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): November 8, 2022

Commission file number 001-39531

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

Delaware	**45-1539785**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**

7380 Coca Cola Drive, Suite 106, Hanover, Maryland 21076
(Address of Principal Executive Offices, Including Zip Code)

(443) 776-3133
(Registrant's Telephone Number, Including Area Code)

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common	PCSA	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 8, 2022, Processa Pharmaceuticals, Inc. (the "Company") issued an earnings release announcing its financial results for the quarter ended September 30, 2022. A copy of the earnings release is furnished as Exhibit 99.1 to this Current Report on Form 8-K (this "Report").

The information in this Item 2.02 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 otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any of the Company's filings under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act.

Item 7.01 Regulation FD Disclosure.

Results of PCS 12852 Phase 2A Trial

On November 8, 2022, the Company issued a press release announcing positive gastric emptying results from its PCS12852 Phase 2A trial in patients with moderate to severe gastroparesis. A copy of the press release is furnished as Exhibit 99.2 to this Report.

Corporate Presentation

On November 8, 2022, the Company posted an updated corporate presentation to its website at https://www.processapharmaceuticals.com/, which the Company may use from

time to time in communications or conferences. A copy of the corporate presentation is attached as Exhibit 99.3 to this Report.

The information in this Item 7.01 and Exhibits 99.2 and 99.3 shall not be deemed "filed" for purposes of Section 18 of 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 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Exhibit 99.3 hereto contains forward-looking statements within the meaning of the federal securities laws. These forward-looking statements are based on current expectations and are not guarantees of future performance. Further, the forward-looking statements are subject to the limitations listed in Exhibit 99.3 and in the other reports of the Company filed with the Securities and Exchange Commission, including that actual events or results may differ materially from those in the forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Exhibit Description
99.1	Earnings release, dated November 8, 2022 announcing Processa Pharmaceuticals, Inc. financial results for the quarter ended September 30, 2022
99.2	Press release, dated November 8, 2022 announcing results from its PCS12852 Phase 2A trial
99.3	Corporate Presentation, dated November 8, 2022
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL documents)

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 November 8, 2022.

PROCESSA PHARMACEUTICALS, INC.
Registrant

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

Exhibit 99.1

Processa Pharmaceuticals Announces Third Quarter Financial Results and Provides Corporate Update

- **PCS12852 successfully demonstrates a positive effect on the gastric emptying rate, clearing the path for a Phase 2B trial in 2023.**

- **Next Generation Capecitabine (a combination of PCS6422 and capecitabine) successfully identifies dosing regimens for a Phase 2B trial to be initiated in 2023 after a meeting with FDA to discuss the alignment of the trial design with the FDA's Project Optimus Oncology Initiative.**

HANOVER, Md., Nov. 8, 2022 (GLOBE NEWSWIRE) — Processa Pharmaceuticals, Inc. (Nasdaq: PCSA) ("Processa" or the "Company"), a diversified clinical-stage company developing drugs for patients who have unmet medical conditions and/or require better treatment options to improve a patient's survival and/or quality of life, today announced financial results for the quarter ended September 30, 2022, and provided an update on its clinical programs.

Dr. David Young, President and CEO of Processa, commented, "We are delighted to report our push to enroll patients in PCS12852 (Gastroparesis) and PCS6422 (Next Generation Capecitabine) has helped us get critical data and report successful preliminary results in both trials. The data from these trials will help us design Phase 2B trials for both programs.

- Next Generation Capecitabine (NGC) (a combination of PCS6422 and capecitabine): we have identified lower capecitabine dosage regimens when administered in NGC that will help avoid dose-limiting toxicities such as hand-foot syndrome, yet provide approximately 50-times greater potency than capecitabine alone. We will complete this study in the near future and seek FDA confirmation of our plans to implement the principles of the Project Optimus Oncology Initiative, wherein the objective is to optimize dosing to achieve a better balance between efficacy and safety than merely using the maximum tolerated dose.
- PCS12852: we have shown a statistical difference in the gastric emptying rate between the 6 patients on 0.5 mg of PCS12852 and the 8 patients on placebo at p-value < 0.10 with mild to moderate adverse events. We anticipate having the analysis of the gastroparesis symptoms completed by the end of the year.

All our energies have been directed towards the completion of these trials that inform the next steps for these much-needed therapies.

Advancing these drugs in their respective clinical trial allows us to obtain the clinical data to better define each pivotal trial as well as provide us with more insight into how the FDA will review each of these products as we plan the road maps for designing the studies for our New Drug Applications to FDA.

