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): September 20, 2021

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

Delaware	001-39531	45-1539785
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)
	7380 Coca Cola Drive, Suite 106, Hanover, Maryland (Address of Principal Executive Offices)	21076 (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 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.	Description
99.1	Processa Pharmaceuticals General Update Presentation dated September 20, 2021

104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

PROCESSA PHARMACEUTICALS, INC.

Date: September 20, 2021

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

Processa Pharmaceuticals

Corporate Overview
September 2021

Disclaimer: Forward Looking Statements

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

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

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

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

Processa Highlights

- **Development Company Focused on Improving QOL or Survival of patients**
  - Agnostic to the indication as long as the drug treats patients with an unmet medical need condition
  - Present programs represent 5 different U.S. markets with potential sales of $500 M to $1.5 B for each drug
  - Each drug has the potential to expand into additional markets
- **Management and Development Team with Track Record of Success**
  - Development Team has 30 FDA approvals over the last 30 years and met with the FDA over 100 times
  - Questcor Pharmaceuticals acquired for $5.7B, Gentium acquired for $1B
- **Regulatory Science Approach (RSA) Improves Probability of Success for Investors & Patients**
  - RSA based on 2 regulatory science collaboration contracts with the FDA in the early 1990s
  - RSA streamlines development process while improving the Benefit-Risk profile for FDA assessment
  - 4 Phase 3 trials to be initiated 2023-2025 and 4 NDA submissions 2025-2028 (2-3 of these NDAs submitted over next 6 years)
- **Capital Efficient with a Tightly Controlled Burn Rate (Overhead < $4M per year with 15 Employees)**
  - ~ $21 M cash, sufficient to obtain key results for 3 clinical trials (499, 6422, 12852) and operate into late 2023
  - 15.6 M outstanding share (~ 30% insiders)
- **High Value Milestones Completed in the Next 2-15 Months**
  - 6422 interim analysis & MTD identified in Phase 1B GI Cancer trial
  - 499 interim analysis & final analysis for the Phase 2B ulcerative necrobiosis lipoidica (uNL) trial
  - 3117 pancreatic cancer biomarker assay developed & Phase 2B trial initiated
  - 12852 completion of Phase 2A gastroparesis trial
- **Potential Monetization of Drugs (U.S. & Non-U.S. Companies Contacting us about Acquiring our Drugs)**

Processa Capital Structure and Financial Highlights

- **PCSA price** on September 16, 2021 was $7.84
- **Market Cap** on September 16, 2021 was approximately $122 million
- **Cash on hand** on June 30,2021 was $20.8 million which provides a cash runway into late 2023.
- **Overhead Cash Burn**, including salaries in 2021 is expected to be less than $4,000,000
- **Shares Outstanding** on June 30, 2021 was 15,604,605 with our fully diluted shares totaled 16,216,828
- **Number of Employees** is currently at 15
- **Research Analyst Reports**:

  Robin Garner at Craig Hallum
  Aydin Huseynov MD, CFA at Benchmark
  Hogan Mullaly at Encode Ideas
  Francois Brisebois at Oppenheimer

Processa's Risk Abated Approach and Criteria for Drug Selection

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

DEVELOP NOT **DISCOVER** REGULATORY SCIENCE PLATFORM

Unmet Medical Need +	Efficacy Evidence +	Regulatory Science +	Capital Efficiency +	Potentially High ROI
• Clear and obvious **patient need** • **Favorable competitive** dynamics	• **Evidence of clinical efficacy** in targeted medical condition • **Higher** probability of **successful development**	• **Improve Benefit/Risk** profile that FDA evaluates for approval • **Optimize trial design** and **anticipate** what **FDA** requires for approval (Trifecta: decreasing risk, time to approval & cost)	• **Leverage** considerable **prior investments** before licensing (tox, CMC, etc.) • **Efficient development** program and clinical trial design	• **Intelligently monetize and partner assets**

Processa Pipeline – Five Drugs Each with $1B Market Opportunity

Multiple High Value Milestones 2021-2022, 4 Phase 3 Trials Initiated 2023-2025, 4 NDAs 2025 - 2028

