UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): August 12, 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 2.02. Results of Operations and Financial Condition.

On August 12, 2021, we issued a press release announcing the earnings and other financial results for the quarter ended June 30, 2021. The full text of the press release is furnished as Exhibit 99.1 along with a Product Development Clinical Update Presentation as Exhibit 99.2. to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1 and 99.2) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release issued on August 12, 2021 (furnished and not filed for purposes of Item 202)

99.2 Processa Product Development Clinical Update Presentation (furnished and not filed for purposes of Item 202)

SIGNATURES

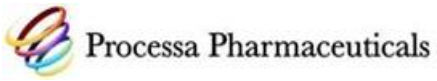
Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PROCESSA PHARMACEUTICALS, INC.

Date: August 12, 2021

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

Exhibit 99.1



Processa Pharmaceuticals Announces Second Quarter 2021 Results and Provides Corporate Update

Adds fourth clinical asset, RX-3117, and targets major milestones in the second half of 2021

HANOVER, Md., August 12, 2021 — Processa Pharmaceuticals, Inc. (Nasdaq: PCSA), a clinical stage biopharmaceutical company developing drugs to improve the survival and/or quality of life for patients who have an unmet medical need condition, announces today financial results for the quarter ended June 30, 2021, and provides corporate update.

Dr. David Young, CEO and chairman of Processa, commented, "During the second quarter we made significant progress advancing our clinical programs, in-licensed another clinical asset - RX-3117 – and will have four clinical programs with addressable markets of $500 million to $1.5 billion. Looking at upcoming milestones, we have begun to develop the biomarker assays for 3117 in pancreatic cancer patients with the expectation that the assay validation will be completed in the first half of 2022. We also anticipate filing an IND in September for PCS12852 with site initiation beginning before year end. Additionally, we expect interim data for PCS6422 in the fourth quarter of 2021 and interim data for PCS499 during the first half of 2022. Taken altogether, we see a consistent cadence of upcoming catalysts and tremendous amount of near-term value creation."

Recent Highlights and New Developments

- Dosed our first two patients in the PCS499 Phase 2B ulcerative Necrobiosis Lipoidica (NL) trial. NL is a rare, chronic, idiopathic, granulomatous disease that can significantly effect a patient's quality of life and is caused by a number of diverse pathophysiological changes in a patient. There are no approved treatments for NL or ulcerative NL and no acceptable standard of care. Approximately 30% of NL patients have the ulcerative form of NL.

- Dosed our first patient in our Phase 1B trial evaluating the safety and PK of PCS6422 and capecitabine when administered to patients with advanced, refractory GI cancer. The combination of PCS6422 and capecitabine is expected to improve the benefit-risk profile of capecitabine by improving capecitabine safety and/or efficacy.

- Licensed in PCS3117 (formerly RX-3117), an oral, anticancer agent with an improved pharmacological profile relative to gemcitabine. PCS3117 has a family of patents extending into 2036 as well as U.S. Food and Drug Administration (FDA) Orphan Designation for the treatment of Pancreatic Cancer. Processa has begun to develop biomarkers assays to better predict which patients with pancreatic or non-small cell lung cancer are more likely to benefit from PCS3117 over gemcitabine and other chemotherapeutic agents.

- Joined the Russell Microcap ®, resulting in automatic inclusion in the appropriate growth and value style indexes. FTSE Russell determines membership for its Russell indexes primarily by objective, market-capitalization rankings and style attributes.

Upcoming Clinical Drug Development Milestones

Second half of 2021

- Complete enrollment of 8-10 patients for the PCS499 Phase 2B interim analysis
- Submit PCS12852 IND application to FDA for Gastroparesis and initiate sites
- Begin assay development of biomarkers for PCS3117 in pancreatic cancer
- Complete interim analysis of PCS6422 Phase 1B trial in GI cancer

2022

- Interim analysis of PCS499 Phase 2B trial in ulcerative NL
- Final analysis of PCS499 Phase 2B trial in ulcerative NL
- Enroll and complete PCS12852 Phase 2A gastroparesis trial
- Complete assay validation of biomarkers for PCS3117 and initiate sites for Phase 2B pancreatic cancer trial
- Determine the maximum tolerated dose for capecitabine in the PCS6422-capecitabine combination Phase 1B GI cancer trial

Financial Results for the second quarter of 2021

Our cash and cash equivalents totaled $20.8 million as of June 30, 2021, compared to $15.4 million as of December 31, 2020 and we had 15.6 million shares of common stock outstanding as of August 2, 2021.

