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

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): September 7, 2022

Commission file number 333-184948

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

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 an updated 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.

Exhibit No.	**Exhibit Description**
99.1	Processa Pharmaceuticals Investor Presentation dated September 2022
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL documents)

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, on September 7, 2022.

PROCESSA PHARMACEUTICALS, INC.
Registrant

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

Processa Pharmaceuticals

The Processa Regulatory Science Approach

David Young, PharmD, PhD
President and CEO
Processa Pharmaceuticals, Inc (NASDAQ: PCSA)

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.

Our People Lead to Success

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

Processa Approach to Building a High ROI Pipeline of Drugs

Track Record of 30 FDA Approvals Across Almost Every Division of FDA

DEVELOP NOT **DISCOVER**

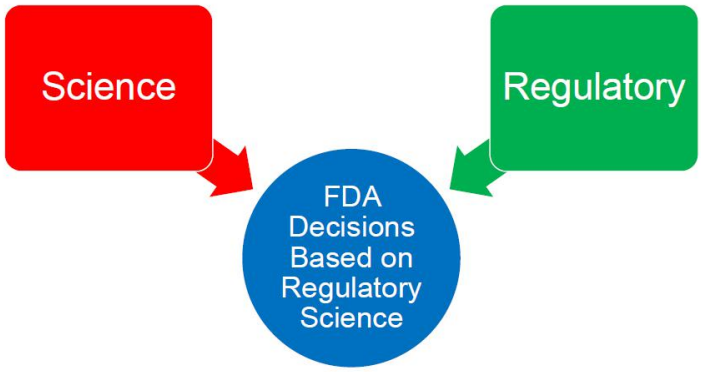
REGULATORY SCIENCE PLATFORM

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**	• **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) Highlights

- The creation of the Processa **Regulatory Science Approach** to drug development began 30 years ago from 2 FDA contracts that addressed multiple regulatory FDA questions and has been refined with approvals in almost every division of FDA
- The Management & Development Team has an enviable track record of approvals and multi-billion exits
- Processa has 5 drugs in its pipeline, each drug with **potential maximum sales of > $1.0B;** 4 of the 5 drugs have INDs, **3 of the 4 drugs are presently in clinical trials**
- 2H2022
  - The Next Generation Capecitabine (PCS6422+Capecitabine) clinical trial has re-booted (after interim analysis protocol changes) and sites are enrolling patients with an expectation that **key data on the improved potency and metabolism will be available and increasing doses of Next Generations Capecitabine will be evaluated**
  - **PCS12852 gastroparesis prokinetic evaluation and the efficacy/safety analysis will be completed**
  - **PCS499 Phase 2B interim analysis cohort** will be completely enrolled
- 2023
  - The Next Generation Capecitabine (PCS6422+Capecitabine) **MTD will be determined and the Phase 2B or 3 trial will be initiated**
  - **PCS12852 Phase 2B trial begins enrollment**
  - **PCS499 Phase 2B interim analysis results**, trial enrollment completed to provide **final results,** end of Phase 2 meeting with FDA, and **Phase 3 site start-up will be initiated**

In Drug Development – How do you Approach Development?
Science vs Regulatory vs Regulatory Science



Benefit-Risk Assessment: Foundation for FDA's Regulatory Review/Approval

FDA States:

"Simply put, for a drug to be approved for marketing, FDA must determine that the drug is effective and that its expected benefits outweigh its potential risks to patients. This assessment is informed by an extensive body of evidence about the drug's safety and efficacy submitted by an applicant. "

Think Like an FDA New Drug Application Review Team:

Some considerations when evaluating the benefit-risk analysis.

