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): October 16, 2023

Commission file number 001-39531

PROCESSA PHARMACEUTICALS, INC.

(Exact name of Registrant as Specified in its Charter)

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

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

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

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

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

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

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

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

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

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock: Par value $.0001	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 7.01. Regulation Disclosure.

A copy of a slide presentation (Presentation Materials") that Processa Pharmaceuticals, Inc. ("Processa Pharmaceuticals") intends to publish to its website, is attached to this Current Report on Form 8-K and Exhibit 99.1. The Presentation Materials speak as of the date of this Current Report on Form 8-K. While Processa Pharmaceuticals may elect to update the Presentation Materials in the future or reflect events and circumstances occurring or existing after the date of this Current Report on Form 8-K, Processa Pharmaceuticals specifically disclaims any obligation to do so. The information contained in this Item 7.01 and Exhibit 99.1 hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

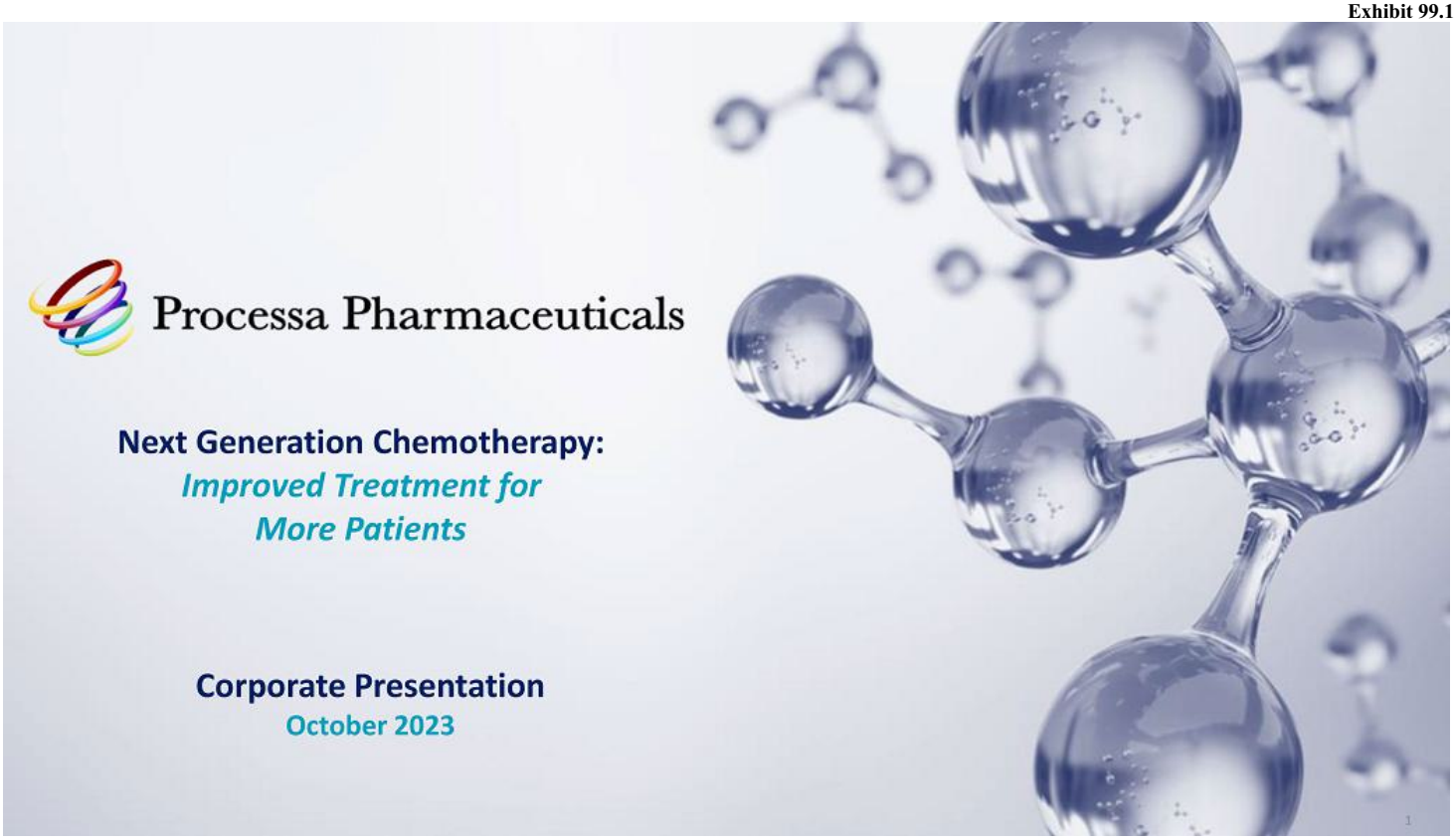
Exhibit No.	**Exhibit Description**
99.1	Processa Pharmaceuticals Investor Presentation dated October 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document)

