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): December 22, 2022

Commission file number 001-39531

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

Delaware	**45-1539785**
(State or Other Jurisdiction of Incorporation or Organization)	**(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.

A copy of a slide presentation (Presentation Materials") that Processa Pharmaceuticals, Inc. ("Processa Pharmaceuticals") intends to publish to its website, is attached to this Current Report on Form 8-K and Exhibit 99.1. The Presentation Materials speak as of the date of this Current Report on Form 8-K. While Processa Pharmaceuticals may elect to update the Presentation Materials in the future or reflect events and circumstances occurring or existing after the date of this Current Report on Form 8-K, Processa Pharmaceuticals specifically disclaims any obligation to do so. The information contained in this Item 7.01 and Exhibit 99.1 hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	**Exhibit Description**
99.1	Processa Pharmaceuticals Investor Presentation dated December 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 December 22, 2022.

PROCESSA PHARMACEUTICALS, INC.
Registrant

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

Exhibit 99.1


Processa Pharmaceuticals, Inc.
(Nasdaq: PCSA)
December 2022
Processa Pharmaceuticals

Disclaimer: Forward Looking Statements

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

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

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

Forward-looking statements, by their very nature, are subject to uncertainties and contingencies and assume certain known and unknown risks. Since the impact of these risks, uncertainties and other factors is unpredictable, actual results and financial performance may substantially differ from the details expressed or implied herein. Please refer to the documents filed by Processa Pharmaceuticals with the SEC, specifically the most recent reports on Forms 10-K and 10-Q, which identify important risk factors which could cause actual results to differ from those contained in the forward-looking statements. The Company does not assume any obligation to release updates or revisions to forward-looking statements contained herein.

Our People Lead to Success

- **30 years ago members of the Processa Development Team were involved with 2 FDA contracts where the concept of Regulatory Science was conceived**
- **Development Team members further developed the Processa Regulatory Science Approach while obtaining > 30 FDA approvals for indications across almost every FDA division**
- **Management Team involved with billion dollar exits (Questcor - $5.7 B & Gentium - $1.0 B)**

Management Team

David Young, PharmD. PhD
President and Chief Executive Officer
Former CSO & Independent Director, Questcor; U.S. Pres AGI Therapeutics; CEO, GloboMax; Assoc. Prof Univ MD; PharmD, PhD USC

Sian Bigora, PharmD.
Chief Development Officer
Former, VP Regulatory at Questcor, ICON, GloboMax; VP Clinical Research, AGI Therapeutics; Clinical Research Assoc, Univ MD; PharmD Univ. MD

Michael Floyd
Chief Operating Officer
Former President & CEO Elion Oncology
U.S. Project Lead, Gentium; President Arpida
BSBA Georgetown University

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

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

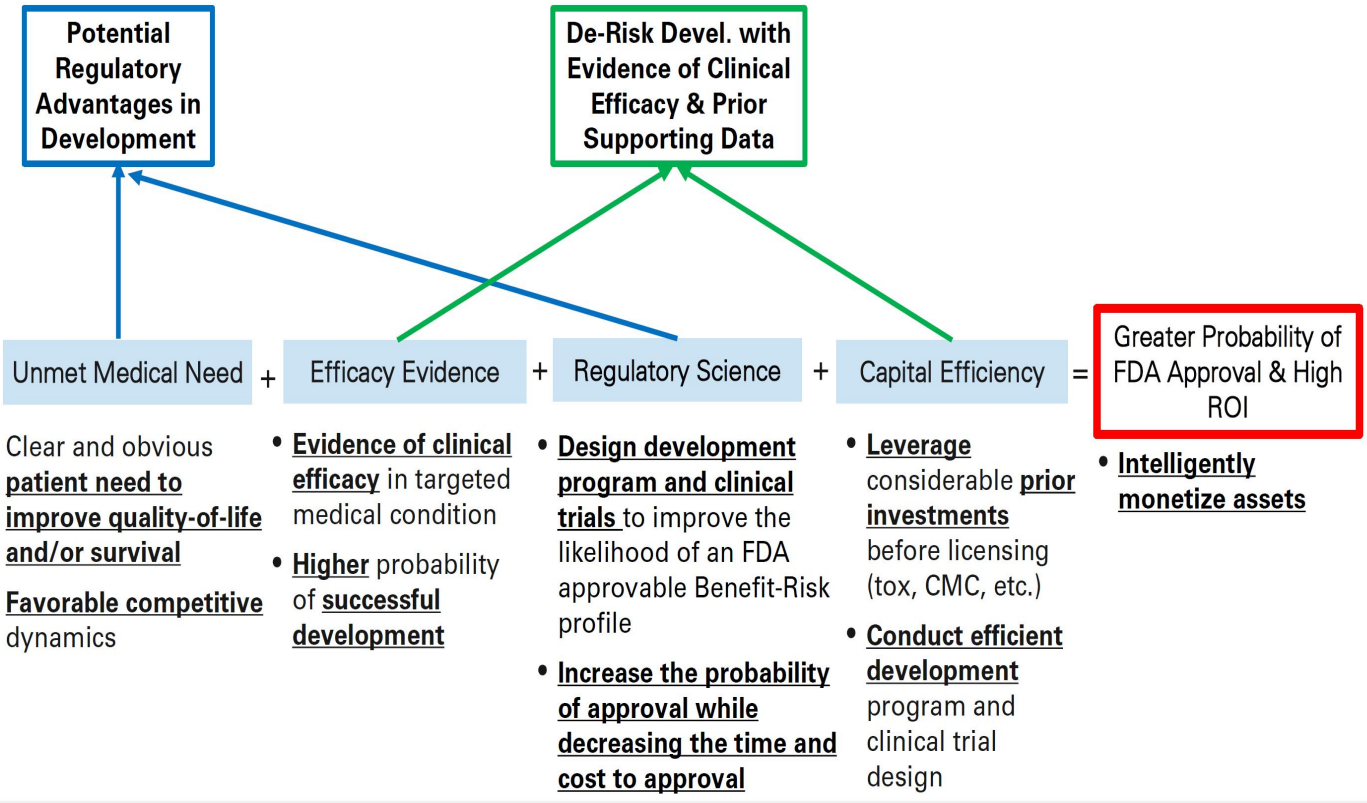
David Young, PharmD. PhD
President and CEO, Processa Pharmaceuticals
Former CSO & Independent Director, Questcor
U.S. Pres AGI Therapeutics; CEO, GloboMax

