

**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): May 13, 2021

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

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39531
(Commission
File Number)

45-1539785
(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 May 13, 2021, we issued a press release announcing earnings and other financial results for the quarter ended March 31, 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 November 2, 2020 \(furnished and not filed for purposes of Item 202\)](#)
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: May 13, 2021

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

Processa Pharmaceuticals Announces First Quarter 2021 Results and Provides Corporate Update

Clinical drug pipeline is funded and targeting major milestones in Q2 and 2H 2021

HANOVER, Md., May 13, 2021 (GLOBE NEWSWIRE) — Processa Pharmaceuticals, Inc. (Nasdaq: PCSA) (“Processa” or the “Company”), a clinical stage company developing drugs for patients who have unmet medical conditions that require better treatment options to improve a patient’s survival and/or quality of life, today announces financial results for the year ended March 31, 2021, and provides corporate update.

Dr. David Young, CEO and chairman of Processa, commented, “During the first quarter we made substantial progress advancing our three clinical in-licensed drugs, each with a potential market exceeding \$1 billion. We expect first patients to be dosed with PCS6422 and PCS499 within the next six weeks, and to receive interim data for PCS6422 near the end of the third quarter of 2021 and interim data for PCS499 during the first quarter of 2022.”

Recent Highlights and New Developments

- We have selected 5 U.S. clinical sites to enroll patients with ulcerative necrobiosis lipoidica and started the screening process for our first patient in our Phase 2B trial “A Randomized, Double-blind, Placebo-Controlled Clinical Trial to Evaluate the Efficacy and Safety of PCS499 in Treating Ulcerations in Patients who Have Necrobiosis Lipoidica.” In order to expedite enrollment for this rare condition, we are evaluating additional clinical sites both within and outside the U.S.
- We are initiating clinical sites to enroll patients into our Phase 1B trial “A Study of the Safety and PK of PCS6422 (Eniluracil) with Capecitabine in Patients with Advanced, Refractory GI Tract Tumors.”
- We have received guidance from the FDA and plan to submit an IND application in the third quarter of 2021. PCS12852 is a small molecule drug in development for the treatment of gastroparesis and functional gastrointestinal motility disorders.
- In February 2021, we closed a private placement with institutional and accredited investors for gross proceeds of \$10.2 million. We sold 1,321,132 shares of the common stock at a purchase price of \$7.75 per share and received net proceeds of \$9.9 million.

Upcoming Clinical Drug Development Milestones

First half of 2021

- Dose our first patient in our PCS499 (Ulcerative NL) Phase 2B trial.
- Dose our first patient in our PCS6422 (cancer) Phase 1B trial.

Second half of 2021

- Submit our IND application for PCS12852 in Gastroparesis to FDA.
- Begin our interim cohort results for PCS6422.

First half of 2022

- Obtain interim results from our PCS499 Phase 2B trial.
- Dose our first patient in a Phase 2A trial for PCS12852.

Financial Results for the first quarter of 2021

Our cash and cash equivalents totaled \$23 million as of March 31, 2021, compared to \$15.4 million as of December 31, 2020. We had 15.5 million shares of common stock outstanding as of March 31, 2021.

Our research and development expenses for the three months ended March 31, 2021 were \$1.5 million compared to \$501 thousand for the three months ended March 31, 2020. General and administrative expenses for the three months ended March 31, 2021 were \$717 thousand compared to \$484 thousand for the three months ended March 31, 2020. We reported a net loss for the three months ended March 31, 2021 of \$2.1 million compared to a net loss for the comparable prior year period of \$874 thousand. Our net loss per share for the three months ended March 31, 2021 was \$0.14 compared to net loss per share for the three months ended March 31, 2020 of \$0.16.

