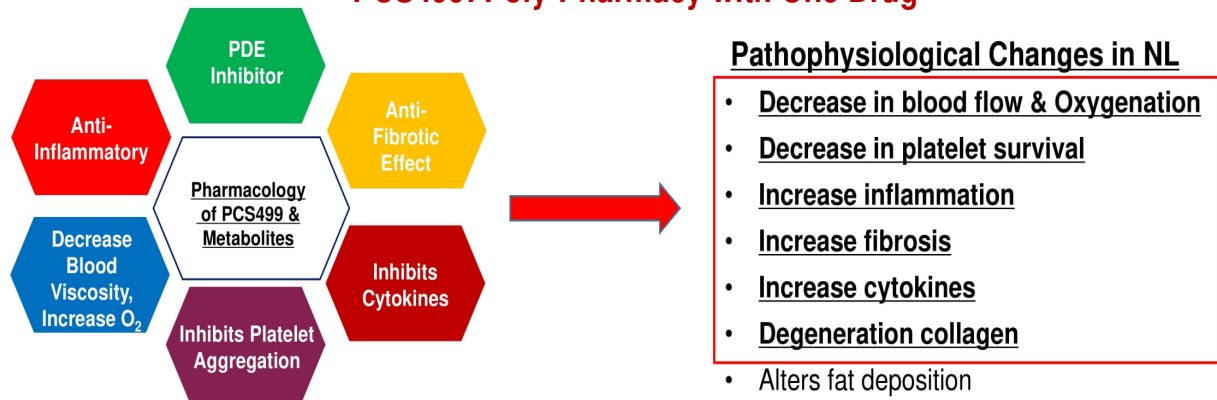
Mild NL



## Unmet Medical Need, Evidence of Clinical Efficacy

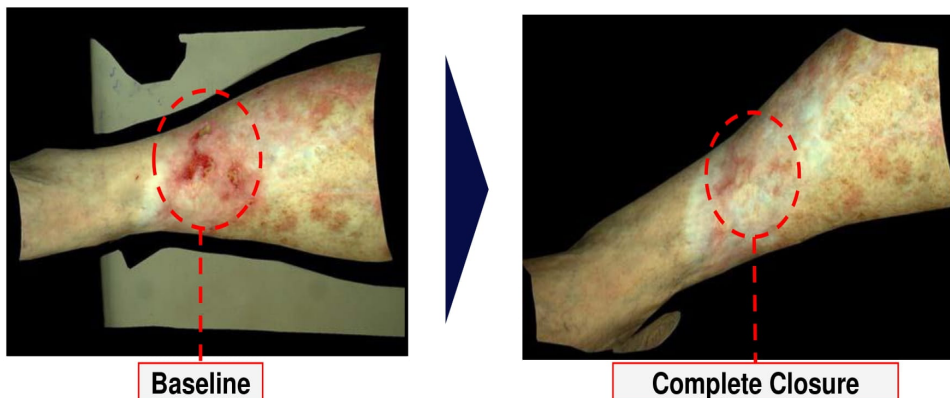
- **No FDA approved treatment** for uNL or NL, no standard of care, all treatments are inadequate
- **Drugs have been used off-label with mixed success (e.g., pentoxifylline (PTX)); provide poor safety profile** given their limited efficacy
- **PCS499 is the deuterated analog of a major metabolite of 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

### PCS499: Poly-Pharmacy with One Drug



## PCS499 Phase 2A Trial Demonstrates Complete Ulcer Closure

- 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.

## PCS499 Milestones in 2023

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- Complete enrollment of the interim analysis group in 1H2023 and evaluate the likelihood of completing full enrollment.
- Meet with FDA and submit an IND for Venous Ulcers, a second indication that requires the diverse pharmacology of PCS499.
- Evaluate additional regulatory approaches to expedite the development program.
- Evaluate current studies to determine the potential for new intellectual property or life extension.
- Initiate Phase 2 trial for Venous Ulcers in 2H2023 depending on priorities, funding, and licensing/partnering opportunities.

Candidate for Monetization by Partnering or Out-Licensing in 2023