- **Benefit refers to clinical benefit, requiring the primary endpoint to be clinically relevant**
- **Risk includes more than drug safety (e.g., the risk associated with existing poor treatment options or no treatment options)**
- **Approval is based on benefit-risk in a definable target population**

Benefit-Risk Integrated Assessment

Dimension	Disease and Drug
Analysis of Condition	• Identify patients and the seriousness of their condition while recognizing and measuring what matters most to patients
Current Treatment Options	• Define standard of care and therapeutic treatment options • Benefit-risk of present options
Benefit of New Approved Treatment	• Identify and measure clinically meaningful endpoints for the patient and FDA • Benefit includes efficacy of the drug and having clinical trial-based evidence of efficacy rather than case study evidence
Risk & Risk Management of New Approved Treatment	• Identify and measure the safety risk of new and existing treatments • Risk includes both safety & potential of not having approved treatment option

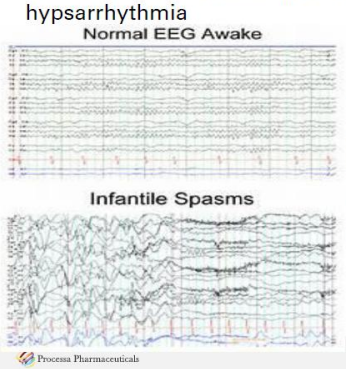
Examples of our Regulatory Science Approach in Drug Development

- **Evaluate and Minimize Risk (Approach Used by Processa Team at Questcor)**
  - Acthar FDA approval: Risk is more than the safety of the drug (Processa Team when at Questcor obtained sNDA approval in 2010 for Infantile Spasms and 18 other indications)

- **Define Clinically Meaningful Endpoint in a Targeted Population (Processa Pipeline Drug)**
  - PCS499 development in ulcerated Necrobiosis Lipoidica (uNL) vs all Necrobiosis Lipoidica (NL) patients (Processa presently running a Phase 2B trial)

Case Study 1: Risk is More than Safety of a Drug in a Serious Life-Threatening Condition such as Infantile Spasms

- Typically occurs in children less than 2 years old; occurs in 2,000 – 2,500 children per year
- Premature death rate of 5-31% and > 60% of untreated/inadequately treated patients have serious mental/physical disabilities with other types of seizures developing over time
- Clinically meaningful endpoint defined by seizures ("spasms") and abnormal EEG called hypsarrhythmia



- In order to improve cognitive development and mortality rate, therapeutic objective is to rapidly control seizures and normalize EEG.

Case Study 1: Acthar Gel Used Off-Label for IS

Acthar is a purified preparation of adrenocorticotropic hormone in a gel that was used off-label for the treatment of IS for over 30 years with a wide range of dosage regimens
IS sales in 2006-2007 represented almost 100% of sales for Questcor

Acthar was approved in 1952 and became a DESI (Drug Efficacy Study Implementation) drug in 1962. Prior to being acquired by Questcor Pharmaceuticals, the Acthar label included over 50 indications including 1978 approval for multiple sclerosis flares

↓

In 2007 Questcor received an FDA Complete Response Letter for the IS sNDA
(Tried to Obtain Approval Based on Need without Efficacy-Safety Clinical Data)

↓

In 2010 FDA approved a new label for Acthar which included IS and 18 other indications
(Approval in IS based on the benefit of Acthar treatment outweighing Acthar safety risks and risks of patients using Acthar off-label or not treating patients)

Case Study 1: Benefit Outweighed Safety Risk & Risks Associated with Off-Label Use

- Negotiated with FDA what was to be included in the sNDA given conducting a trial when patients are treated off-label for IS was not ethical
- BENEFIT
  - Emphasized that approval would provide consistent guidance on Acthar IS treatment given the different regimens that were used off-label
  - Evaluated Acthar in a previous academic trial of 29 patients (Acthar vs prednisone), not powered to FDA standards; Combined endpoint of spasms and EEG improvement was statistically better in the Acthar treated group than prednisone group; other smaller studies supported the efficacy and regimen
- RISK
  - Safety supported through evaluation of 311 patients on Acthar (134 patients on proposed labelled regimen, 177 on different regimens than proposed)
  - Safety profile was acceptable to FDA, but a Risk Evaluation and Mitigation Strategy (REMS) drug safety program was required