Conference Call Information

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

Date: May 13, 2021

Time: 5:30 p.m. ET

Toll Free: 888-506-0062; Entry Code: 396394

International: 973-528-0011; Entry Code: 396394

Live Webcast: <https://www.webcaster4.com/Webcast/Page/2572/41274>

Conference Call Replay Information

Toll-free: 877-481-4010

International: 919-882-2331

Replay Passcode: 41274

Replay Webcast: <https://www.webcaster4.com/Webcast/Page/2572/41274>

About Processa Pharmaceuticals, Inc.

The mission of Processa is to develop products with existing clinical evidence of efficacy for patients with unmet or underserved medical conditions who need treatment options

that improve survival and/or quality of life. The Company uses well-defined criteria to select drugs for its pipeline in order to achieve high-value milestones effectively and efficiently. Active pipeline programs include: PCS499 (ulcerative necrobiosis lipoidica), PCS12852 (GI motility/gastroparesis) and PCS6422 (metastatic colorectal cancer and breast cancer). The members of the Processa development team have been involved with more than 30 drug approvals by the FDA (including drug products targeted to orphan disease conditions) and more than 100 FDA meetings throughout their careers. For more information, visit the company's website at www.ProcessaPharma.com.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 that reflect the current beliefs, expectations and assumptions of the "Company regarding the future of the Company's business, our future plans and strategies, regulatory approvals, clinical results, future financial condition and other future conditions. All statements other than statements of historical facts contained in this press release, including expressed or implied statements regarding future results of operations and financial position, business strategy, product candidates, regulatory approvals, expected research and development costs, planned preclinical studies and clinical trials, expected results of clinical trials, and their timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. The words "if approved," "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include information about qualitative assessments of available data, potential benefits, expectations for clinical trials, and anticipated timing of clinical trial readouts and regulatory submissions. This information involves risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, including the impact of the COVID-19 pandemic on our business, operations, and regulatory and clinical development timelines, plans and expectationsregulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preliminary and interim data, including the possibility of unfavorable new clinical trial data and further analyses of existing clinical trial data; the risk that clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities. These and other risks and uncertainties are more fully described in our periodic filings with the Securities and Exchange Commission ("SEC"), including the risk factors described in the section entitled "Risk Factors" in the quarterly and annual reports that we file with the SEC. Any forward-looking statements that we make in this press release speak only as of the date of this press release. Except as required by law, we assume no obligation to update forward-looking statements contained in this press release whether as a result of new information, future events, or otherwise, after the date of this press release.

For More Information:

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Processa Pharmaceuticals

1Q 2021 Earnings Call | May 13, 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.

Summary Timeline for Clinical Trials

	1Q 2021	2Q 2021	3Q 2021	4Q 2021	1H 2022	2H 2022	2023-2026
PCS6422 Phase 1B	Initiate Sites, <u>Begin Patient Dosing</u>		<u>Analysis First 2 Cohorts 2H'21.</u> Final Analysis 2H'22			Phase 2 or 3 Initiate 2023	
PCS499 Phase 2B	Initiate Sites, <u>Begin Patient Dosing</u>		<u>Interim Analysis 1Q'22.</u> Final Analysis 2H'22			Phase 3 Initiate 2023	
PCS12852 Phase 2A	Pre-IND Meeting, IND, Initiate Sites				Initiate Sites, <u>Begin Patient Dosing</u> <u>1H'22, Interim Results 2H'22.</u> Final Analysis 1H'23		Phase 2B Initiate 2023

Highlights of 1Q2021

Continued Development of Drug Pipeline Each Having Potential Sales of \$1 B or More

- ✓ PCS499
 - Selected clinical sites for Phase 2B trial in patients with ulcerative necrobiosis lipoidica (uNL)
 - Have begun screening patients for uNL trial
 - Adding sites
- ✓ PCS6422
 - Selected sites for PCS6422 Phase 1B trial in patients with GI cancers
 - Have begun initiating sites
- ✓ PCS12852
 - Completed pre-IND FDA meeting with FDA
 - Obtained drug supply from Yuhan Corp. and presently qualifying the drug supply
 - Preparing IND documents, including protocol
- ✓ PCS11T
 - Further defined development plan and began evaluating CMO to manufacture drug supply and drug product