Our research and development expenses for the three months ended June 30, 2021 were $1.6 million compared to $427 thousand for the three months ended June 30, 2020. General and administrative expenses for the three months ended June 30, 2021 were $1.3 million compared to $375 thousand for the three months ended June 30, 2020. Our total stock-based compensation included in general and administrative expenses for the three months ended June 30, 2021 was $674 thousand compared to $87 thousand for the three months ended June 30, 2020. We reported a net loss for the three months ended June 30, 2021 of $3.2 million compared to a net loss for the comparable prior year period of $733 thousand. Our net loss per share for the three months ended June 30, 2021 was $0.20 compared to net loss per share for the three months ended June 30, 2020 of $0.13.

Conference Call Information

To participate in this event, please dial in approximately 5 to 10 minutes before the beginning of the call.

Date: August 12, 2021

Time: 5:30 p.m. ET
Toll Free: 888-506-0062; Entry Code: 628453
International: 973-528-0011; Entry Code: 628453
Live Webcast: https://www.webcaster4.com/Webcast/Page/2572/42137

Conference Call Replay Information
Toll-free: 877-481-4010
International: 919-882-2331
Replay Passcode: 42137
Replay Webcast: https://www.webcaster4.com/Webcast/Page/2572/42137

About Processa Pharmaceuticals, Inc.

Our mission is to develop drug products that improve the survival and/or quality of life for patients with high unmet medical need conditions. We are a development company, not a discovery company, that seeks to identify and develop drugs for patients who need better treatment options than presently exist for their medical condition. To increase the probability of development success, our pipeline only includes drugs which have previously demonstrated some efficacy in the targeted population or a drug with very similar pharmacological properties has been shown to be effective in the population. We currently have three drugs in various stages of clinical development: PCS499 for Ulcerative Necrobiosis in Phase 2B; PCS3117 for metastatic pancreatic cancer and non-small cell lung cancer in Phase 2B; and PCS6422 for metastatic colorectal cancer and breast cancer in Phase 1B. The PCS12852 IND for the treatment of gastroparesis will be submitted in the third quarter of 2021. For more information, visit the company's website at www.ProcessaPharma.com.

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Processa Pharmaceuticals

2Q 2021 Earnings Call | August 12, 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's Differentiated Approach

Repeatable, Capital-efficient Blueprint Platform with Potential to Generate Significant ROI

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

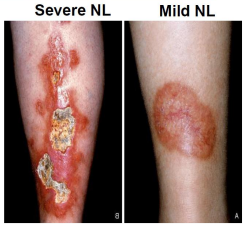
Processa Pipeline – Multiple Opportunities For Success

Drug	Disease Target	Preclin	Phase 1	Phase 2	Phase 3	Status	Milestones
PCS499 Phase 2B	Ulcerative Necrobiosis Lipoidica			*		2 Patients Enrolled; 1 Patient in Screening; 10 Patients Pre-Screen Failures; 3/9 Sites Active	Interim Analysis 1H'22; Final Analysis 2H'22; FPI Phase 3 SPA 2023
PCS12852 Phase 2A	Gastroparesis, Constipation Disorders					IND Being Reviewed and Finalized	Phase 2A IND Submission 3Q'21; FPI Phase 2A 1H'22; Final Analysis 2H'22 - 1H'23
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 SPA 2023 – 2024
PCS6422 Phase 1B	Metastatic Colorectal, Breast Cancer			*		1 Patient Enrolled; 1 Patient Pre-Screen Failure; 2 Patients in Screening Waiting Room; 4/5 Sites Active	Interim Cohort Analysis 4Q'21; MTD Determined 2H'22; FPI Phase 2B/3 2023 – 2024
PCS11T Pre-IND	Small Cell Lung, Colorectal Cancer					CMOs Being Evaluated	Complete IND Enabling Studies; Phase 1B IND Submission 1H'23

* Cleared by FDA for Clinical Trial

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

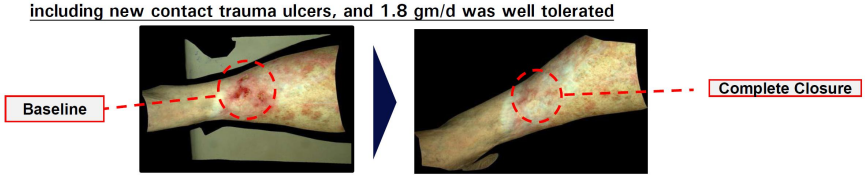
PCS499 to Be First to Market for the Treatment of Ulcerative Necrobiosis Lipoidica (uNL)



