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): July 15, 2021

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, $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.	**Exhibit Description**
99.1	Processa Pharmaceuticals Investor Presentation dated July 2021

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 July 15, 2021.

PROCESSA PHARMACEUTICALS, INC.
Registrant

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

Processa Pharmaceuticals

Access to Giving
July 15, 2021

David Young, PharmD, PhD
Chairman and CEO

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

Increase Prob. of Approval
- Experienced Exec. Team & Staff
- Drug Development Regulatory Science Platform
- Pipeline Drugs Selected to Increase Prob of Success & Mitigate Risk

Capital Efficient
- $3.5 M/yr Overhead with 15 Staff
- $21 M Cash
- 15.5 M Outstanding Share, ~ 35% Insiders

Drug Development Platform
- 30 FDA Approvals, 100 FDA Meetings, 2 FDA Regulatory Science Contracts
- Programs Designed to Improve Benefit-Risk Profile as Viewed by FDA

Processa

Increasing ROI

Potential Markets
- Improved Efficacy/Safety Profile
- Each Drug $500 M - $1.5 B U.S. Market

6-18 Month Clinical Catalysts
- 499 Phase 2B uNL Interim Analysis, Study Completion
- 12852 Phase 2A Gastroparesis IND, Initiate Phase 2A
- 3117 Complete Biomarker Assay, Initiate Phase 2B
- 6422 Phase 1B GI Cancer Interim Analysis, MTD Identified

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 Capital Structure and Share Information on March 31, 2021

- **Stock Listing:** PCSA – NASDAQ
- **52 Week Low-High:** $3.95 - $13.15
- **Price (July 9, 2021):** $8.14
- **Market Cap (July 9, 2021):** $126,345,954
- **Shares Outstanding:** 15,521,616
- **Fully Diluted Shares:** 16,511,147
- **Cash, Cash Equivalents:** $23,048,000
- **Expected 2021 Overhead Cash Burn, Including Salaries:** $3,500,000
- **Employees:** 15
- **Research Analyst Reports:**
  Robin Garner – Craig Hallum
  Aydin Huseynov MD, CFA - Benchmark
  Hogan Mullaly – Encode Ideas

Processa Pipeline– Multiple Opportunities For Success

Pipeline of Drugs with Funding to Obtain Results for Key Milestones

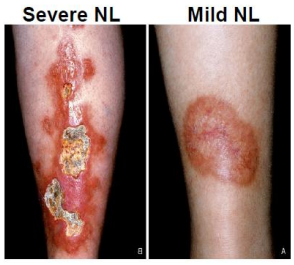
Drug	Disease Target	Preclinical	Phase 1	Phase 2	Phase 3	Key Milestones
PCS499 Phase 2B	Ulcerative Necrobiosis Lipoidica			*		FPI May 2021; Interim Analysis 1H'22; Final Analysis 2H'22; FPI Phase 3 SPA 2023
PCS12852 Phase 2A	Gastroparesis, Constipation Disorders					Phase 2A IND Clearance 4Q'21; FPI Phase 2A 1H'22; Final Analysis 2H'22 - 1H'23
PCS3117 Phase 2B	Pancreatic, Non-Small Cell Lung Cancer			*		Complete Biomarker Assays 1H'22; FPI Phase 2B 2H'22; FPI Phase 3 SPA 2023 - 2024
PCS6422 Phase 1B	Metastatic Colorectal, Breast Cancer		*			FPI 3Q'21; Interim Cohort Analysis 2H'21; MTD Determined 2022; FPI Phase 2B/3 2023 - 2024
PCS11T Pre-IND	Small Cell Lung, Colorectal Cancer					Complete IND Enabling Studies; Phase 1B IND Clearance 1H'23

* Pipeline Drug with IND

FPI – First Patient In (i.e., randomized)
SPA – FDA Special Protocol Assessment

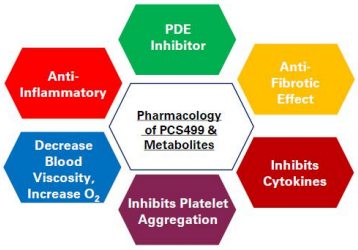
First to Market for the Treatment of Ulcerative Necrobiosis Lipoidica (uNL)