Financial Results for the Nine Months Ended September 30, 2022

Our cash balance on September 30, 2022, was $9.1 million, which should be sufficient to complete our three on-going clinical trials and fund our operations into the third quarter of 2023. During the nine months ended September 30, 2022, we spent $7.1 million in cash for these three clinical trials and in our operations. This is significantly less than our GAAP net loss of $14.4 million due to the effect of non-cash items like amortization and stock-based compensation, and the application of amounts we had prepaid to our CROs last year.

Our net loss for the nine months ended September 30, 2022, was $14.4 million or $0.90 per share compared to a net loss of $8.2 million, or $0.54 per share for the same period of 2021. The increase in our net loss relates primarily to increased clinical trial costs we incurred in our three ongoing trials. For the nine months ended September 30, 2022, we incurred $8.3 million in research and development costs, an increase of $3.5 million when compared to the same period of 2021. We anticipate clinical trial costs will continue to increase for the rest of the year as our trials continue to progress and we fund development activities for the other drugs in our pipeline.

During the nine months ending September 30, 2022, our general and administrative expenses totaled $6.1 million compared to $3.4 million for the same period in 2021. The increase related primarily to increases in non-cash or stock-based compensation costs, along with other operating and consulting costs. We allocated $6.1 million of non-cash compensation costs between our R&D and G&A costs, with the majority recorded as G&A.

Our net cash used in operating activities during the nine months ended September 30, 2022, increased by $1.1 million to $7.1 million, compared to $6 million for the same period in 2021. While we experienced increased GAAP costs related to our clinical trials and operations, we continued to make use of equity incentives to compensate our executive and development team, thereby reducing our cash outflow, and we were able to apply previously made advanced payments to our CROs against current trial costs.

As of September 30, 2022, we had 15.9 million common shares outstanding.

Conference Call Information

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

Date: November 8, 2022
Time: 4:30 p.m. ET
Toll Free: 888-506-0062
International: 973-528-0011
Entry Code: 178912
Live Webcast: https://www.webcaster4.com/Webcast/Page/2572/46906

Conference Call Replay Information
Toll-free: 877-481-4010
International: 919-882-2331
Replay Passcode: 46906
Replay Webcast: https://www.webcaster4.com/Webcast/Page/2572/46906

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 these criteria for selection to further develop its pipeline programs to achieve high-value milestones effectively and efficiently. Active clinical pipeline programs include Next Generation Capecitabine (formerly identified as PCS6422) for metastatic colorectal cancer and breast cancer, PCS499 (ulcerative necrobiosis lipoidica) and PCS12852 (GI motility/gastroparesis). 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 release contains forward-looking statements. The statements in this press release that are not purely historical are forward-looking statements which involve risks and uncertainties. Actual future performance outcomes and results may differ materially from those expressed in forward-looking statements. 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.

For More Information:
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Patrick Lin
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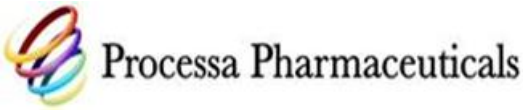
plin@processapharma.com

Exhibit 99.2



PCS12852 Improves Gastric Emptying in Gastroparesis Patients

- In a Phase 2A Proof-of-Concept trial, the Gastric Emptying Breath Test (GEBT) results demonstrated statistical improvement in gastric emptying in gastroparesis patients receiving 0.5 mg of PCS12852 (6 patients) as compared to placebo (8 patients) at a $p < 0.10$ level.
- Adverse events associated with this Phase 2A trial were mild to moderate with no clinically significant cardiovascular or serious adverse events.
- Evaluation of the effect of PCS12852 on gastroparesis symptoms is expected before the end of this year.
- Processa plans to initiate a Phase 2B trial in 2023.

HANOVER, MD – November 8, 2022 — Processa Pharmaceuticals, Inc. (Nasdaq: PCSA), a diversified clinical-stage company developing products to improve survival and/or the quality of life for patients who have an unmet medical need condition, announces positive gastric emptying results from its PCS12852 Phase 2A trial in patients with moderate to severe gastroparesis. This Phase 2A trial was a 4-week placebo-controlled, randomized, dose-response trial designed to evaluate the effect of PCS12852 on gastric emptying, safety, pharmacokinetics, and gastroparesis symptoms. Two dosage regimens of PCS12852 versus placebo were evaluated in patients with moderate to severe gastroparesis.

PCS12852 is a novel, potent, and highly selective 5-hydroxytryptamine-4 (5-HT4) receptor agonist. While there are other 5-HT4 receptor agonists used to treat gastrointestinal (GI) motility disorders, these have less 5-HT4 selectivity and are associated with serious cardiovascular side effects due to the binding to other receptors. Although 2-5 million patients have moderate to severe chronic gastroparesis in the U.S., the only FDA-approved treatment options for gastroparesis have black box warnings and can only be used for 12 weeks due to adverse events.