Case Study 1: Benefit-Risk Integrated Assessment

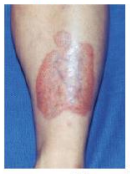
Dimension	Disease and Drug
Analysis of Condition	• Identify patients and the seriousness of their condition while recognizing and measuring what matters most to patients **IS - Very Serious Orphan Condition**
Current Treatment Options	• Define standard of care and therapeutic treatment options • Benefit-risk of present options **No approved drug, Acthar used off-label with various regimens**
Benefit of New Approved Treatment	• Identify and measure clinically meaningful endpoints for the patient and FDA • Benefit includes efficacy of the drug as well as having clinical trial-based evidence of efficacy rather than case study off-label evidence **Conducting a new trial not possible, approving Acthar provided guidance**
Risk & Risk Management of New Approved Treatment	• Identify and measure the safety risk of new and existing treatments • Risk includes both safety & potential of not having approved treatment option **Risks associated with both off-label use of Acthar & not treating patients**

Case Study 2: Select Clinically Meaningful Primary Endpoint in Targeted Population

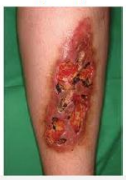
Targeting Ulcerative Necrobiosis Lipoidica (uNL) Patients Instead of all Necrobiosis Lipoidica (NL) Patients Given FDA Requires a Clinically Meaningful, Measurable Primary Endpoint

- **In NL patients the skin and tissue below the skin becomes necrotic** and can last from months to years with complications such as infections, amputation, and cancer; improvement of NL has not been quantified
- 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**
- 30% of NL patients have ulcers occurring naturally or from contact trauma to the lesion; **the clinically beneficial endpoint of complete wound closure has been previously defined by FDA in the Ulcer and Wound Guidance**
- Epidemiological prevalence estimates range between 75,000 – 185,000 for NL & 22,000 – 55,000 for uNL patients in the U.S.
- **Natural complete healing of moderate to severe ulcers** during the first 1-2 years after onset occurs **in less than 5% of these patients**

Mild NL

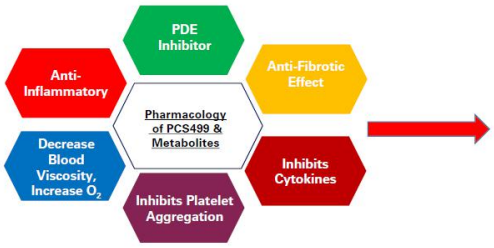


Ulcerative NL (uNL)



Case Study 2: Why PCS499 for the Treatment of uNL?

- **Drugs used off-label with mixed success given their side effect profile and/or limited efficacy** (for example; pentoxifylline (PTX), immunomodulating agents)
- **PCS499 is the deuterated analog of a major metabolite of PTX**; has identical metabolites and pharmacological targets but **PK of PCS499 + metabolites is different than PK of PTX + metabolites resulting in a better PCS499 safety profile and allowing the administration of a higher dose of PCS499**

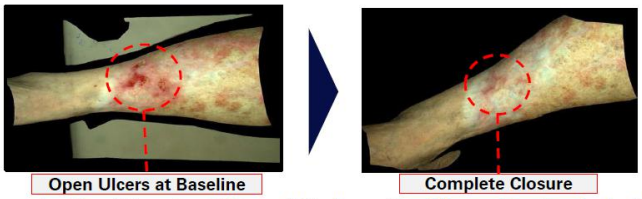


Pathophysiological Changes in NL

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

Case Study 2: PCS499 Safe and Efficacious in NL and uNL Patients

- In open-label trial of 10 NL and 2 uNL patients, **all ulcers closed** in the 2 uNL patients, **including new contact trauma ulcers &** non-ulcerated patients reported an improvement
- **1.8 gm/d of PCS499 was well tolerated in the 12 patients**



Open Ulcers at Baseline — Complete Closure

- Now conducting 20 patient Phase 2B ulcerative NL **randomized, double-blind, placebo-controlled trial, primary endpoint = proportion of patients with complete ulcer closure**
- **One adequately powered pivotal Phase 3 trial initiated in 2023-2024** with a supportive phase 2B may be sufficient to demonstrate that the benefit-risk profile is approvable given the lack of treatment options and the seriousness of the condition