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 October 16, 2023.

PROCESSA PHARMACEUTICALS, INC.
Registrant

By: */s/ George Ng*
George NG
Chief Executive Officer



Forward Looking Statement and Disclosures

Processa Pharmaceuticals

This presentation includes forward-looking statements based upon our current expectations. Forward-looking statements include, but are not limited to, statements that express our intentions, beliefs, expectations, strategies, predictions, anticipated milestones, and any other statements relating to our future activities or other future events or conditions. These statements are based on current expectations, estimates and projections about our business based, in part, on assumptions made by management. Actual results and the timing of events could differ materially from those anticipated in such forward looking statements as a result of various risks and uncertainties, which include, without limitation: (i) our ability to raise additional money to fund our operations for at least the next 12 months as a going concern and need to raise additional capital to advance our product candidates and preclinical programs, including in light of current stock market conditions; risks related to our ability to successfully implement our strategic plans, including reliance on our lead product candidate; (ii) uncertainties associated with the clinical development and regulatory approval of product candidates, including in light of our recent and ongoing FDA communications; (iii) uncertainties in obtaining successful clinical results for product candidates and unexpected costs that may result therefrom; (iv) risks related to the failure to realize any value from product candidates and preclinical programs being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market; (v) intellectual property risks; (vi) the impact of COVID-19 on our operations, enrollment in and timing of clinical trials; reliance on collaborators; reliance on research and development partners; and (vii) risks related to cybersecurity and data privacy.

These and other risks and uncertainties are more fully described in periodic filings with the SEC, including the factors described in the section entitled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, as amended or supplemented by our Quarterly Reports on Form 10-Q and in other filings that we have made and future filings we will make with the SEC. You should not place undue reliance on these forward-looking statements, which are made only as of the date hereof or as of the dates indicated in the forward-looking statements. We expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations with regard thereto or any change in events, conditions, or circumstances on which any such statements are based.

About Processa Pharmaceuticals

Processa Pharmaceuticals

Next-Generation Chemotherapies (NGCs) Designed to Improve Survival and Quality of Life for Cancer Patients

- A de-risked strategy of developing new chemical entities (NCEs) based on improving pharmacokinetics of existing, proven treatments.
- Management team with decades of experience taking drugs through the FDA's approval process using our proven Regulatory Science Approach which focuses on reforming dose optimization based on maintaining or improving efficacy while reducing toxicities.
- Actively advancing three anti-cancer NCEs, two in clinical development and one near clinic-ready.
- Potential to out-license or partner non-NGC and select NGC drug candidates.