In contrast, PCS12852 has been shown in normal healthy volunteers and constipation patients to increase GI function with no cardiovascular and no serious adverse effects. Adverse events associated with this Phase 2A trial were mild to moderate, occurring within the first few days after starting treatment, and quickly resolved without any sequelae. There were no clinically significant cardiovascular, unexpected, or serious adverse events (SAEs) reported during the study.

Since the gastric emptying rate in gastroparesis patients is known to be delayed, the gastric emptying rate in the Phase 2A study was assessed using the Cairn Diagnostic ^{13}C Spirulina Gastric Emptying Breath Test (GEBT), which is an FDA-approved diagnostic tool used for measuring the rate of solid-phase gastric emptying and for identifying delayed gastric emptying. The gastric emptying rate half time (t_{50}), as measured by the GEBT from baseline to Day 28, was calculated for each patient.

GEBT results from this small Phase 2A Proof-of-Concept study, which included a total of 14 patients in the 0.5 mg (6 patients) and placebo (8 patients) groups, demonstrated statistical improvement in gastric emptying in patients receiving 0.5 mg of PCS12852 as compared to placebo at a $p < 0.10$ level. The mean (±SD) t_{50} change from baseline was decreased for 0.5 mg PCS12852 compared with placebo by -31.90 ± 50.53 min vs -9.36 ±42.43 min, respectively. Differences were not observed between the placebo and the 0.1 mg dose.

“We are pleased that this first Phase 2A study with PCS12852 was able to demonstrate a prokinetic effect and improve gastric emptying in gastroparesis patients,” said Dr. Sian Bigora, Chief Development Officer at Processa. “The data from this study will inform the design of our planned Phase 2B study. Gastroparesis continues to be a serious disease that has unmet needs, and we are hopeful that PCS12852 will ultimately help improve the quality of life of gastroparesis patients.”

About Gastroparesis

Gastroparesis is a disorder characterized by delayed gastric emptying of solid food in the absence of mechanical obstruction, particularly pyloric stenosis. This delay may result in the cardinal symptoms of early satiety, postprandial fullness, nausea, vomiting, belching, bloating, and pain. Gastroparesis can be idiopathic, associated with diabetes mellitus, can occur after a medical intervention (iatrogenic or post-surgical), may be associated with neurological disorders, or may occur after a bacterial or viral infection. Although there have been advances in understanding the mechanisms and pathophysiology of gastroparesis, there are still significant gaps in knowledge, inconsistencies across studies, and potential differences between different etiological groups (e.g., diabetic versus idiopathic). Gastroparesis is associated with significantly lower survival. In addition to its effect on mortality, gastroparesis symptoms negatively impact the quality of life and day-to-day functioning of patients. With the limitation on currently approved treatments for gastroparesis, there still is a need for new, effective treatments for the millions of patients with this disorder

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 its Regulatory Science Approach criteria when selecting drugs for development in order to achieve high-value milestones effectively and efficiently. Active clinical pipeline programs include: PCS6422 (metastatic colorectal cancer, breast cancer), PCS12852 (gastroparesis, functional constipation), and PCS499 (ulcerative necrobiosis lipoidica). Members of the Processa development team have been involved with more than 30 approvals for indications in almost every division of the FDA (including drug products targeted to orphan disease conditions) and more than 100 FDA meetings throughout their careers. For more information, visit our website at www.processapharma.com.

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Exhibit 99.3


Processa Pharmaceuticals, Inc.
(Nasdaq: PCSA)
November 8, 2022
3Q2022
Processa Pharmaceuticals

Disclaimer: Forward Looking Statements

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

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

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

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

3Q2022 Highlights of Positive Next Generation Capecitabine (NGC) and PCS12852 Trials

- In the ongoing NGC Phase 1B trial, Processa has successfully identified NGC dosage regimens and 5-Fluorouracil (5-FU) exposures that were well tolerated as well as NGC regimens and 5-FU exposures that had dose-limiting side effects
- From the different NGC regimens evaluated, the timeline for the formation of new DPD is approximately 24-72 hours after the PCS6422 dose while NGC potency, based on 5-FU systemic exposure, was increased to 50-times greater than reported for FDA-approved capecitabine
- In 2023, Processa plans to initiate an efficacy/safety Phase 2B trial following FDA's Project Optimus Initiative after meeting with the FDA