Drug	Disease Target	Preclin	Phase 1	Phase 2	Phase 3	Status	2021-2022 Milestones	2023 – 2028 Milestones
PCS499 Phase 2B	Ulcerative Necrobiosis Lipoidica			→ *		3 Patients Dosed; 4 Patients in Screening or Scheduled	8-10 Patients for Interim Analysis Enrolled 4Q'21 & Completed 1H'22; Final Analysis 2H'22	FPI Phase 3 2023; NDA 2025-2026
PCS12852 Phase 2A	Gastroparesis, Constipation Disorders			→		IND Submitted Sept. 2021	FPI Phase 2A 1H'22; Final Analysis 2H'22 - 1H'23	FPI Phase 3 2025-2026, NDA 2027-2028
PCS3117 Phase 2B	Pancreatic, Non-Small Cell Lung Cancer			→ *		Biomarker Assay Lab Being Selected and Protocols Being Prepared	Complete Biomarker Assays 1H'22; FPI Phase 2B 2H'22	FPI Phase 3 2023 – 2024; NDA 2026-2027
PCS6422 Phase 1B	Metastatic Colorectal, Breast Cancer		→ *			Cohort 1: no DLTs; Cohort 2: 1 Patient Dosed, 2 Patients in Screening or Scheduled	Interim Cohort Analysis 4Q'21; MTD Determined 2H'22;	FPI Phase 2B/3 2024 – 2025; NDA 2027 - 2028
PCS11T Pre-IND	Small Cell Lung, CRC Cancer	→				CMOs Being Evaluated	Initiate IND Enabling Studies;	Phase 1B IND Submission 1H'23

* Cleared by FDA for Clinical Trial

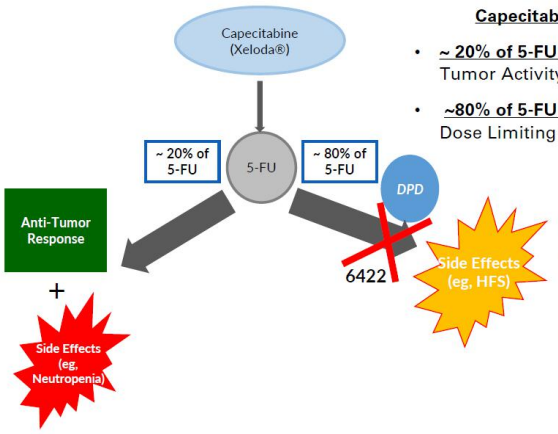
Blue - Use of Existing Cash

FPI – First Patient In (i.e., randomized)
MTD – Maximum Tolerated Dose

Pipeline Review Based on Timeline of 2021 – 2022 Milestones

4Q'21 - PCS6422 Interim Analysis with MTD Determined in 2H'22

PCS6422 Chemotherapy Modifier of Capecitabine (Xeloda®) Irreversibly Inhibiting DPD Enzyme



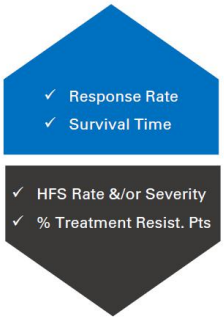
Capecitabine Converts to 5-FU in the body

- **~ 20% of 5-FU** Metabolizes to Molecules with Anti-Tumor Activity and side effects such as neutropenia
- **~80% of 5-FU** Metabolizes to Molecules that Cause Dose Limiting Side Effects with no efficacy

6422 Inhibits DPD (Dihydropyrimidine Dehydrogenase)

- **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

PCS6422 + Capecitabine Combination Different than Capecitabine



➢ **Economic Value: Initial Markets**

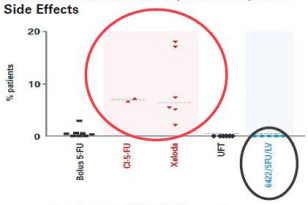
- 6422 + Capecitabine combination potential 1st line therapy for a number of cancers (e.g., metastatic colorectal and breast cancer)
- Colorectal cancer; > 145,000 new patients/yr U.S., > 1.8 M total colorectal cancer patients worldwide
- Breast cancer; > 275,000 new patients/yr U.S., > 2.0 M total patients with breast cancer worldwide
- > 45% of the new patients with colorectal cancer presently receive capecitabine
- Potential for 6422+capecitabine combination to **replace capecitabine in treatment of colorectal cancer and other cancers**
- **U.S. market potential in colorectal cancer is $700 M - $1.5 B**