Processa Pharmaceuticals (NASDAQ: PCSA)	
Stock Price (as of 10/15/23)	$0.48
Shares Outstanding (as of 8/4/23)	24.5M
Market Capitalization	$11.81M
Cash & Equivalents (at 6/30/23)	$8.7M
Insider Ownership	22%

Processa Senior Management

Processa Pharmaceuticals

George Ng
Chief Executive Officer

Joined Processa 2023

Former Roles:

- President, COO, & Director, Calidi Biotherapeutics
- Partner, PENG Life Science Ventures
- Founder and President, Scilex Pharmaceuticals
- JD, University of Notre Dame; B.A.S. Dual Degree, University of California, Davis

David Young, Pharm.D, Ph.D.
President, Research and Development

Joined Processa 2017

Former Roles:

- CSO & Independent Director, Questcor
- U.S. President, AGI Therapeutics
- CEO, GloboMax
- Associate Professor, University of Maryland
- Pharm.D., PhD, University of S. California

Sian Bigora, Pharm.D.
Chief Development Officer

Joined Processa 2017

Former Roles:

- VP Regulatory, Questcor
- VP Clinical Research, AGI Therapeutics
- VP Regulatory, ICON Plc, GloboMax
- Dir Clinical Research Unit, Univ. of Maryland
- Pharm.D., University of Maryland

Patrick Lin
Chief Business & Strategy Officer

Joined Processa 2017

Former Roles:

- Founder and Managing Partner, Primarius Capital
- Robertson Stephens & Co.
- Co-Founding Partner, E*Offering
- MBA, Kellogg Graduate School; BS, University of S. California

James Stanker, CPA
Chief Financial Officer

Joined Processa 2018

Former Roles:

- Audit Partner, Grant Thornton
- CFO, NASDAQ listed company and a privately-held life science company
- Director/Audit Committee Chairman, Hesperos
- MBA, California State University; BS, San Jose University

Wendy Guy
Chief Administrative Officer

Joined Processa 2017

Former Roles:

- Senior Manager, Business Operations, Questcor
- Senior Manager, AGI Therapeutics
- Senior Manager, Administration, ICON Plc, GloboMax
- AA, MWCC

Oncology Opportunity

Processa Pharmaceuticals

- More than 200,000 new cancer diagnoses worldwide across multiple indications for each NGC in development.
- NGC compounds will potentially address efficacy and toxicity at an ***optimized*** dose to show ***improvement over*** standard of care.
- Development process aligns with FDA's Oncology Center of Excellence Project Optimus initiative to reform dose optimization and dose selection[1].
- With these improved, newer chemotherapies, either as new singular agents or combinations, we can potentially deliver better oncology therapies.

[1]https://www.fda.gov/about-fda/oncology-center-excellence/project-optimus

Processa's Pipeline

Processa Pharmaceuticals

Next Generation Chemotherapies Improving Safety and Efficacy						
		Development Stage				
Drug	**Cancer Indications**	**Preclin**	**Phase 1**	**Phase 2**	**Phase 3**	**NDA**
Next Generation Capecitabine (PCS6422)	Hepatocellular, Pancreatic, Colorectal, Breast, Gastric, & Other Solid Tumor Cancers		Phase 1b Near Completion			
Next Generation Gemcitabine (PCS3117)	Pancreatic, Gall Bladder, Non-Small Cell Lung, & Other Solid Tumor Cancers			Phase 2a Completed		
Next Generation Irinotecan (PCS11T)	Pancreatic, Ovarian, Lung, Colorectal, Gastric, Cervical & Other Cancers	Pre-clinical				

Processa Pharmaceuticals

How Our Oncology Assets Differ from Current Chemotherapy

Standard of Care Problem	Potential Patient Benefits with Our NGCs
Capecitabine – Low treatment response with high side effect profile.	Change in metabolism and distribution of cancer-killing molecules that ***reduces AEs and expands patient pool***.
Gemcitabine –High drug resistance and/or acquired resistance; administered as IV.	***Oral therapy*** that increases metabolism to cancer-killing molecules, ***increasing the amount*** of cancer-killing molecules and ***limiting resistance***.
Irinotecan – Significant side-effect profile limits dosing and drug use.	Cancer-killing molecules ***preferentially enter cancer cells over normal cells*** to provide ***additional efficacy*** with ***less toxicity***.