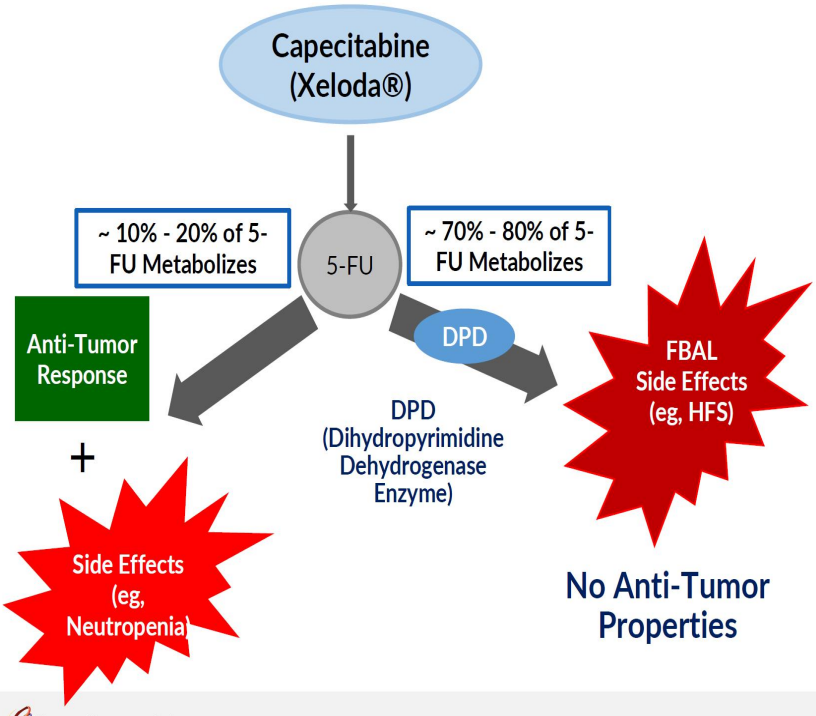
- The PCS12852 Proof-of-Concept Phase 2A trial in gastroparesis patients has been completed with the results showing that the change in gastric emptying rate after 28 days of treatment on 0.5 mg of PCS12852 was statistically better than placebo treatment at a p-value less than 0.10
- The change in gastroparesis symptoms for 12852 vs placebo is expected by the end of the year
- Processa plans to initiate an efficacy/safety Phase 2B trial in 2023

Processa Pharmaceuticals

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

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

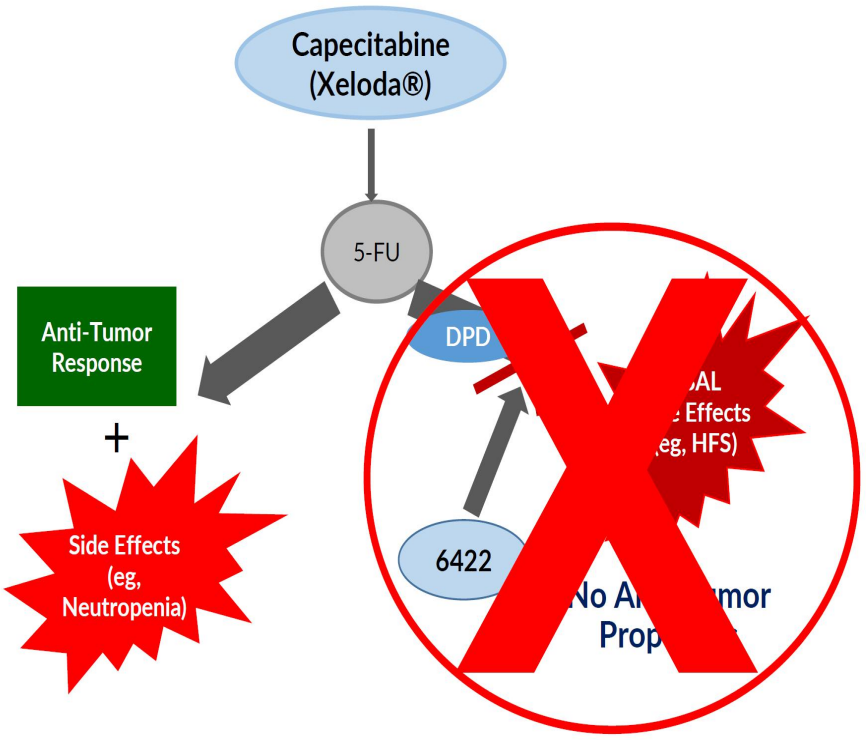
5-Fluorourcail Approved by FDA in 1962 & Capecitabine (Oral Form of 5-Fluorouracil) Approved by FDA in 1998