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

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

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

Pipeline of Assets that Differentiates Processa



Processa Pharmaceuticals, Inc (NASDAQ: PCSA) Differentiated Business Model

- Processa has a **capital-efficient approach** based on very low overhead, disciplined licensing, and intelligent/efficient development, all leading to a potentially high ROI (6 C-suite to received < $600,000 total cash salary in 2022)
- **Management and Board investment > $6 M**
  - **C-Suite exchanged approx. $1.4 M of salary for PCSA shares in 2022**
- Processa has **enough cash to complete the 3 ongoing clinical trials in 3 separate $1B markets** with key value-added milestones occurring in 2022 and 2023
  - **Next Generation Capecitabine (PCS6422+capecitabine) Phase 1B** trial in GI cancer
  - **PCS12852 Phase 2A** trial in gastroparesis
  - **PCS499 Phase 2B trial** in ulcerative necrobiosis lipoidica (PCS499 has an orphan designation for necrobiosis lipoidica)
- Three cancer drugs in the 5-drug pipeline
  - **Next Generation Capecitabine (PCS6422+capecitabine) -** Phase 1B trial in GI cancer
  - **PCS3117 (similar to Gemcitabine) Orphan Designation and IND for pancreatic cancer -** Phase 2B trial design underway with the possibility of biomarkers
  - **PCS11T (next generation irinotecan) – to b**egin CMC, IND enabling tox studies for small cell lung cancer

Pipeline of Five Drugs Each with $1B Market Opportunity

Drug	Disease Target	Market
Next Generation Capecitabine (PCS6422) Phase 1B	Metastatic Colorectal Cancer and Other Types of Cancer	U.S. Incidence of Metastatic Colorectal Cancer : > 60K Pts U.S. Max Ann. Sales mCRC: $500 M – $1.0 B U.S. Max Ann. Sales All Cancers: > $1.0 B
PCS3117 Phase 2B	Pancreatic, Other Cancers	1st Line if Biomarkers Identify 3117 and Gemcitabine Responders and Non-responders, Otherwise 3rd Line Therapy U.S. Max Ann. Sales: $250 M – $1.0 B
PCS11T Pre-IND	SC Lung, Other Cancers	PCS11T Market Targets Patients who Would Normally Receive Irinotecan Given Similar Efficacy and Better Safety U.S. Max Ann. Sales: $500 M – $1.5 B
PCS499 Phase 2B	Ulcerative Necrobiosis Lipoidica (uNL) and other Unmet Med. Need Conditions	U.S. Prevalence of uNL: 10K - 50K Pts U.S. Max Ann. Sales uNL: $500 M - $1.0 B Global Max Sales uNL: > $1.0 B
PCS12852 Phase 2A	Moderate/Severe Gastroparesis and Other GI Motility Conditions	U.S. Prevalence of Mod/Sev Gastroparesis: 2M - 5M Pts U.S. Max Ann. Sales Mod/Sev Gastroparesis: > $1.0 B

Pipeline with High Value 2022-2023 Milestones

Prioritize Oncology Assets While Being Opportunistic with Non-Oncology Assets
Conduct Clinical Trials and Interact with FDA to Expand Licensing/Partnering Opportunities