Unmet Medical Need and Evidence of Clinical Benefit

➢ **Safety Differentiation of 6422+Capecitabine vs Existing Cancer Chemotherapy**

- 50-70% of capecitabine patients have adverse events from FBAL resulting in decreasing capecitabine dose or stopping chemotherapy
- Clinical trial of the 6422 + capecitabine combination provides preliminary evidence that the combination will **decrease FBAL related adverse events**

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



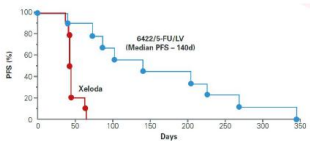
Revollo et al. 2008 Clin Cancer Res;
Masuda et al. 2017. NEJM

Unmet Medical Need, Evidence of Clinical Benefit, Regulatory Science Platform

- **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**
- **Regulatory Science**
  - **Treatment of metastatic colorectal cancer**
  - **Measuring biomarker(s)** may help to increase probability of successful treatment
  - 6422+capecitabine combination **provides patients with a better benefit-risk profile (less adverse events and/or better efficacy) than just capecitabine**

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

Adherex files & Rivera E et al, 2014. Clin. Breast Cancer

PCS6422 Chemotherapy Modifier of Capecitabine (Xeloda®)

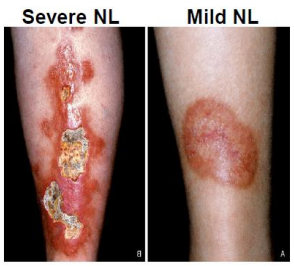
- **Present Phase 1B Trial to Determine Appropriate Dosing of 6422 and Capecitabine**
  - **General Design**: MTD Stage 1 will be a 3+3 cohort capecitabine trial after a single safe dose of 6422; 1 dose 6422, 7d of capecitabine, 7d of no capecitabine; up to 6 cohorts of capecitabine b.i.d. at 75mg/d to 600 mg/d followed; followed by Stage 2 dose confirmation of the MTD
  - **Objective:** To determine safe maximum tolerated dose of capecitabine after single safe dose of 6422
  - **Inclusion Criteria Examples:** Advanced, metastatic or unresectable refractory GI cancer; not received treatment with 5-FU or capecitabine in 4 weeks; life expectancy > 12 wks
  - **Exclusion Criteria Examples:** Has current brain metastasis, has clinically significant cardiac condition; self-reported to be DPD enzyme deficient
  - **Key Additional Information**: *Evaluation of potential biomarkers*

- MTD Stage 1: **Cohort 1 - Completed with No DLTs; Cohort 2 - 1 Patient Dosed, 2 in Screening or Scheduled; Interim Analysis 4Q'21; MTD Determined 2H'22**
- Dose Confirmation Stage 2: 1st Patient Expected 2H'22, Final Analysis 2023/2024

FDA SPA Phase 3 Trial Initiated
2024–2025
NDA Submission
2027 - 2028

4Q'21 - PCS499 Complete Patients Enrolled for 1H'22 Interim Analysis

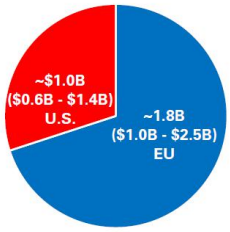
- First to market for the treatment of Ulcerative Necrobiosis Lipoidica (uNL)
- Skin, tissue below the skin becomes necrotic, can last from months to years with complications such as infections, amputation, and cancer
- 70% of the patients are women between 20 – 60 years old; 60% of NL patients are diabetic but NL is not dependent on glucose control and is **not the same histologically as diabetic ulcers**
- Patients seen by primary care, endocrinologist, dermatologist
  - NL diagnosis requires histopathology biopsy to differentiate from other wounds
- **30% of NL patients have painful ulcers occurring naturally or from contact trauma to the lesion**
- **Natural complete healing of moderate to severe ulcers** during the first 1-2 years after onset occurs **in less than 5% of these patients**