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

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

PCS6422 Irreversibly Inhibits DPD (Dihydropyrimidine Dehydrogenase Enzyme)



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

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

- Each Next Generation Capecitabine (NGC) dosage regimen is a combination of a PCS6422 regimen and a separate capecitabine regimen; Example of a single treatment cycle:

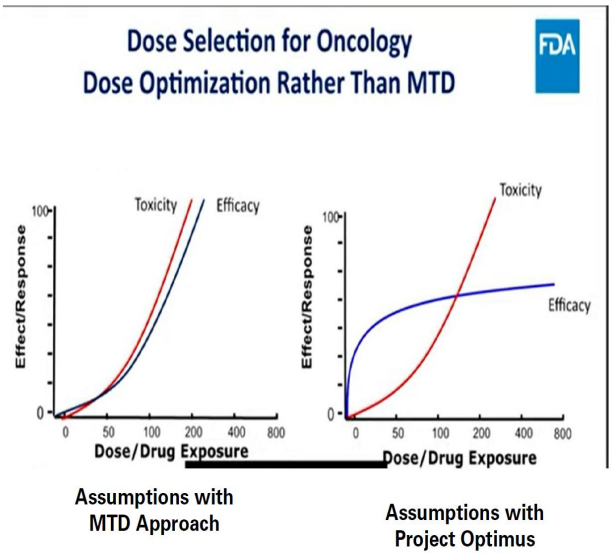
Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9-14
6422	----	----	----	----	----	----	----	----
----	Cap	Cap	Cap	Cap	Cap	Cap	Cap	----

- **From the different NGC regimens evaluated, the timeline for the formation of new DPD is approximately 24-72 hours after the PCS6422 dose while NGC potency, based on 5-FU systemic exposure, was increased to 50-times greater than reported for FDA-approved capecitabine**

- **Processa has successfully identified NGC dosage regimens and 5-Fluorouracil (5-FU) exposures that were well tolerated as well as NGC regimens and 5-FU exposures that had dose-limiting side effects**

- **In 2023, Processa plans to initiate an efficacy/safety Phase 2B trial following FDA's Project Optimus Initiative after meeting with the FDA**

FDA Wants Sponsors to Develop Oncology Drugs Using Principles of Project Optimus



Assumptions with MTD Approach

Assumptions with Project Optimus

Optimizing the Next Generation Capecitabine Regimen Using FDA Project Optimus Initiative

- The approach used for oncology drugs has assumed efficacy and toxicity follow a parallel path; determine the DLT dosing regimen and then use the MTD regimen (the greatest exposure that is still "safe") for the pivotal trial
- The Project Optimus Initiative recommended by the FDA Oncology Division suggests that the MTD approach may not find the optimal efficacy/safety regimen
- The relationship between clinical response and dosage regimen or drug exposure needs to be evaluated to determine if there is a regimen with similar efficacy but significantly fewer and/or less severe side effects
- **Project Optimus Initiative is especially important for combination drug therapy such as NGC where the optimal efficacy/safety balance is dependent on two regimens**

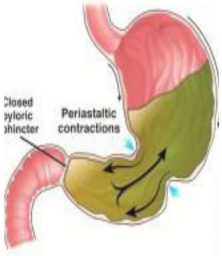
Processa Pharmaceuticals

PCS12852

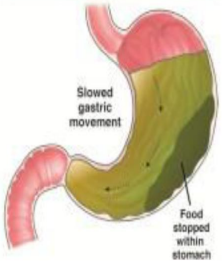
GI Motility Conditions (eg, Gastroparesis)

Gastroparesis

Normal Gastric Emptying



Gastroparesis



Gastroparesis is a condition that affects the normal spontaneous movement of the muscles (motility) in your stomach. The typical symptoms are:

- Feeling full soon after starting a meal
- Feeling full long after eating a meal
- Nausea, Vomiting
- Too much bloating, Too much belching
- Pain in your upper abdomen
- Heartburn
- Poor appetite

- Target Indication:
  - Treatment of moderate to severe gastroparesis
- Target Claims:
  - Improves gastric emptying rate and the symptoms associated with moderate to severe gastroparesis

Treatment of Gastroparesis (> $1.5B Market)