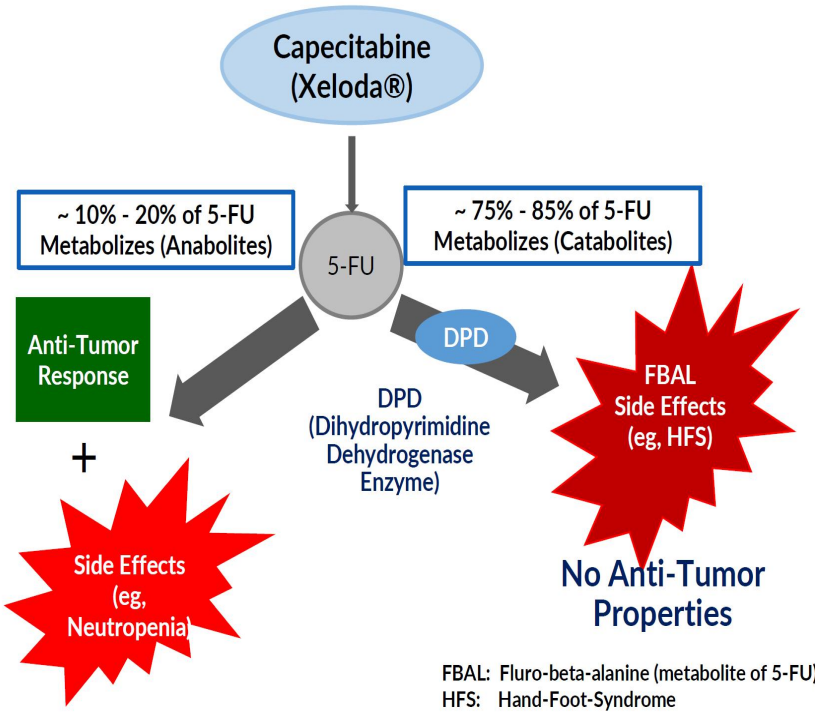
Drug	Disease Target	Non-clin	Phase 1	Phase 2	Phase 3	Status	Milestones
Next Generation Capecitabine Phase 1B (PCS6422)	Metastatic Colorectal, Other Cancers		→			Completing Phase 1B Trial to Determine Design and Regimens for Phase 2B Trial	1H'23 – Complete Phase 1B Trial; Meet with FDA Regarding Next Steps 2H'23 – Initiate Phase 2B Trial 2025 – Ready to Initiate Phase 3 Trial
PCS3117 Phase 2B	Pancreatic, Other Cancers			→		Biomarker Assay Started; Assessing Possible Regulatory Development Paths With and Without Biomarker	1H'23 – Complete Biomarker Assay Evaluation, 2H'23 – Ready to Initiate Phase 2B Trial Depending on Biomarker Assay and Funds
PCS11T Pre-IND	SC Lung, Other Cancers		→			Manufacturing Sites Being Selected; Assessing Possible Regulatory Development Paths	2023 – Select Manufacturing Sites; Initiate Tox Studies 2024 – Submit IND; Ready to Phase 1B Trial
PCS499 Phase 2B	Ulcerative NL, Other Unmet Med. Need Conditions			→		4 Patients Dosed; Patients in Pre-Screening; Preparing IND for Additional Indication	1H'23 – Complete Interim Group Enrollment; Submit New IND in New Indication 2H'23 – Complete Phase 2B Trial; Meet with FDA; Ready to Initiate Phase 2 for New IND
PCS12852 Phase 2A	Gastroparesis			→		Phase 2B Completed; Interact with FDA on Reg. Path	1H'23 – Complete Reg Submission for Fast Track & Phase 2B Trial 2023 – Ready to Initiate Phase 2B Trial

Processa Pharmaceuticals

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

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

5-Fluorourcail Approved by FDA in 1962 & Capecitabine (Oral Form of 5-Fluorouracil) Approved by FDA in 1998

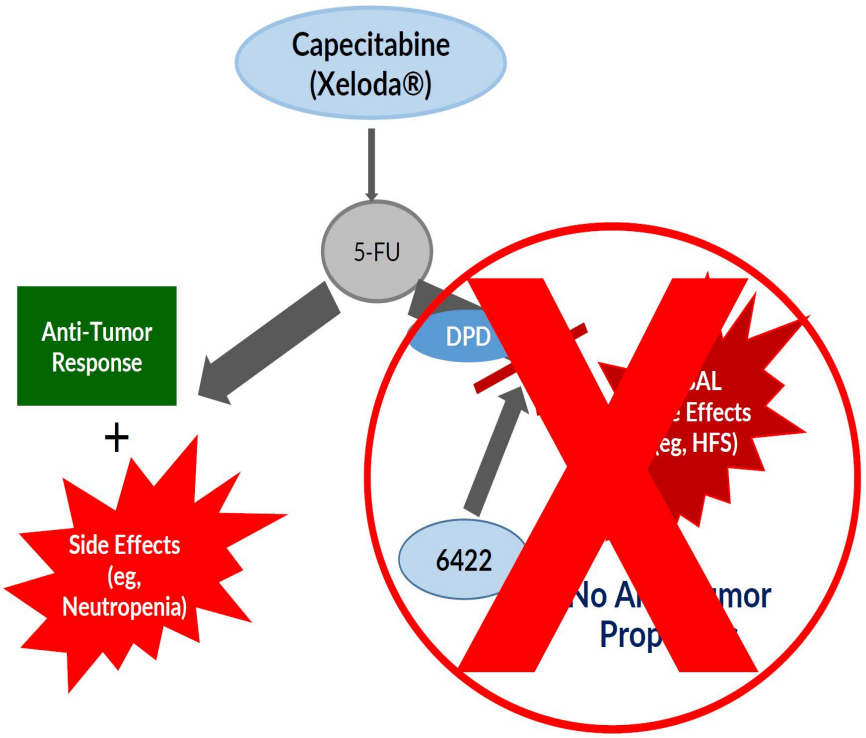


FBAL: Fluro-beta-alanine (metabolite of 5-FU)
HFS: Hand-Foot-Syndrome

- **5-Fluorouracil (5-FU) and capecitabine are the most widely used cancer chemotherapeutic agents** for the treatment of a variety of cancers; mainly used as 1st and 2nd line therapy (approx. 750,000 patients in the U.S. and 2 million worldwide)
- **~30% of patients do not respond at all to capecitabine and ~30% are partial responders**
- **Side effects occur from both types of metabolites -** catabolites (no anti-tumor properties) and anabolites (killing both replicating cancer cells and normal cells)
- **25% to 70% of patients have dose-limiting side effects** (either from catabolites, anabolites, or both) **requiring dose modifications or discontinuation**