- Skin, tissue below the skin becomes necrotic, last from months to years with complications such as infections, amputation; Histopathology ≠ diabetic ulcers
- 30% of NL patients have painful ulcers occurring naturally or from contact trauma;
- Natural complete healing of moderate to severe ulcers in less than 5% of these patients during the first 1-2 years after onset
- **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
- Economic Value: Initial Market
  - 75,000 – 185,000 NL patients in U.S.
  - 22,000 – 55,000 uNL patients in U.S.
  - 499 has orphan designation for NL (7-year market exclusivity) and patent exclusivity until 2030
  - **U.S. market potential in uNL is ~ $1 B annual gross sales**

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

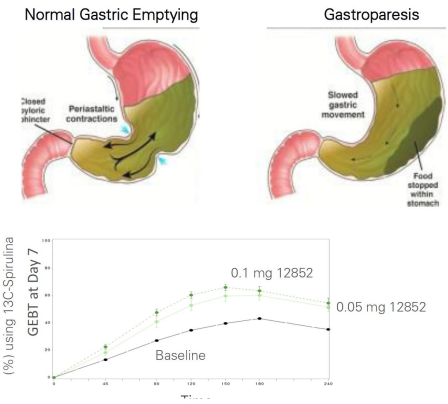
- **PCS499 is the deuterated analog of a major metabolite of PTX**; has identical metabolites and pharmacological targets but **PK of 499 + metabolites is different than PTX + metabolites resulting in a better 499 safety profile and allowing the administration of a higher, more efficacious dose of 499**
- **499 + metabolites target pharmacology that directly affect 6 of the 7 NL pathophysiological changes**
- **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, **all ulcers closed** in the 2 ulcerative NL patients, **including new contact trauma ulcers, and 1.8 gm/d was well tolerated**



Status	Milestones
2 Patients Enrolled; 1 Patient in Screening; 10 Patients Pre-Screen Failures; 3/9 Sites Active	Interim Analysis 1H'22; Final Analysis 2H'22; FPI Phase 3 SPA 2023

PCS12852 Potent-Selective 5HT4 Agonist: Gastroparesis ($1 B Market)

Submit IND for Phase 2A Trial in 3Q'21, FPI in 1Q'22



	12852	Other 5HT4 Drug (e.g., Cisapride, Prucalopride, Mosapride)	Dopamine D2 Antagonist (.e.g., Metoclopramide)
Binding	• Very specific 5HT4 Agonist • 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 CV side effects** (e.g., cisapride removed from market) • Suicidal ideation	• 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 approved for treatment of gastroparesis

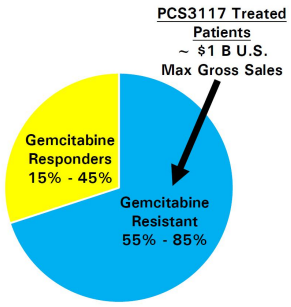
PCS12852 Potent-Selective 5HT4 Agonist for Treatment of Gastroparesis

- 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

Status	Milestones
IND Being Reviewed and Finalized	Phase 2A IND Submission 3Q'21; FPI Phase 2A 1H'22; Final Analysis 2H'22 - 1H'23

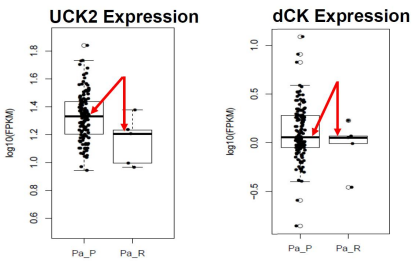
In Licensed PCS3117 for Gemcitabine Resistant Pancreatic and Lung Cancer Patients

- PCS3117 has 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 and non-small cell lung cancer
- **55% - 85% of patients are inherently resistant to gemcitabine or acquire resistance**; inherent or acquired resistance 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 formation of cancer killing nucleotides but does not affect PCS3117 which is activated by UCK2 enzyme
  - Up-regulation of RRM1/RRM2 increases formation of endogenous cytidine nucleotide while increases production of cancer killing PCS3117 nucleotides