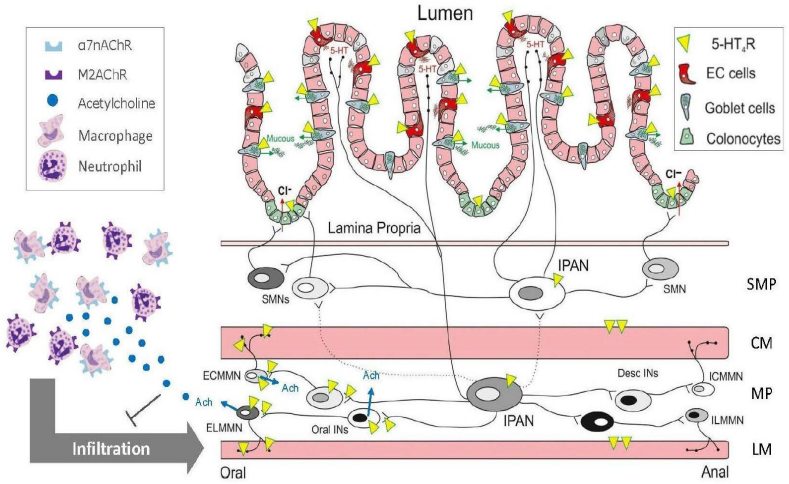
- Existing FDA approved drugs and off-labeled prescribed drugs are mainly used for the treatment of diabetic gastroparesis
- **All these drugs have a poor side effect profile limiting their use**
- Present market size for gastroparesis is estimated to be over $1.0 B in the U.S.

	PCS12852	Other 5HT4 Drug (e.g., Cisapride, Prucalopride, Mosapride)	Dopamine D2 Antagonist (.e.g,, Metoclopramide)
Target Population	• Potentially all gastroparesis patients (e.g., diabetic, idiopathic)	• Diabetic gastroparesis patients	• Diabetic gastroparesis patients
Binding	• Specific & potent 5HT4 receptor binding	• Less specific binding to 5HT4 than 12852 • Less potent than 12852	• Binds to Dopamine D2 receptors
Side Effects	• **No serious side effects in clinical studies to date**	• **Serious cardiovascular side effects (e.g., cisapride removed from market)** • **Suicidal ideation (e.g., prucalopride)**	• **Black Box Warning serious neurological side effects, Side effects require limited use**
Efficacy	• Increase gastric emptying rate in patients with constipation	• Increase gastric emptying rate • Successful treatment demonstrated	• Only drug FDA approved for treatment of gastroparesis

PCS12852: 5-HT4 Receptor Agonist - Wide Range of GI Motility Disorders

Clinically Proven Mechanism of Action

- **Enhancement of both GI motility & secretion** via increased Ach, 5-HT, Cl-and mucus release
- Neural anti-inflammatory effects on post-operative ileus by inhibiting macrophage and neutrophil infiltration
- Wide development potential to treat POGD, gastroparesis, CIC, IBS-c, OIC, and overlap syndrome



Adopted from Gwynne, R.M(2019), Neurogastroenterology & Motility 31(10) and Tsuchida, Y. (2011), Gut 60, 638–647

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

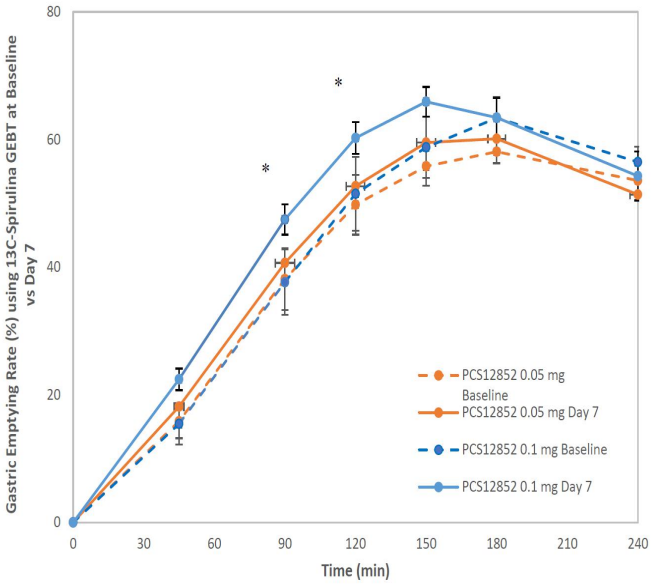
PCS12852 Effect on Gastric Emptying: South Korean and US Trials

PCS12852 is a More Potent and More Selective 5HT4 Agonist than Previous 5HT4 Agonists