Ulcerative NL (uNL) Target Population

- **Economic Value: Initial Markets**
  - 75,000 – 185,000 NL patients in U.S.
  - **22,000 – 55,000 uNL patients in U.S.**
  - Presently no approved treatment and off-labeled drugs have mixed efficacy/safety results in patients with NL or uNL
  - **499 has orphan designation for NL (7-year market exclusivity)** and patent exclusivity until 2030
  - 499 would be the first approved drug to treat patients with uNL or NL
  - **U.S. market potential in uNL is ~ $1 B annual gross sales**

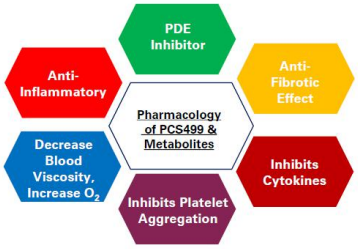
Ulcerative Necrobiosis Lipoidica (uNL)
Max Gross Sales



- **22,000 – 55,000 uNL Patients in US**
- **150,000 – 400,000 uNL Patients Worldwide**

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)**) - side effect profile, limited efficacy
- **PCS499 is the deuterated analog of a major metabolite of PTX**; has identical metabolites and pharmacological targets but **PK of 499 + metabolites is different than PTX + metabolites resulting in a better 499 safety profile and allowing the administration of a higher, more efficacious dose of 499**
- 499 + metabolites target pharmacology that directly affect 6 of the 7 NL pathophysiological changes

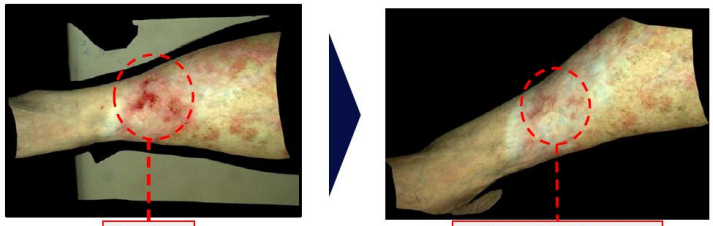


Pathophysiological Changes in NL

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

Phase 2A PCS499 Improves Benefit-Risk Profile

- **1.8 gm/d of 499 has better safety profile than 1.2 gm of PTX** in animal tox studies and Phase 1 healthy human volunteer studies
- In the Phase 2A study of 10 NL and 2 ulcerative NL patients, a**ll ulcers closed** in the 2 ulcerative NL patients, **including new contact trauma ulcers and 1.8 gm/d was well tolerated in all patients**
- Non-ulcerated patients reported improvement in NL but clinical significance could not be determined



Baseline | Complete Closure

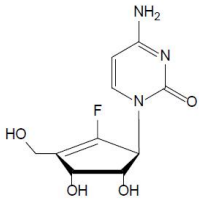
PCS499 FDA Designated Orphan Drug - Ulcerative Necrobiosis Lipoidica (uNL)

- **Phase 2B to Better Define Variables for Phase 3:**
  - **General Design:** Randomized, double-blind, placebo-controlled trial of 1.8 gm/d of 499 in 20 uNL patients with primary efficacy evaluation at 6 months
  - **Objective:** To determine complete closure response rate of ulcers in patients on placebo vs 499
  - **Inclusion Criteria Examples:** Biopsy-confirmed diagnosis of ulcerated NL; at least one (1) ulcer with a minimum surface area of 1 cm^2, total ulcer area of a minimum of 2 cm^2, and no more than 6 ulcers
  - **Exclusion Criteria Examples:** In the last 6 weeks took other drugs such as oral corticosteroids, topical drugs, systemic pentoxifylline, theophylline, immunosuppressant or immunomodulatory drugs