Next Generation Capecitabine (NGC): Improved Efficacy & Side Effect Profile

PCS6422 Irreversibly Inhibits DPD (Dihydropyrimidine Dehydrogenase Enzyme)



- **By combining a regimen of PCS6422 with a capecitabine regimen, the 5-FU formed from capecitabine is only metabolized to anabolites** eliminating the adverse events from the catabolites while increasing the potency and potential anti-tumor and replicating cell side effects from the anabolites
- After administration of PCS6422 until new DPD is formed in the patient, 5-FU is only cleared from the body by renal excretion and metabolism to the anabolites within the cells
- **Dosage regimens for NGC** (both the PCS6422 and the capecitabine regimens) **in a Phase 2B trial need to be evaluated to obtain the right balance between efficacy** (anti-tumor response) **and safety** (for example, damage to replicating cells such as neutropenia, mucositis)

Why Does Processa Believe in NGC: Evidence of Clinical Benefit

➢ Safety Differentiation of NGC 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

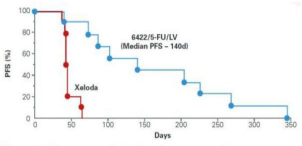
Revollo et al. 2008 Clin Cancer Res; Masuda et al. 2017. NEJM

➢ Efficacy Differentiation of NGC 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 in 9 patients 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



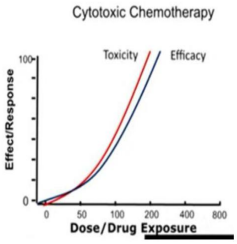
5-FU = 5-Fluoruracil; LV = Leucovorin; PFS = Progression Free Survival, SD = Stable Disease; PR = Partial Response; PD = Progressive Disease

Moving Closer to NDA: Phase 1B Trial to Evaluate Safety

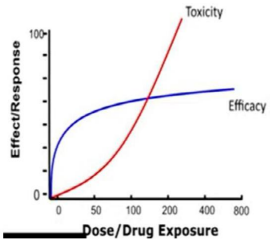
	PCS6422 Regimen A	PCS6422 Regimen B (Exposure > Reg A)	PCS6422 Regimen D (Exposure Similar to Reg A)
Capecitabine Regimen 1	0 DLTs (1 Pt)		
Capecitabine Regimen 2 (Exp > Reg 1)	0 DLTs (3 Pts)	2 DLTs (5 Pts) Discontinued (neutropenia, mucositis)	DLTs TBD (2 Pts Enrolled, no DLTs, Need 1 More Pt)
Capecitabine Regimen 3 (Exp > Reg 2)		Do Not Enroll Given DLTs	DLTs TBD (Add 3-6 Pts ?)

- Next Generation Capecitabine dosage regimens (combinations of PCS6422 regimens and capecitabine regimens) have been and are being evaluated for their effect on DPD enzyme irreversible inhibition, the timeline for the formation of new DPD (24-72 hrs after PCS6422 dose), potency based on 5-FU exposure over time, and their adverse event profile
- Multiple safe NGC regimens have been identified from this trial that will provide different systemic 5-FU exposure profiles and different exposure to FBAL (major 5-FU catabolite associated with AEs) that cause dose-limiting toxicities (DLTs) and regimens/5-FU exposure that will not cause DLTs
- NGC dosage regimens have been identified that can increase the potency of NGC to 50-times greater than reported for FDA-approved capecitabine and extend exposure to 5-FU

FDA Project Optimus



Assumptions with MTD Approach



Assumptions with Project Optimus

Historical Approach To Identify Efficacious and Safe Dosage Regimen

- Approach used for oncology drugs for 30-40 years assumes efficacy and toxicity follow a parallel path
- The dosage regimens evaluated for approval and treatment have been the regimens with the greatest exposure that is still "safe" (or the Maximum Tolerated Dose - MTD); the dosage regimen just less than the regimen that causes Dose Limiting Toxicities (DLTs)

Current Recommendation to Optimize the Benefit-Risk Profile (Efficacy-Safety Profile)

- The Project Optimus Initiative recommended by the FDA Oncology Division suggests that the MTD approach may not find the best benefit-risk (efficacy-safety) regimen
- The relationship between clinical response and dosage regimen or drug exposure needs to be evaluated to determine if there is a regimen with similar efficacy but significantly fewer and/or less severe side effects
- **Project Optimus Initiative is especially important for combination drug therapy such as NGC where the optimal efficacy/safety balance is dependent on two regimens**