South Korean Trial

7 – 8 patients per group

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

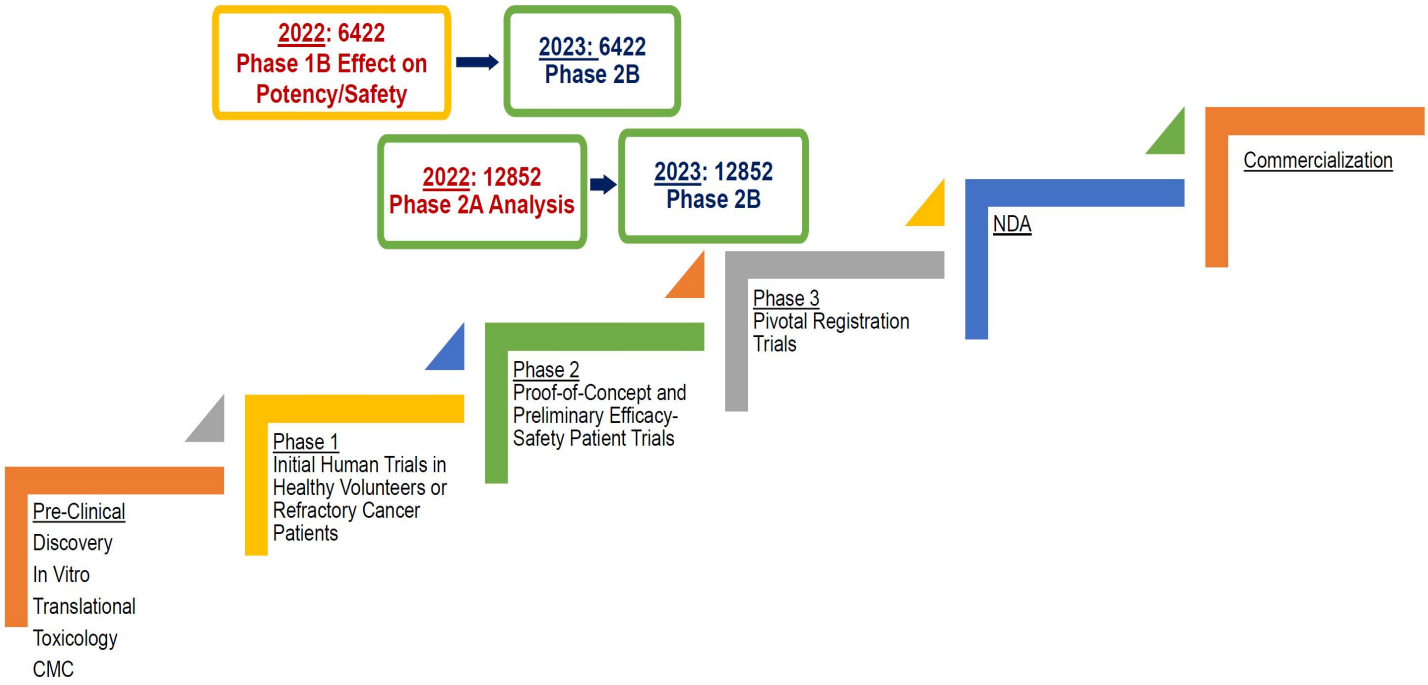


U.S. Phase 2A Proof-of-Concept Trial in Gastroparesis Patients

- Gastric Emptying Breath Test (GEBT) results demonstrated **statistically significant improvement in gastric emptying rate** in patients receiving 0.5 mg of PCS12852 (6 patients) as compared to placebo (8 patients) **at a p < 0.10 level**
- GEBT for 0.1 mg of PCS12852 was not significantly different from the placebo in contrast to what was found in the previous healthy volunteer/constipation patient trial
- **Adverse events were mild to moderate with no clinically significant cardiovascular or serious adverse events**
- Effect on gastroparesis symptoms expected by end of 2022
- **Processa plans to initiate a Phase 2B trial in 2023**

Moving Closer to NDA for 3 Drugs, Each with the Potential of $1B Sales

- 2022 Milestones in Dark Red Text
- 2023 Study Start-Up in Dark Blue Text



Processa Pharmaceuticals

Corporate Overview

Our People Lead to Success

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

Management Team

David Young, PharmD. PhD
President and Chief Executive Officer

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

Justin Yorke
Chairman of the Board
Manager of the San Gabriel Fund, JMW Fund and the Richland Fund

David Young, PharmD. PhD
President and CEO, Processa Pharmaceuticals
Former CSO and Independent Director, Questcor Pharmaceuticals