Expanded Financial and Human Capital

- ✓ Expanded Financial Capital
 - Raised \$10.2 M in a PIPE
 - Funding provides further support for 3 clinical trials and the evaluation of possible biomarkers
 - Funding provides cash through 2023
- ✓ Expanded Human Capital
 - Added 2 additional staff in development
 - Searching for additional staff to further support development and corporate

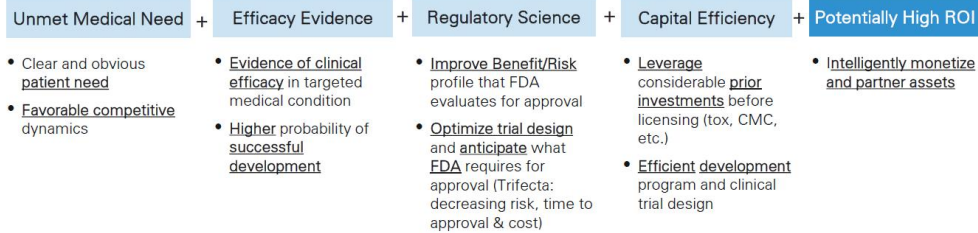
Processa's Differentiated Approach

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

DEVELOP NOT DISCOVER



REGULATORY SCIENCE PLATFORM



Processa Pipeline– Multiple Opportunities For Success

Processa Pipeline – Multiple Opportunities For Success

Drug	Disease Target	Preclinical	Phase 1	Phase 2	Phase 3	Market Size
PCS6422	Metastatic Colorectal, Breast Cancer	→				> \$1 B
PCS499	Ulcerative Necrobiosis Lipoidica	→				> \$1 B
PCS12852	Gastroparesis, Functional Constipation	→				> \$1 B
PCS11T	Small Cell Lung, Colorectal Cancer	→				> \$1 B

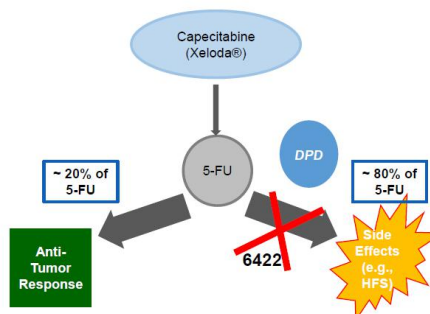
PCS6422 Chemotherapy Modifier of Cancer Drug Capecitabine (Xeloda®)

Target Indication:

- Treatment of metastatic colorectal cancer when combined with capecitabine

Target Claims:

- 6422+capecitabine combination provides patients with a better benefit-risk profile (less adverse events and/or better efficacy) than just capecitabine

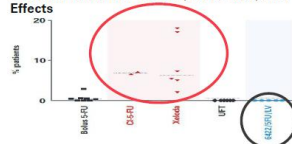


PCS6422 Chemotherapy Modifier of Cancer Drug Capecitabine (Xeloda®)

Safety Differentiation of 6422+Capecitabine vs Existing Cancer Chemotherapy

- 50-70% of capecitabine patients have adverse events from FBAL resulting in a decrease in capecitabine dose or stopping capecitabine chemotherapy
- 6422+capecitabine combination likely to significantly decrease these adverse events

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



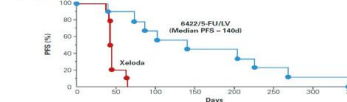
Revollo et al. 2008 Clin Cancer Res; Masuda et al. 2017. NEJM

Efficacy Differentiation of 6422+Capecitabine vs Existing Cancer Chemotherapy

- ~30% of patients do not respond to capecitabine
- 6422+capecitabine combination may be able to extend progression free survival (PFS) in the 30% non-responders and increase the length of PFS over existing chemotherapy including capecitabine