Next Generation Capecitabine (NGC) in 2023

Development and Regulatory

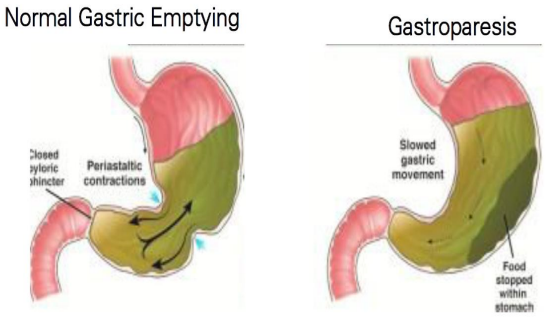
- Potential NGC regimens have been identified for a Phase 2B trial which will provide the regimen/exposure range required for FDA's Project Optimus Oncology Initiative to define a regimen that will provide an FDA-approvable benefit/risk profile
- Discuss the development program and Phase 2B trial design with FDA in 1H2023
- 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 2H2023 depending on priorities, funding, and licensing/partnering opportunities

Processa Pharmaceuticals

PCS12852

GI Motility Conditions (eg, Gastroparesis)

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)

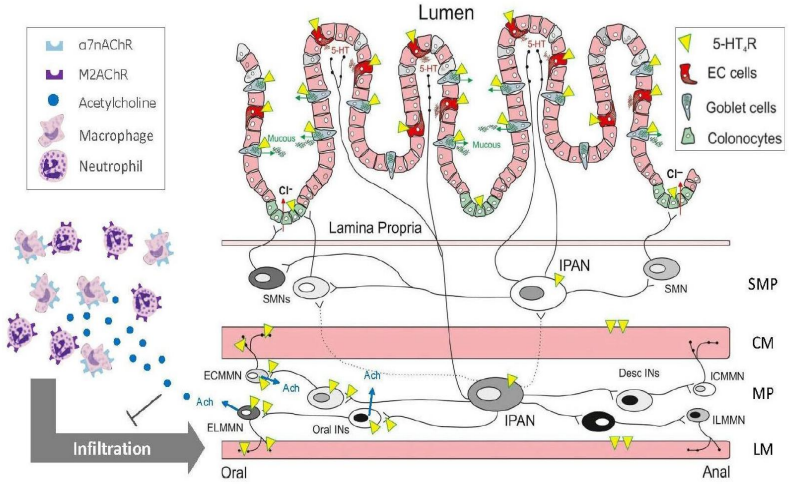
- Existing FDA approved drugs and off-labeled prescribed drugs are mainly used for the treatment of diabetic gastroparesis
- All these drugs have a poor side effect profile limiting their use
- Present market size for gastroparesis is estimated to be over $1.5B

	PCS12852	Other 5HT4 Drug (e.g., Cisapride, Prucalopride, Mosapride)	Dopamine D2 Antagonist (.e.g,, Metoclopramide)
Target Population	• 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 • 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) • 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 • Successful treatment demonstrated	• Only drug FDA approved for treatment of gastroparesis

PCS12852: 5-HT4 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

** Abbreviation*
POGD : postoperative gastrointestinal dysfunction
CIC : chronic idiopathic constipation
IBS-c : irritable bowel syndrome with constipation
OIC : opioid-induced constipation
Ach : acetylcholine
α7nAChR : alpha-7-nicotinic acetylcholine receptor
M2AChR : muscarinic acetylcholine receptor M2
5-HT4R : 5-hydroxytryptamine 4 receptor
EC cell : enterochromaffin cell
CM: circular muscle layer
CMMN: circular muscle motor neuron
E : excitatory
I : inhibitory
IN : interneuron
IPAN : intrinsic primary afferent neuron
LM : longitudinal muscle layer
LMMN : longitudinal muscle motor neuron
MP : myenteric plexus
SMN : secretomotor neuron
SMP : submucosal plexus