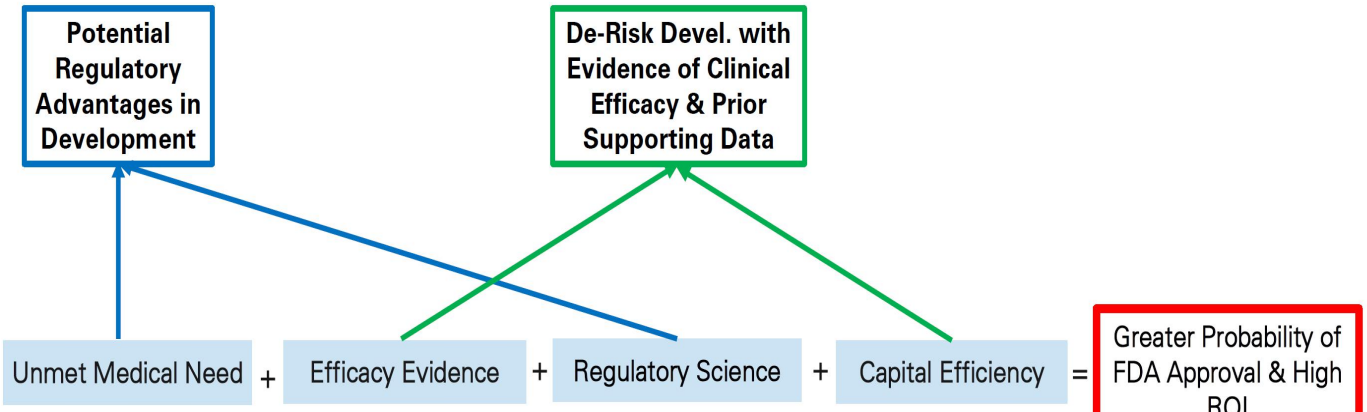
Khoso Baluch
Independent Director
Former CEO of CorMedix, Inc.
Independent Director, Poxel SA

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

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

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

Approach to Building the Processa 5 Drug Pipeline
Drug Development Company Not a Discovery Company



- Clear and obvious **patient need to improve quality-of-life and/or survival**
- **Favorable competitive** dynamics

- **Evidence of clinical efficacy** in targeted medical condition
- **Higher** probability of **successful development**

- **Design development program and clinical trials** to improve the likelihood of an FDA approvable Benefit-Risk profile
- **Increase the probability of approval while decreasing the time and cost to approval**

- **Leverage** considerable **prior investments** before licensing (tox, CMC, etc.)
- **Conduct efficient development** program and clinical trial design

- **Intelligently monetize assets**

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

- Processa has a **capital-efficient approach** based on very low overhead, disciplined licensing, and intelligent/efficient development, all leading to a potentially high ROI (6 C-suite to receive < $600,000 total cash salary in 2022)
  - **Management and Board investment > $6 M**
  - **C-Suite exchanged approx. $1.25 M of salary for PCSA shares in 2022**
- Processa has **enough cash to complete the 3 ongoing clinical trials in 3 separate $1B markets** with key value-added milestones occurring in 2022 and 2023 while moving closer to NDA
  - **Next Generation Capecitabine (PCS6422+capecitabine) Phase 1B** trial in GI cancer
  - **PCS12852 Phase 2A** trial in gastroparesis
  - **PCS499 Phase 2B trial** in ulcerative necrobiosis lipoidica
- Three cancer drugs in the 5 drug pipeline
  - **Next Generation Capecitabine (PCS6422+capecitabine)** Phase 1B trial in **GI cancer**
  - **PCS3117 (similar to Gemcitabine) Orphan Designation and IND for pancreatic cancer;** Phase 2B study design underway with the possibility of biomarkers
  - **PCS11T (next generation irinotecan)** to begin CMC and IND enabling tox studies for **small cell lung cancer**

Pipeline of Five Drugs Each with $1B Market Opportunity

Drug	Disease Target	Market
Next Generation Capecitabine (PCS6422) Phase 1B	Metastatic Colorectal Cancer and Other Types of Cancer	U.S. Incidence of Metastatic Colorectal Cancer : > 60K Pts U.S. Max Ann. Sales mCRC: $500 M – $1.0 B Global Max Ann. Sales mCRC: > $1.0 B
PCS12852 Phase 2A	Moderate/Severe Gastroparesis and Other GI Motility Conditions	U.S. Prevalence of Mod/Sev Gastroparesis: 2M - 5M Pts U.S. Max Ann. Sales Mod/Sev Gastroparesis: > $1.0 B
PCS499 Phase 2B	Ulcerative Necrobiosis Lipoidica (uNL) and other Rare Diseases	U.S. Prevalence of uNL: 10K - 50K Pts U.S. Max Ann. Sales uNL: $500 M - $1.0 B Global Max Sales uNL: > $1.0 B
PCS3117 Phase 2B	Pancreatic, Other Cancers	PCS3117 market would target patients who receive Gemcitabine (both Gemcitabine resistant and non-resistant patients)
PCS11T Pre-IND	SC Lung, Other Cancers	PCS11T market would target patients who receive Irinotecan (PCS11T potentially has a better side effect profile)

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