Processa Pharmaceuticals

PCS6422 / Next Generation Capecitabine (NGC-Cap)

	NGC-Cap
Efficacy	• Alters metabolism to increase distribution of 5-FU and cancer-killing molecules to cancer cells while reducing the metabolites that only cause side effects • Active molecule same as Capecitabine but provides improved treatment at a lower dose
Side Effects	• Better side effect profile
Clinical Development	• Ongoing Phase 1B trial in pancreatic cancer with four cohorts enrolled and complete enrollment expected by YE 2023 • Anticipated to begin Phase 2 trial in 2024 following FDA collaboration

PCS3117 / Next Generation Gemcitabine (NGC-Gem)

Oral Drug with Same MOA as Gemcitabine

Processa Pharmaceuticals

	NGC-Gem
Efficacy	• Provides improved treatment over Gemcitabine seen in previous pancreatic cancer trial data; cancer cells exposed to more NGC-Gem cancer-killing molecules given more activating enzyme
Side Effects	• Side effect profile similar to Gemcitabine
Clinical Development	• Company to collaborate with FDA on the development program, including target population, design of the next safety-efficacy trial, dosage regimen(s), and comparator treatment arm within the trial

PCS11T / Next Generation Irinotecan (NGC-Iri)

Processa Pharmaceuticals

	NGC-Iri
Efficacy	• Active molecule SN-38 is same active molecule in Irinotecan • Distributes SN-38 differently, entering the cell membrane of cancer cells preferentially over normal cells, improving cancer-killing effect
Side Effects	• Given MNM-SN38 specificity for cancer cells over normal cells, animal data suggests fewer side effects; likely that patients will have less diarrhea and less myelosuppression (a BlackBox warning for Irinotecan)
Clinical Development	• Analyzing pre-clinical data • Evaluating sites to manufacture PCS11T • Pre-IND enabling toxicology studies and CMC studies to be completed prior to IND submission

Summary of Activities/Milestones

Processa Pharmaceuticals

Milestone	Approx. Date
NGC-Cap: Complete Phase 1B MTD Trial Enrollment and Analyze Data to Assist in Phase 2 Design	2H2023
NGC-Cap: Define Regulatory Paths to Approval and ODR Phase 2 Design with FDA	2H2023
NGC-Cap: Submit ODR Phase 2 Protocol to IND and Continue Study Preparation	2H2023/1Q2024
NGC-Gem: Define Regulatory Paths to Approval and ODR Phase 2 and 3 Designs with FDA Including Combo Treatment	2H2023/1Q2024
NGC-Gem: Submit ODR Phase 2 or 3 Protocol to IND and Begin Study Preparation	1H2024
NGC-Iri: Complete Re-Analysis of Animal Cancer Data using Project Optimus Approach	YE2023

Why Processa Now?

Processa Pharmaceuticals

- Upcoming Catalysts/Milestones:
  - PCS6422/NGC-Cap
    - Complete Phase 1B enrollment & dose regimen safety evaluation.
    - Finalize Phase 2 study design based on FDA feedback.
  - PCS3117/NGC-Gem
    - Collaborate with FDA to further define development program (target population, design of the next safety-efficacy trial, dosage regimen(s), and comparator treatment arm).
- New CEO (August 2023) with extensive turnaround, BD track record and significant oncology experience.
- Potential non-core asset out-licensing transaction(s) to generate non-dilutive funds

Up-Side Opportunity with a Strategy of Optimizing Proven Therapeutics via NCEs

- Developing Next-Generation Chemotherapy (NGC) drugs with near term achievable milestones using cancer-killing molecules presently in FDA-approved drugs.
- NCEs with potential for expanded use in multiple cancer indications due to favorable profiles.
- Experienced management team with multiple regulatory approvals and successful exits.
- > Billion-dollar US market potential across multiple cancer types.
- Cash of $8.7M as of June 2023 provides an operating runway into 2H2024.
- Potential to out-license or partner non-NGC and select NGC drug candidates.