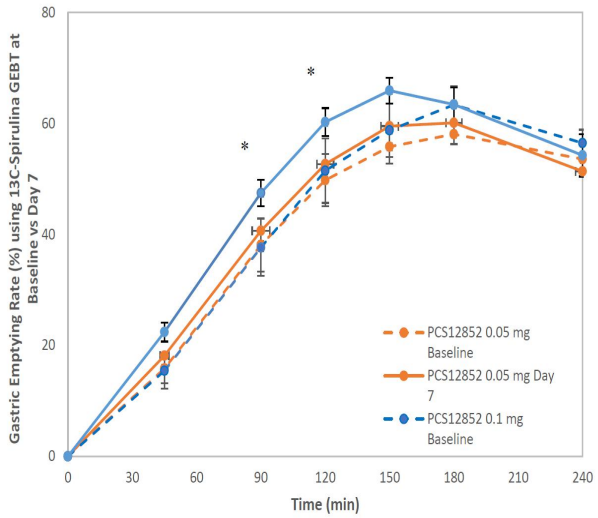
PCS12852 Increase Gastric Emptying

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

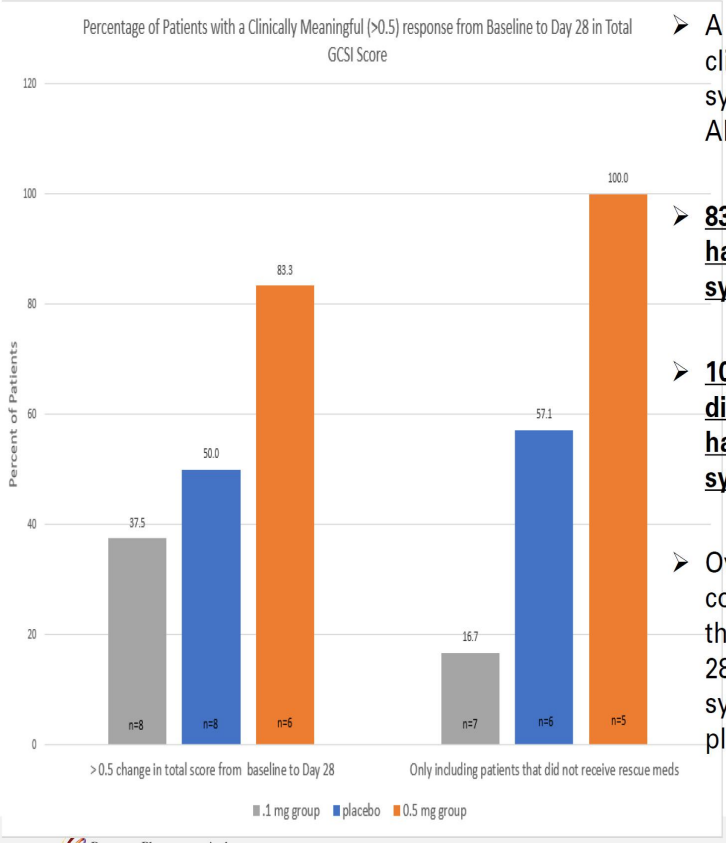
Healthy Volunteers (< 3 Bowel Movements per Wk) or Functional Constipation Patients



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 in 2023

Development and Regulatory

- 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

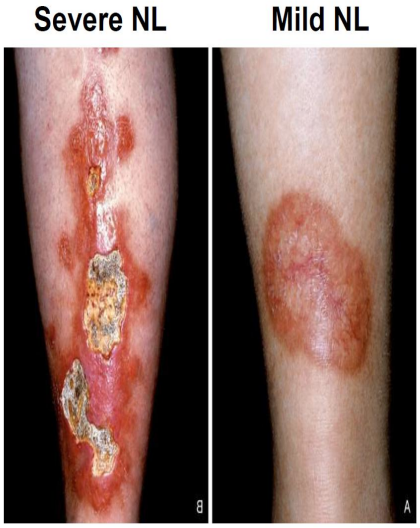
Processa Pharmaceuticals

PCS499

Ulcerative Necrobiosis Lipoidica (uNL) and Other Indications

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

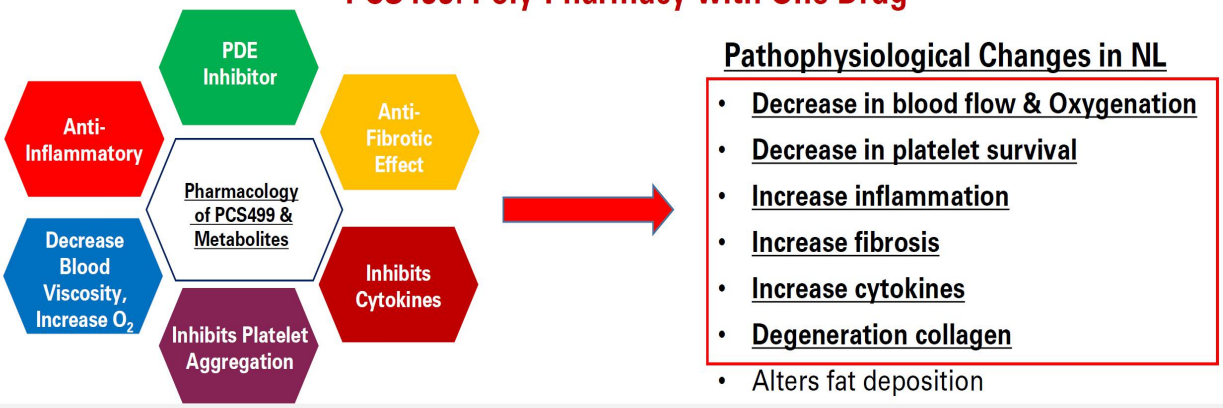
- Skin, tissue below the skin becomes necrotic forming open ulcers; can last from months to years with complications such as infections, amputation, and cancer
- Literature reports a **prevalence of approximately 22,000 – 55,000** uNL patients in the U.S. will have painful ulcers occurring naturally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



Unmet Medical Need, Evidence of Clinical Efficacy

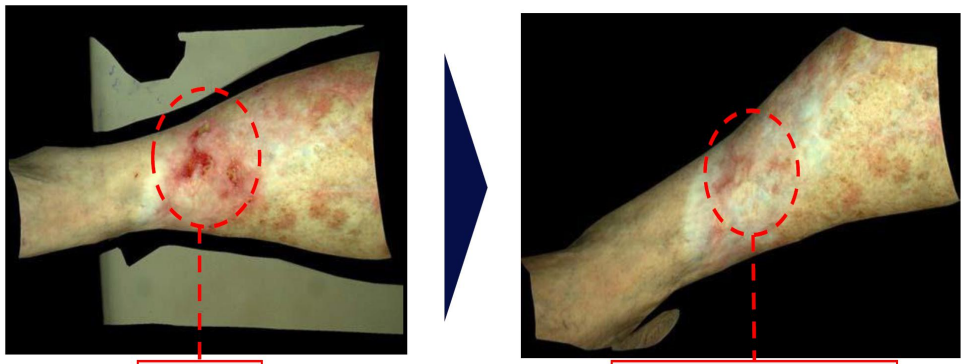
- **No FDA approved treatment** for uNL or NL, no standard of care, all treatments are inadequate
- **Drugs have been used off-label with mixed success (e.g., pentoxifylline (PTX)); provide poor safety profile** given their limited efficacy
- **PCS499 is the deuterated analog of a major metabolite of 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 in 2023