- 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**



Unmet Medical Need, Evidence of Clinical Efficacy, PCS499 Improves Benefit-Risk

- **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

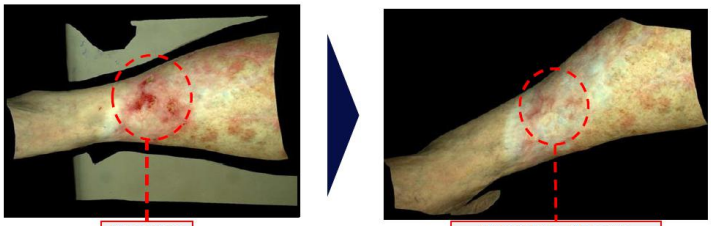


Pathophysiological Changes in NL

- **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**
- Non-ulcerated patients reported improvement in NL but clinical significance could not be determined

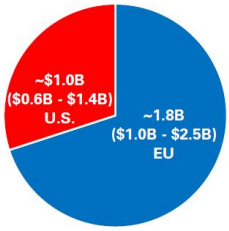


Baseline | Complete Closure

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**

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

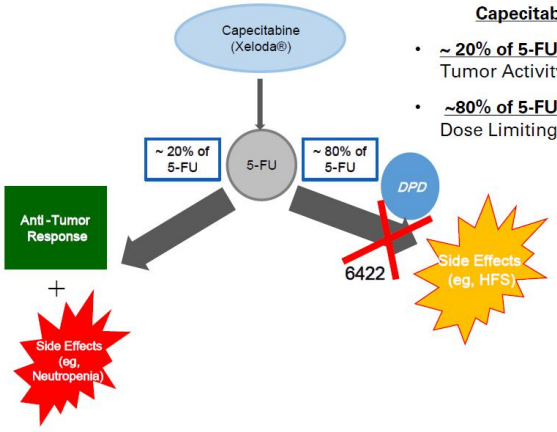
- **First patient has been randomized and dosed**
- **Interim Analysis 1H'22**
- **Final Analysis 2H'22**

Next Trial

Phase 3 in 2023 Under Special Protocol Assessment

PCS6422 Chemotherapy Modifier of Capecitabine (Xeloda®)

PCS6422 Irreversibly Inhibits Dihydropyrimidine Dehydrogenase (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 Allowing Two Ways to Win

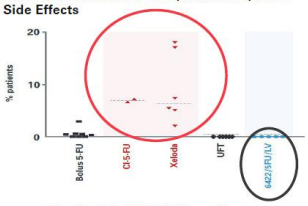
- **Lower Side Effects** by Lowering 5-FU Metabolite FBAL– Potentially Improve QOL & Reduce Treatment Discontinuations
- **Improve Capecitabine Efficacy** – Potentially Increase Response Rate by Increasing Tumor Exposure to Cancer Killing 5-FU Metabolites

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**

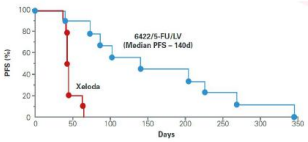
- ~30% of patients do not respond at all to capecitabine and ~30% are partial responders
- Clinical trial of the 6422 + capecitabine combination provides preliminary evidence that the combination may **extend progression free survival (PFS) in patients who do not respond to capecitabine as well as increase 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:

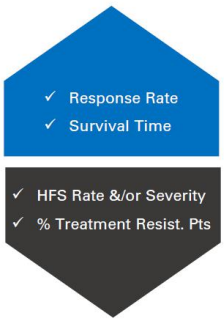
Lower Dose of 6422 Administered Hours Before 5-FU/LV in Capecitabine Resistant Patients



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- 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**

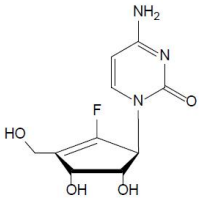
PCS6422 Chemotherapy Modifier of Capecitabine (Xeloda®)

- **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*

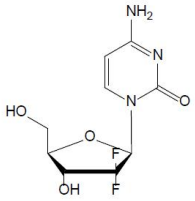
- Initiating Clinical Sites
- MTD Stage 1: **1st Patient Expected to Enroll 3Q'21; Interim Analysis 2H'21;** MTD Determined 2022
- Dose Confirmation Stage 2: 1st Patient Expected 2H'22, Final Analysis 2023/2024