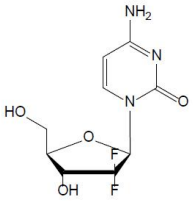
- 3 Patients Enrolled; 4 Patients in Screening or Scheduled
- **8-10 Patients for Interim Analysis Enrolled 4Q'21 & Completed 1H'22**
- Final Analysis 2H'22

FDA SPA Phase 3 Trial Initiated
2023
NDA Submission
2025-2026

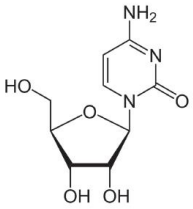
1H'22 - PCS3117 Biomarker Assay Development Completed



RX-3117
Oral Administration
(Cytosine + Ribose Analog)



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



Cytidine
(Cytosine + Ribose Ring)

➢ **Gemcitabine Market**

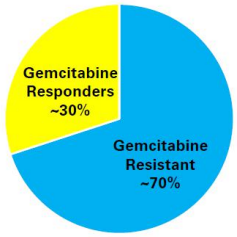
- First-line treatment for locally advanced or metastatic pancreatic cancer; inoperable, locally advanced or metastatic non-small cell lung
- Second-line and third-line treatment for ovarian cancer and other types of cancer
- Gross Sales: $815 M U.S., $1.7 B worldwide

PCS3117 Treatment Resistant Gemcitabine Patients

➢ **55% - 85% of patients are inherently resistant to gemcitabine or acquire resistance**

- Gemcitabine overall response or disease control rate is 15% to 45% depending on type of cancer and trial
- Inherent or acquired resistance caused by
  - ✓ **Increase in CDA activity**
  - ✓ Deficiency in hENT1 - decreases gemcitabine transport through the cell membrane
  - ✓ **Down-regulation of rate-limiting dCK enzyme** – decreases formation of cancer killing nucleotides
  - ✓ **Up-regulation of RRM1/RRM2** - increases formation of endogenous cytidine nucleotide
  - ✓ Nongenetic influences on gene expression - genetic and epigenetic abnormalities

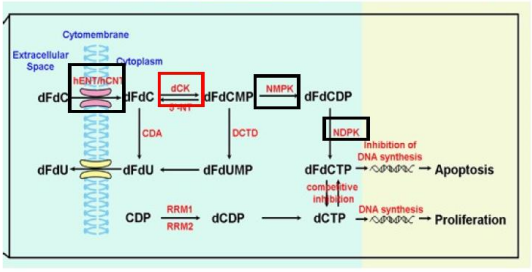
Gemcitabine Treated Patients
$815 M U.S. - $1.7 B Worldwide Max Gross Sales



Differences Between Gemcitabine vs PCS3117

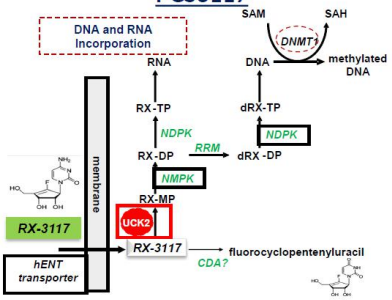
Activation to Cancer Killing Metabolites and Mechanism of Cancer Cell Death

Gemcitabine



- hENT1 - human equilibrative nucleoside transporter-1
- dCK - deoxycytidine kinase
- NMPK - nucleotide monophosphate kinase
- NDPK - nucleotide diphosphate kinase
- RRM – ribonucleotide reductase
- CDA - cytidine deaminase

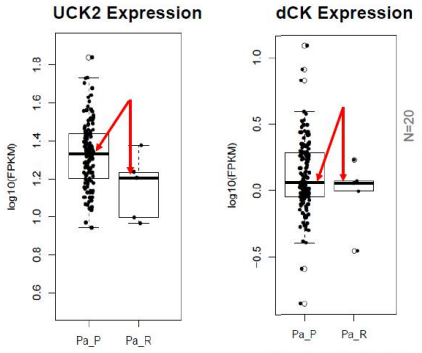
PCS3117



- hENT1 - human equilibrative nucleoside transporter-1
- UCK2 -uridine-cytidine kinase
- NMPK - nucleotide monophosphate kinase
- NDPK - nucleotide diphosphate kinase
- RRM - ribonucleotide reductase
- CDA - cytidine deaminase