Case Study 2: Benefit-Risk Integrated Assessment

Dimension	Disease and Drug
Analysis of Condition	• Identify patients and the seriousness of their condition while recognizing and measuring what matters most to patients **Serious condition - affects QOL & may lead to other medical issues**
Current Treatment Options	• Define standard of care and therapeutic treatment options • Benefit-risk of present options **No approved drug, off-label drug efficacy & safety not adequate**
Benefit of New Approved Treatment	• Identify and measure clinically meaningful endpoints for the patient and FDA • Benefit includes efficacy of the drug as well as having clinical trial-based evidence of efficacy rather than case study off-label evidence **Clinical benefit and endpoint in uNL well defined, but not in non uNL**
Risk & Risk Management of New Approved Treatment	• Identify and measure the safety risk of new and existing treatments • Risk includes both safety & potential of not having approved treatment option **Risks associated with both off-label use of drugs & not treating patients**

Pipeline of Five Drugs Each with $1B Market Opportunity

- 4 Drugs in the clinical stage of development and 1 in Pre-IND
  - 3 Drugs targeting the treatment of cancer (Phase 1B, Phase 2B, Pre-IND Stage) (Blue Box, Blue Arrows)
  - 1 Drug in Phase 2B targeting an orphan condition with no approved treatments and no effective standard of care and 1 drug in Phase 2A targeting an unmet medical need condition where the existing treatment options have limited use with serious adverse events (Orange Box, Yellow Arrow)

Drug	Disease Target	Non-clin	Phase 1	Phase 2	Phase 3
Next Generation Capecitabine Phase 1B (PCS6422)	Metastatic Colorectal, Other Cancers	→	→		
PCS12852 Phase 2A	Gastroparesis	→	→		
PCS499 Phase 2B	Ulcerative Necrobiosis Lipoidica	→	→	→	
PCS3117 Phase 2B	Pancreatic, Other Cancers	→	→	→	
PCS11T Pre-IND	SC Lung, Other Cancers	→			

Pipeline Milestones 2022 and 2023

Drug	Disease Target	Status and Milestones
Next Generation Capecitabine Phase 1B (PCS6422)	**Metastatic Colorectal Cancer** **U.S. Incidence: > 60K Pts** **U.S. Max Ann. Sales: $500 M – $1.0 B** **Global Max Ann. Sales: > $1.0 B**	• Cohorts 1, 2A, and 2B Completed • **2H2022**: Complete Enrollment of Cohort 2B, 2C and Conduct Interim Analysis of Cohort 2A-C to Evaluate the Inhibition & De Novo Formation Timeline of the DPD Enzyme to Improve Potency/Safety Profile; Increase Dose; New Site Added for a Total of 6 Sites • **2023**: Complete 1B Trial & MTD Analysis; Define Potential Paths to Approval; Meet with FDA to Define Path Forward; Initiate Phase 2B or Adaptive Designed Phase 3 Trial
PCS12852 Phase 2A	**Moderate to Severe Gastroparesis** **U.S. Prevalence: 2M - 5M Pts** **U.S. Max Ann. Sales: > $1.0 B**	• Enrollment Completed in Moderate to Severe Gastroparesis Patients • **2H2022**: Complete Prokinetic Primary Endpoint Analysis and Efficacy/Safety Analysis • **2023**: Initiate Phase 2B Trial
PCS499 Phase 2B	**Ulcerative Necrobiosis Lipoidica** **U.S. Prevalence: 10K - 50K Pts** **U.S. Max Ann. Sales: $500 M - $1.0 B** **Global Max Sales: > $1.0 B**	• 3 Pts Completed Trial, 1 Pt in Trial, Supplemental Patient Enrollment Programs Improving Recruitment • **2H2022**: Complete Interim Cohort Enrollment • **2023:** Complete Analysis of Primary Endpoint for Interim Cohort; Complete Trial Enrollment; Complete Phase 2B Trial and Analysis; Finalize Potential Regulatory Paths to FDA Approval; Meet with FDA for an End-of-Phase 2 Meeting; Phase 3 Site Start-up to be Initiated
PCS3117 Phase 2B	**Pancreatic, Other Cancers**	• Finalize Potential Paths to FDA Approval & Meet with FDA to Define Path Forward
PCS11T Pre-IND	**SC Lung, Other Cancers**	• Select Manufacturing Sites & Design Initial Clinical Program