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**

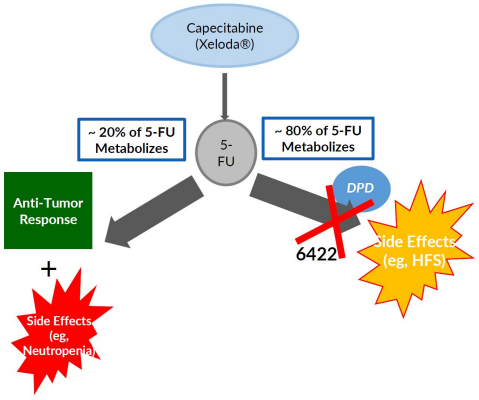


Pa_P : Pancreatic Tumor, N=134
Pa_R : Normal pancreas, N=5
(Data from Univ. of Toronto)

Status	Milestones
Biomarker Assay Lab Being Selected and Protocols Being Prepared	Complete Biomarker Assays 1H'22; FPI Phase 2B 2H'22; FPI Phase 3 SPA 2023 – 2024

PCS6422 Combined with Capecitabine To Provide Better Safety/Efficacy Profile

PCS6422 Irreversibly Inhibits Dihydropyrimidine Dehydrogenase (DPD) Enzyme



6422 Inhibits DPD Allowing Two Ways to Win

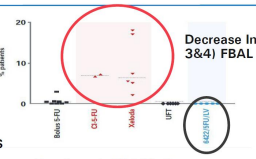
- **Lower Side Effects** by Lowering 5-FU Metabolite FBAL– Potentially Improve QOL & Reduce Treatment Discontinuations
- **Improve Capecitabine Efficacy** – Potentially Increase Response Rate by Increasing Tumor Exposure to Cancer Killing 5-FU Metabolites

Economic Value: Initial Markets

- 6422 + Capecitabine combination potentially 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; > 45% of the new patients with colorectal cancer presently receive capecitabine
- **U.S. market potential in colorectal cancer is ~ $1.0 B**

Unmet Medical Need and Evidence of Clinical Benefit

- **Safety Differentiation of 6422 + Capecitabine vs Existing Chemotherapy**
  - 50-70% of capecitabine patients have adverse events from FBAL resulting in decreasing capecitabine dose or stopping therapy
  - Clinical trial of the 6422 + capecitabine provides preliminary evidence that the combination will decrease FBAL adverse events
- **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

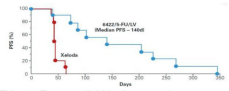


Decrease Incidence of HFS (Grade 3&4) FBAL Side Effects

Revollo et al, 2008 Clin Cancer Res; Masuda et al, 2012 Invest New

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

Status	Milestones
1 Patient Enrolled; 1 Patient Pre-Screen Failure; 2 Patients in Screening Waiting Room; 4/5 Sites Active	Interim Cohort Analysis 4Q'21; MTD Determined 2H'22; FPI Phase 2B/3 2023 – 2024

Summary Timeline of Pipeline and Key Clinical Milestones

	1H 2021	2H 2021	1H 2022	2H 2022	2023-2025
PCS499 Phase 2B	• Initiate Sites • FPI		• **Interim Analysis**	• **Final Analysis**	• **Phase 3 Trial** • NDA Submission
PCS12852 Phase 2A	• Pre-IND Meeting • Prepare IND	• **IND Submission (3Q'21)** • Select CRO; Initiate Sites	• **FPI**	• **Final Analysis**	• **Final Analysis** • **Phase 2B Trial** • **Phase 3 Trial**
PCS3117 Phase 2B	• Licensed	• Initiate Biomarker Assay Development	• **Complete Biomarker Assay Development**	• **Initiate Sites** • **FPI**	• **Phase 3**
PCS6422 Phase 1B	• Initiate Sites • FPI	• **Interim Analysis 4Q'21**		• **Determine MTD** • **Initiate Dose Confirmation Stage 2**	• **Final Analysis Stage 2** • **Phase 2B/3 Trial**
PCS11T IND	• Evaluate CMOs	• Evaluate CMOs	• Initiate Tox		• Complete Tox • Complete IND • **IND Submission**

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

What's Expected Over the Next 6 Months?

- Complete enrollment of patients for the interim analysis of PCS499
- IND Clearance for PCS12852 in Gastroparesis
- Analysis of Cohort 1 & 2 in the 6422 Phase 1B Dose Escalation Study
- Development of PCS3117 Biomarker Assays and Initiation of Assay Validation
- Invited Presentation: World Orphan Drug Congress USA 2021, Aug 25 - 27, 2021
- Invited Presentation: Oppenheimer Fall Healthcare Life Sciences & MedTech Summit, Sept 20-23, 2021
- Research Analyst Reports:

  Robin Garner – Craig Hallum

  Aydin Huseynov - Benchmark

  Hogan Mullaly – Encode Ideas

  Francois Brisebois - Oppenheimer