Development and Regulatory

- 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 a second indication for PCS499, an 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 new indication in 2H2023 depending on priorities, funding, and licensing/partnering opportunities

Financial Highlights and Capital Structure

- Our cash on hand on September 30, 2022 of $9.1 million provides a cash runway into the third quarter of 2023.
- Overhead Only Cash Burn, including development team salaries, is expected to be less than $4.5 million in 2022.
- Shares Outstanding on September 30 , 2022 was 15,895,087, and our fully diluted shares(1) totaled 19,225,006.
- 24% of our outstanding common stock (32% of our fully diluted common stock) is held by officers and directors
- We currently have 15 employees
- Research Analyst Reports:

  Francois Brisebois, Oppenheimer; Robert Wasserman, Benchmark;

  Naz Rahman, Maxim; Hogan Mullaly, Encode Ideas
- Dilutive securities consist of the following:

	Dilutive Securities	Weighted-Average Exercise Price	Weighted-Average Remaining Life
Stock options	178,496	17.07	2.8 years
Warrants	285,618	10.25	1.1 years
Restricted stock awards	129,012	-	-
Restricted stock units	2,736,793	-	-
Total	3,329,919	-	-

Processa Pharmaceuticals

BACKUP SLIDES

Overview of Intellectual Property and Other Oncology Drugs to Treat Metastatic Pancreatic, Biliary, Small Cell Lung, and Other Cancers

Intellectual Property Overview

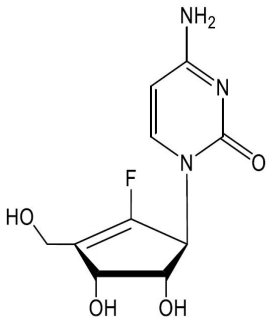
Program	Description of IP	Status
PCS499	Substituted xanthine derivatives and deuterium substituted	• 2 Composition of Matter Issued • Methods of treating hyperglycemia
PCS6422	Preventing neurotoxicity and combination with 5FU and 5-FU prodrugs Treatment approaches and use	• 2 Method patents Issued • Additional provisional patent filings are being prepared
PCS6422	Dosing regimens, treatment approaches, & use	• Provisional Filed
PCS12852	Composition, methods, manufacturing & use	• 3 Patent families Issued • Additional provisional patent filings are being prepared
PCS3117	Method and manufacturing	• 2 Issued patents
PCS11T	Composition of matter	• 2 Issued patents

- The different patents for the portfolio of drugs expire between approximately 2030 - 2036
- Additional IP information available under a Confidentiality Agreement

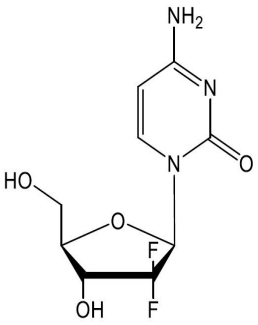
Processa Pharmaceuticals

PCS3117
Metastatic Pancreatic Cancer, Biliary Cancer, Other Cancers

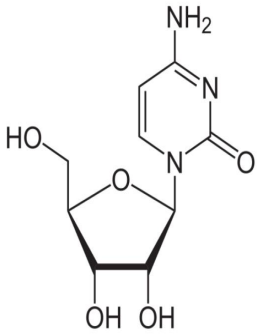
1H'22 - PCS3117 Biomarker Assay Development Completed



RX-3117
Oral Administration
(Cytosine + Ribose Analog)



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

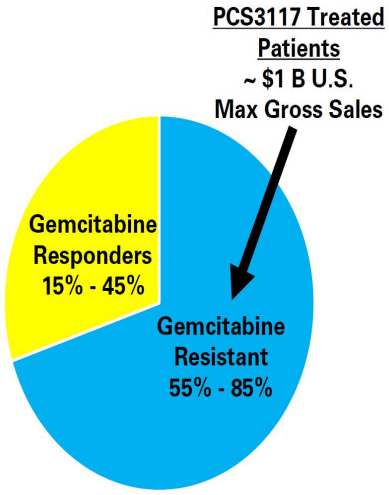


Cytidine
(Cytosine + Ribose Ring)

- 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

2023 Milestones – PCS3117

Development and Regulatory

- Complete the evaluation of potential biomarkers in pancreatic cancer patients to determine if biomarkers can identify potential responders to 3117 as 1st line therapy prior to treatment using a Precision Medicine approach
- Although 3117 already has FDA Orphan Designation for the treatment of pancreatic cancer, drug development "roadmaps" are also being defined for
  - 1st line therapy for recurrent pancreatic cancer after surgery with Adjuvant Chemotherapy of FOLFIRINOX (folinic acid, fluorouracil, irinotecan, and oxaliplatin) without biomarkers,
  - 1st or 2nd line therapy in the treatment of biliary tract cancer with or without biomarkers, and
  - 2nd or 3rd line therapy in metastatic pancreatic cancer without biomarkers
- Complete evaluation of other regulatory paths to expedite the development of 3117 in pancreatic cancer
- Initiate Phase 2B trial in 2H2023 depending on priorities, funding, and licensing/partnering opportunities