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

- **Treat patients more likely to respond to 3117 than gemcitabine** which will include inherent resistant and acquired resistant gemcitabine patients **who use gemcitabine as 1st line therapy or 2nd line therapy**
- **Biomarker assays are being developed and evaluated** to potentially define a targeted, personalized medicine approach to identifying patients who will respond to 3117 better than gemcitabine
- **Patients more likely to respond to or activate 3117 than gemcitabine**
  - Patients with high UCK2 levels
  - Patients who catabolize (breakdown) 3117 less than gemcitabine
  - Patients who have inherent or acquired resistance to gemcitabine but not 3117
- **3117 has FDA Orphan Designation for pancreatic cancer and patents to 2036**



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

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 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 were reported with an 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**

PCS3117 3-15 Month Development Plan in Pancreatic Cancer

- **Refine and evaluate biomarker assays for 3117 over the next 6-9 months:**
  - A number of assays presently exist that could potentially be used
  - Assays need to be evaluated and refined for more routine use as required in a Phase 3 pivotal trial as well as for potential routine clinical use
- **Prepare Phase 2B protocol for FDA submission over the next 6 – 12 months:**
  - Meet with KOLs and CROs
  - Meet with FDA

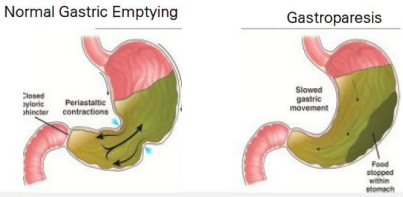
- **Pancreatic Cancer Biomarker Assays Developed to Enrich Population Treated with 3117**
- **Phase 2B Trial Initiated 2H'22**

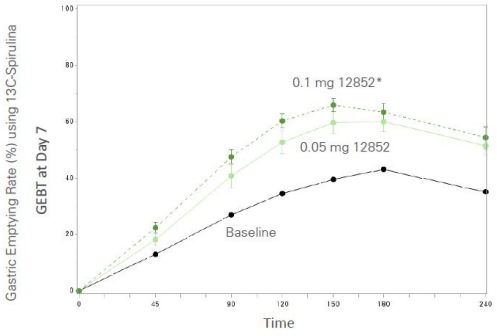
FDA SPA Phase 3 Trial Initiated
2023 - 2024
NDA Submission
2026-2027

2H'22 - PCS12852 Trial Conduct Completed

PCS12852 Potent-Selective 5HT4 Agonist for Treatment of Gastroparesis

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





PCS12852 Potent-Selective 5HT4 Agonist for Treatment of Gastroparesis

- **Differentiation of 12852 from Existing therapy**
  - Present use of approved drugs and off-labelled drugs in gastroparesis is limited by side effects of these drugs
  - All FDA approved drug products for gastroparesis have active ingredient of metoclopramide
  - 12852 - Highly specific, potent 5HT4 agonist (more specific, potent than other 5HT4 drugs developed or in development)
  - 12852 pre-clinical pharmacology and toxicology studies show less side effects than metoclopramide, approved 5HT4 agonists, and 5HT4 agonists in development

	12852	Other 5HT4 Drug (e.g., Cisapride, Prucalopride, Mosapride)	Dopamine D2 Antagonist (.e.g,, Metoclopramide)
Binding	• Very specific 5HT4 receptor binding • Drug very potent to 5HT4	• 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
Efficacy	• Increase gastric emptying rate • Gastroparesis patient study required	• Increase gastric emptying rate • Successful treatment demonstrated	• Only drug FDA approved for treatment of gastroparesis

PCS12852 Potent-Selective 5HT4 Agonist for Treatment of Gastroparesis

- **Economic Value: Initial Markets**
  - Prevalence of moderate to severe gastroparesis in U.S. reported to be over 200,000 to > 1,500,000 patients depending on formal diagnosis vs symptom presentation
  - Present use of approved drugs and off-labelled drugs in gastroparesis is limited by side effects
  - U.S. market potential is $500 M to > $1.5 B