Pipeline Milestones 2022 and 2023

Drug	Disease Target	Status and Milestones
Next Generation Capecitabine Phase 1B (PCS6422)	**Metastatic Colorectal Cancer** **U.S. Incidence: > 60K Pts** **U.S. Max Ann. Sales: $500 M – $1.0 B** **Global Max Ann. Sales: > $1.0 B**	• Cohorts 1, 2A, and 2B Completed • **2H2022:** Complete Enrollment of Cohort 2B, 2C and Conduct Interim Analysis of Cohort 2A-C to Evaluate the Inhibition & De Novo Formation Timeline of the DPD Enzyme to Improve Potency/Safety Profile; Increase Dose; New Site Added for a Total of 6 Sites • **2023**: Complete 1B Trial & MTD Analysis; Define Potential Paths to Approval; Meet with FDA to Define Path Forward; Initiate Phase 2B or Adaptive Designed Phase 3 Trial

Pipeline Milestones 2022 and 2023

Drug	Disease Target	Status and Milestones
PCS12852 Phase 2A	**Moderate to Severe Gastroparesis** **U.S. Prevalence: 2M - 5M Pts** **U.S. Max Ann. Sales: > $1.0 B**	• Enrollment Completed in Moderate to Severe Gastroparesis Patients • **2H2022**: Complete Prokinetic Primary Endpoint Analysis and Efficacy/Safety Analysis • **2023**: Initiate Phase 2B Trial

Pipeline Milestones 2022 and 2023

Drug	Disease Target	Status and Milestones
PCS499 Phase 2B	**Ulcerative Necrobiosis Lipoidica** **U.S. Prevalence: 10K - 50K Pts** **U.S. Max Ann. Sales: $500 M - $1.0 B** **Global Max Sales: > $1.0 B**	• 3 Pts Completed Trial, 1 Pt in Trial, Supplemental Patient Enrollment Programs Improving Recruitment • **2H2022**: Complete Interim Cohort Enrollment • **2023:** Complete Analysis of Primary Endpoint for Interim Cohort; Complete Trial Enrollment; Complete Phase 2B Trial and Analysis; Finalize Potential Regulatory Paths to FDA Approval; Meet with FDA for an End-of-Phase 2 Meeting; Phase 3 Site Start-up to be Initiated

Pipeline Milestones 2022 and 2023

Drug	Disease Target	Status and Milestones
PCS3117 Phase 2B	**Pancreatic, Other Cancers**	• Finalize Potential Paths to FDA Approval & Meet with FDA to Define Path Forward
PCS11T Pre-IND	**SC Lung, Other Cancers**	• Select Manufacturing Sites & Design Initial Clinical Program

Processa Pharmaceuticals, Inc (NASDAQ: PCSA) in 2022

Multiple High-Value Milestones to Be Achieved during the Next 4 Months for the 3 Drugs in Clinical Trials

- A PCS6422 dosage regimen in **Next Generation Capecitabine (combination of PCS6422 and Capecitabine)** will be determined that will alter DPD enzyme activity and significantly increase capecitabine potency over 7 days
- The dosing of Next Generation Capecitabine will be further increased in 2022 with the expectation to have the final MTD analysis completed in 1H2023
- The prokinetic (gastric motility) evaluation of **PCS12852** will be completed in gastroparesis patients
- The proof-of-concept Phase 2A efficacy/safety analysis will be completed in gastroparesis patients
- The **PCS499** Phase 2B interim analysis cohort will be completely enrolled with the expectation to readout of the interim data in 1H2023, complete the total trial enrollment in 1H2023, and have final trial analysis in 2H2023