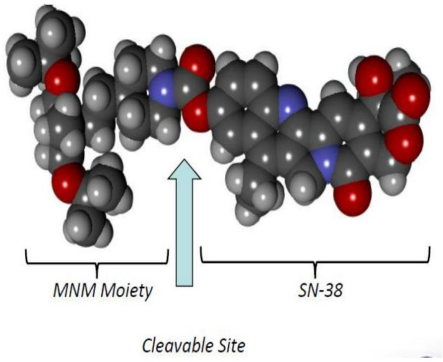
Processa Pharmaceuticals

PCS11T

Small Cell Lung, Pancreatic, Colorectal, Other Cancers

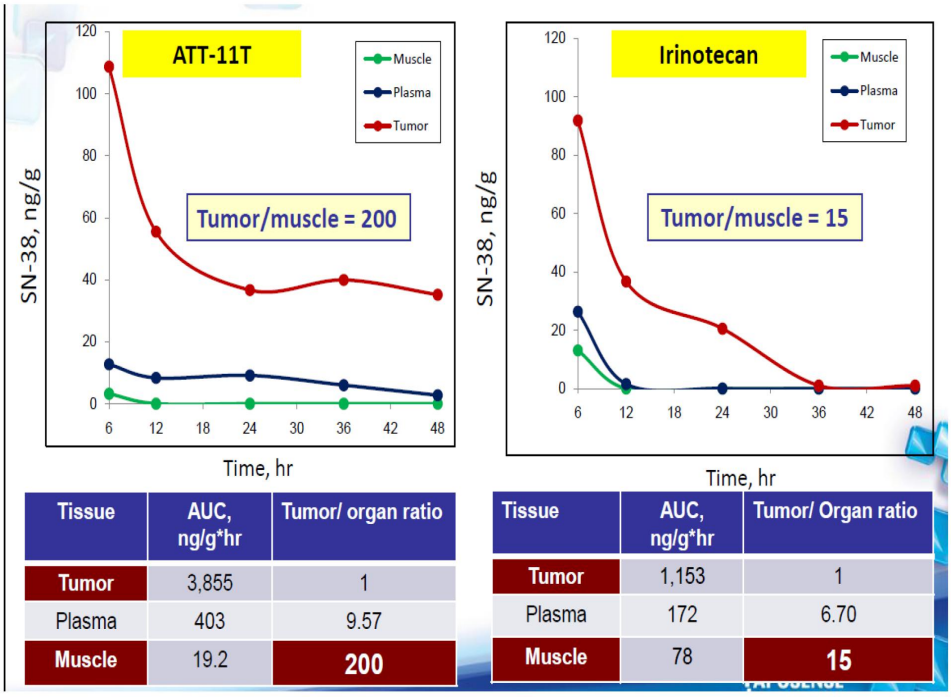
PCS11T: Lipophilic Prodrug of SN-38 (Irinotecan Active Metabolite)

- 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

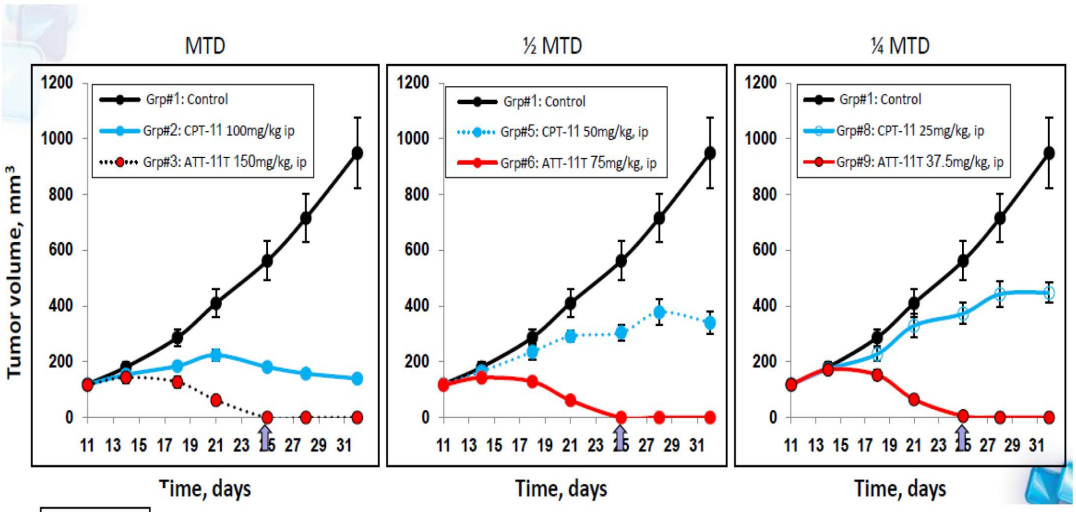
Tumor-bearing mice had 200x higher drug in tumor vs muscle compared to 15x with Irinotecan



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

PCS11T in 2023

Development and Regulatory

- 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