Next Trial
Phase 2/3 Trial in 2023-2024

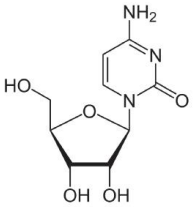
PCS3117 vs Gemcitabine vs Cytidine



RX-3117
Oral Administration
(Cytosine + Ribose Analog)



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



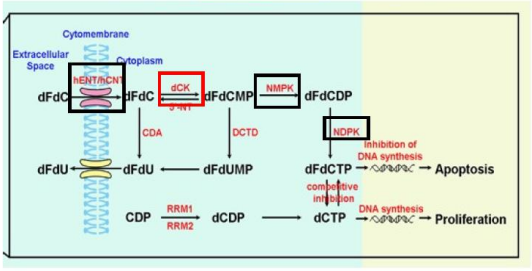
Cytidine
(Cytosine + Ribose Ring)

- **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

Differences Between Gemcitabine vs PCS3117

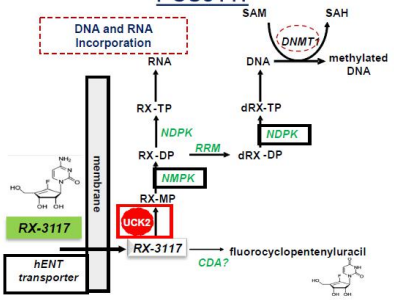
Activation to Cancer Killing Metabolites and Mechanism of Cancer Cell Death

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



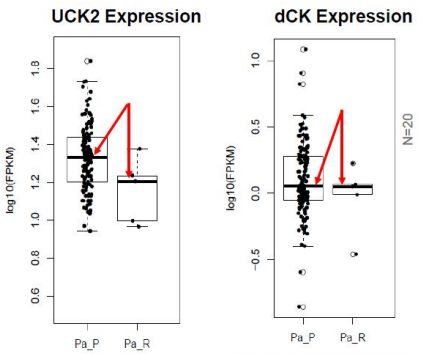
- hENT1 - human equilibrative nucleoside transporter-1
- UCK2 -uridine-cytidine kinase
- NMPK - nucleotide monophosphate kinase
- NDPK - nucleotide diphosphate kinase
- RRM - ribonucleotide reductase
- CDA - cytidine deaminase

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**

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

- **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**

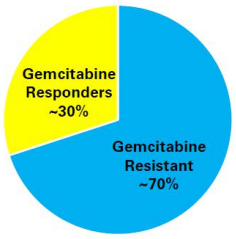


Pa_P : Pancreatic Tumor, N=134
Pa_R : Normal pancreas, N=5
(Data from Univ. of Toronto)

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



PCS3117 6-18 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

Phase 2B FPI 2H'22 → **Next Trial** Phase 3 in 2023-2024 Under SPA

FPI – First Patient In (i.e., randomized)
SPA – FDA Special Protocol Assessment

Summary Timeline of Pipeline and Key Clinical Catalysts

	1H 2021	2H 2021	1H 2022	2H 2022	2023-2025
PCS499 Phase 2B	• Initiated Sites • **FPI (May)**		• **Interim Analysis**	• **Final Analysis**	• Phase 3 Trial • NDA Submission
PCS12852 Phase 2A	• Pre-IND Meeting • Prepare IND	• **IND Submitted and Safe to Proceed** • Initiate Sites	• **FPI (1H'22)**	• **Final Analysis (2H'22 - 1H'23)**	• Phase 2B Trial • Phase 3 Trial
PCS3117 Phase 2B		• **Initiate Biomarker Assay Develop. & Eval.** • Prepare Phase 2B Protocol	• FDA Type C Meeting	• Select CRO and Initiate Sites • FPI (2H'22)	• Phase 3 Trial
PCS6422 Phase 1B	• Initiate Sites • Screen Patient	• **FPI (3Q'21)** • **Interim Analysis**	• **Final Analysis MTD Stage 1 (2022)**	• Initiate Dose Confirmation Stage 2	• Final Analysis Stage 2 • Phase 2B/3 Trial
PCS11T IND	• Evaluate CMOs	• Initiate Preliminary CMC	• Initiate Tox		• Complete Tox • Complete IND • IND Safe to Proceed

FPI – First Patient In
CMO – Contract Manufacturing Organization
CMC – Chemistry, Manufacturing, Control

Bold & Underlined = Key Clinical Catalysts
Red, Bold, Underlined = Key Clinical Catalyst Achieved

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.