Improve Capecitabine Efficacy with 6422:

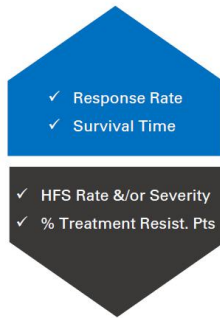
Lower Dose of 6422 Administered Hours Before 5-FU/LV in Capecitabine Resistant Patients



5-FU = 5-Fluorouracil; 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 Cancer Drug Capecitabine (Xeloda®)



➤ 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 Cancer Drug Capecitabine (Xeloda®)

➤ Present Phase 1B Trial to Determine Appropriate Dosing of 6422 and Capecitabine

- **General Design:** 3+3 cohort capecitabine MTD 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
- **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

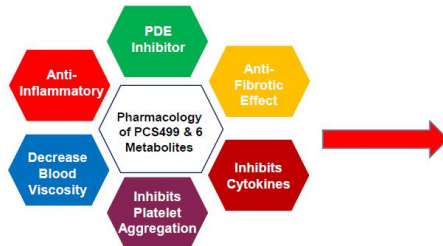


In 2023 Begin
Phase 2 Followed by Phase 3
OR
Adaptive Design Phase 3

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

Provides Efficacious/Safe Treatment for Patients with No Treatment Options

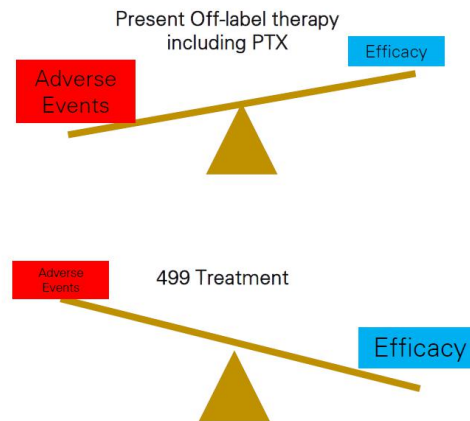
- **Target Indication:**
 - Treatment of ulcerative necrobiosis lipoidica (“uNL”)
- **Target Claims:**
 - Completely closes open necrobiosis lipoidica ulcers; improves non-ulcerated NL lesions
 - Natural healing of small ulcers in the first few years ~ 0-15%, for larger ulcers ~ 0 - 5%
 - Open ulcers can lead to infections and amputation of limb



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

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

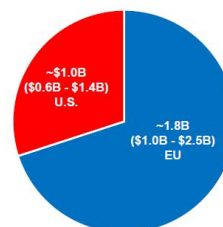
- **Differentiation of PCS499 from Existing Therapy**
 - No approved NL or uNL treatment in U.S. or worldwide
 - Off-label drugs are prescribed to treat NL with mixed results, many have side effects limiting their use (e.g., pentoxifylline (PTX))
 - PCS499 = deuterated analog of a major metabolite of PTX
 - 499 – orally administered, tolerated much better than PTX (1.8gm 499 well tolerated, 1.2gm tolerated in some patients)
 - In Phase 2A trial 499 closed all ulcers in the two patients who had ulcers and improved NL lesion in patients with no ulcers



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

- **Economic Value: Initial Markets**
 - 22,000 – 55,000 patients in U.S. have uNL
 - Presently no approved treatment and off-labeled drugs not proven to be significantly effective/safe in patients with NL or uNL
 - 499 has orphan designation for NL
 - 499 would be the first approved drug to treat patients with uNL or NL
 - U.S. market potential in uNL is ~\$600 M - \$1.4 B

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 cm², total ulcer area of a minimum of 2 cm², 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



In 2023 Begin
Phase 3 to Begin after Obtaining Special Protocol Assessment from FDA

PCS12852 Potent-Selective 5HT₄ Agonist for Treatment of Gastroparesis

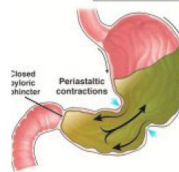
➤ Target Indication:

- Treatment of moderate to severe gastroparesis

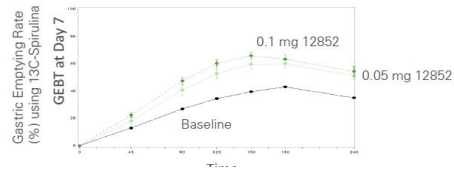
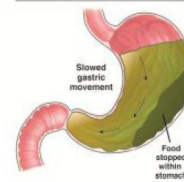
➤ Target Claims:

- Improves gastric emptying rate and the symptoms associated with moderate to severe gastroparesis (e.g., bloating, pain, nausea, vomiting)

Normal Gastric Emptying



Gastroparesis



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	<ul style="list-style-type: none"> • Very specific 5HT4 receptor binding • Drug very potent to 5HT4 	<ul style="list-style-type: none"> • Less specific binding to 5HT4 than 12852 • Less potent than 12852 	<ul style="list-style-type: none"> • Binds to Dopamine D2 receptors
Side Effects	<ul style="list-style-type: none"> • <u>No serious side effects</u> in clinical studies to date 	<ul style="list-style-type: none"> • <u>Serious cardiovascular side effects</u> (e.g., cisapride removed from market) • Suicidal ideation (e.g., prucalopride) 	<ul style="list-style-type: none"> • Black Box Warning <u>serious neurological side effects</u>
Efficacy	<ul style="list-style-type: none"> • Increase gastric emptying rate • Gastroparesis patient study required 	<ul style="list-style-type: none"> • Increase gastric emptying rate • Successful treatment demonstrated 	<ul style="list-style-type: none"> • 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

- 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 1H2022
- Interim analysis 2H2022

Summary Timeline for Clinical Trials

	1Q 2021	2Q 2021	3Q 2021	4Q 2021	1H 2022	2H 2022	2023-2026
PCS6422 Phase 1B	Initiate Sites, <u>Begin Patient Dosing</u>		<u>Analysis First 2 Cohorts 2H'21</u> , Final Analysis 2H'22			Phase 2 or 3 Initiate 2023	
PCS499 Phase 2B	Initiate Sites, <u>Begin Patient Dosing</u>		<u>Interim Analysis 1Q'22</u> , Final Analysis 2H'22			Phase 3 Initiate 2023	
PCS12852 Phase 2A	Pre-IND Meeting, IND, Initiate Sites				Initiate Sites, <u>Begin Patient Dosing 1H'22</u> , <u>Interim Results 2H'22</u> , Final Analysis 1H'23		Phase 2B Initiate 2023

Key Clinical Catalysts

	1Q 2021	2Q 2021	3Q 2021	4Q 2021	1H 2022	2H 2022	2023-2026
PCS6422 Phase 1B		← FPI →		← Cohort 1, 2 Analyses →	← Cohort 3 & 4 Analyses →	← Final Analysis →	← Phase 2 or 3 →
PCS499 Phase 2B		← FPI →			← Interim Analysis →	← Final Analysis →	← Phase 3 →
PCS12852 Phase 2A				← IND →	← FPI →	← Interim Analysis →	← Final Analysis → Phase 2B →

What's Coming Over the Next 6 Months?

- First Patient Dosed in PCS499 Phase 2B Ulcerative NL Trial
- First Patient Dosed in PCS6422 Phase 1B GI Cancer Trial and Analysis of Cohort 1 & 2 Data
- IND Clearance for PCS12852 in Gastroparesis
- Invited Presentation at the Oppenheimer Rare & Orphan Disease Summit on May 21, 2021
- Invited Presentation at the World Orphan Drug Congress USA 2021 from Aug 25 - 27, 2021
- Research Analyst Reports:
 - Robin Garner – Craig Hallum
 - Aydin Huseynov MD, CFA - Benchmark
 - Hogan Mullaly – Encode Ideas