- **Next Clinical Trial**
  - IND submitted in September 2021 for Phase 2A Placebo-controlled, Randomized Dose Response Study of the Safety and Efficacy of PCS12852 on Gastric Emptying Rate Assessed by 13C Spirulina GEBT in Patients with Moderate to Severe Gastroparesis
  - Phase 2A planned to begin enrolling patients 1H'22
  - Final analysis 4Q'22 - 1Q'23

- **NDA Submission 2027-2028**

Processa Highlights

- **Development Company Focused on Improving QOL or Survival of patients**
  - Agnostic to the indication as long as the drug treats patients with an unmet medical need condition
  - Present programs represent 5 different U.S. markets with potential sales of $500 M to $1.5 B for each drug
  - Each drug has the potential to expand into additional markets
- **Management and Development Team with Track Record of Success**
  - Development Team has 30 FDA approvals over the last 30 years and met with the FDA over 100 times
  - Questcor Pharmaceuticals acquired for $5.7B, Gentium acquired for $1B
- **Regulatory Science Approach (RSA) Improves Probability of Success for Investors & Patients**
  - RSA based on 2 regulatory science collaboration contracts with the FDA in the early 1990s
  - RSA streamlines development process while improving the Benefit-Risk profile for FDA assessment
  - 4 Phase 3 trials to be initiated 2023-2025 and 4 NDA submissions 2025-2028 (2-3 of these NDAs submitted over next 6 years)
- **Capital Efficient with a Tightly Controlled Burn Rate (Overhead < $4M per year with 15 Employees)**
  - ~ $21 M cash, sufficient to obtain key results for 3 clinical trials (499, 6422, 12852) and operate into late 2023
  - 15.6 M outstanding share (~ 30% insiders)
- **High Value Milestones Completed in the Next 2-15 Months**
  - 6422 interim analysis & MTD identified in Phase 1B GI Cancer trial
  - 499 interim analysis & final analysis for the Phase 2B ulcerative necrobiosis lipoidica (uNL) trial
  - 3117 pancreatic cancer biomarker assay developed & Phase 2B trial initiated
  - 12852 completion of Phase 2A gastroparesis trial
- **Potential Monetization of Drugs (U.S. & Non-U.S. Companies Contacting us about Acquiring our Drugs)**

Summary of Key Clinical Data Obtained over the Next 2-15 Month

Multiple High Value Milestones 2021-2022, 4 Phase 3 Trials Initiated 2023-2025, 4 NDAs 2025 - 2028

	2H 2021	1H 2022	2H 2022	2023-2029
PCS6422 Phase 1B	• **Interim Analysis 4Q'21**		• **Determine and Confirm MTD**	• Final Analysis Stage 2 • **FPI Phase 2B/3 (2024-2025)** • **NDA (2027–2028)**
PCS499 Phase 2B	• Continue Patient Recruitment	• **8-10 Patients Complete Trial for Interim Analysis**	• **Final Analysis**	• **FPI Phase 3 (2023)** • **NDA 2025-2026**
PCS3117 Phase 2B	• Initiate Biomarker Assay Development	• **Complete Biomarker Assay Development**	• Initiate Sites • FPI	• **FPI Phase 3 (2023-2024)** • **NDA (2026-2027)**
PCS12852 Phase 2A	• IND Submission • Select CRO; Initiate Sites	• FPI	• **Final Analysis**	• Phase 2B Trial • **FPI Phase 3 (2025-2026)** • **NDA (2027-2028)**
PCS11T IND	• Evaluate CMOs	• Initiate Tox		• Complete Tox • IND Submission

FPI – First Patient In
CMO – Contract Manufacturing Organization

Our People Lead to Success

Management Team

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

Sian Bigora, PharmD.
Chief Development Officer

Michael Floyd
Chief Operating Officer

Patrick Lin
Chief Business – Strategy Officer

James Stanker, CPA
Chief Financial Officer

Wendy Guy
Chief Administrative Officer

Board of Directors

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

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

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

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

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