

**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): February 20, 2024

Commission file number 001-39531

PROCESSA PHARMACEUTICALS, INC.

(Exact name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

45-1539785
(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)

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.

Mr. George Ng, CEO for Processa Pharmaceuticals, Inc. ("**Processa**") presented at the Winter Wrap-Up MicroCap Rodeo Conference on February 20, 2024.

Processa's presentation is furnished as Exhibit 99.1 and will also be made available in the "Investors" section on Processa's website, located at <https://www.processapharmaceuticals.com>.

Processa undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time through the filing of other reports or documents with the Securities Exchange Commission, through press releases, or through other public disclosure, including in the "Investors" section of Processa's website. Processa routinely uses its website as a means of disclosing material non-public information and for complying with its disclosure obligations under Regulation FD.

The information in this Item 7.01 and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
99.1	Processa Pharmaceuticals Presentation dated February 20, 2024

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 February 21, 2024.

PROCESSA PHARMACEUTICALS, INC.
Registrant

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



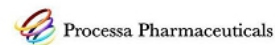
Processa Pharmaceuticals

Next Generation Chemotherapy:
*Improved Treatment for
More Patients*

Corporate Presentation
February 2024



Forward Looking Statement and Disclosures



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



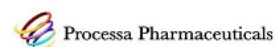
Next-Generation Chemotherapies (NGCs) Designed to Improve Survival and Quality of Life for Cancer Patients

- 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
- Cash runway into 2025

Processa Pharmaceuticals (NASDAQ: PCSA)		
	At 12/31/23	At 12/31/23 (pro forma for January 2024 financing)
Cash & Equivalents	\$4.7M	\$11.1M
Shares Outstanding (post-reverse split)	1.3M	2.8M
Insider Ownership	24.2%	13.1%
Stock Price (as of 02/13/24)	\$2.34	
Market Capitalization	\$6.7M	

NASDAQ: PCSA

Processa Senior Management



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

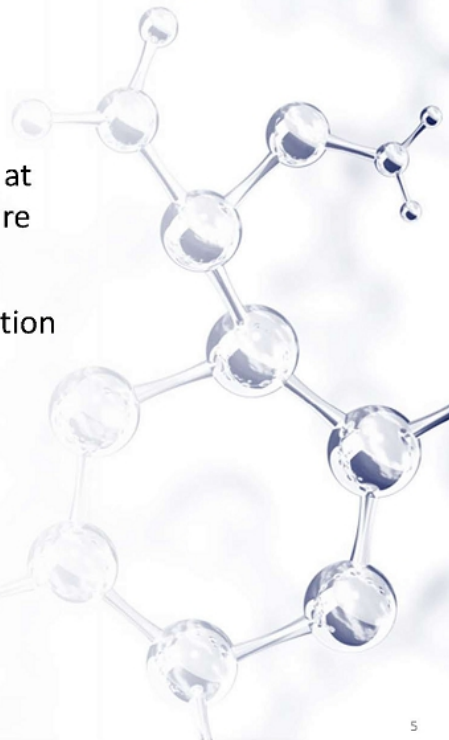
Oncology Opportunity

- 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 selection¹
- With these improved, newer chemotherapies, either as new singular agents or combinations, we can potentially deliver better oncology therapies

NOTE:

1. <https://www.fda.gov/about-fda/oncology-center-excellence/project-optimus>

NASDAQ: PCSA



Processa's Pipeline

Next Generation Chemotherapies Improving Safety and Efficacy						
Drug	Cancer Indications	Development Stage				
		Preclin	Phase 1	Phase 2	Phase 3	NDA
Next Generation Capecitabine (PCS6422)	Breast, Colorectal, Hepatocellular, Pancreatic, Gastric, & Other Solid Tumor Cancers	Phase 2 Being Planned				
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				

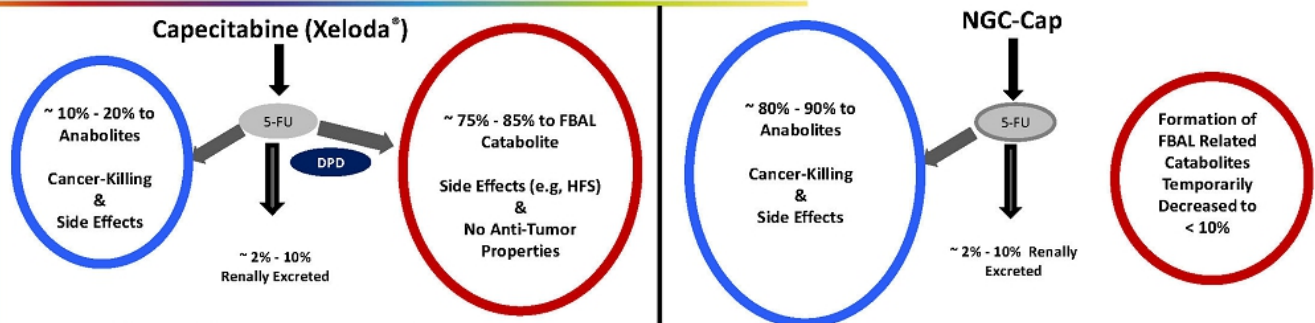
How Our Oncology Assets Differ from Current Chemotherapy

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

PCS6422 / Next Generation Capecitabine (NGC-Cap)

	NGC-Cap
Efficacy	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Better side effect profile
Clinical Development	<ul style="list-style-type: none">• Phase 1B completed, dosing identified for Phase 2• Based on the FDA meeting in December 2023, anticipate Phase 2 trial in advanced or metastatic breast cancer patients

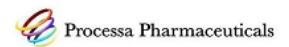
NGC-Cap is Not the Same Treatment or Drug as FDA-Approved Capecitabine



- Capecitabine (Cap), an oral pro-Drug of 5-FU, and 5-FU are most widely used cancer chemotherapy agents
- Therapeutic dose determined by side effects from Catabolites (non-cancer killing molecules) and Anabolites (cancer killing molecules)
- 35% - 70% of patients have dose-limiting side effects from Catabolites (non-cancer killing molecules), requiring a change in therapy
- Only 20%-40% of patients respond to Cap

- The mechanism of killing cancer cells is the same as Cap/5-FU
- Formation of Catabolites almost non-existent
- Exposure profile of the cancer cells to cancer-killing Anabolites is GREATER than existing FDA-approved Cap even though the amount of Cap administered is 10% of FDA-Approved Cap
- Therapeutic dose to be determined solely by exposure profile of Anabolites

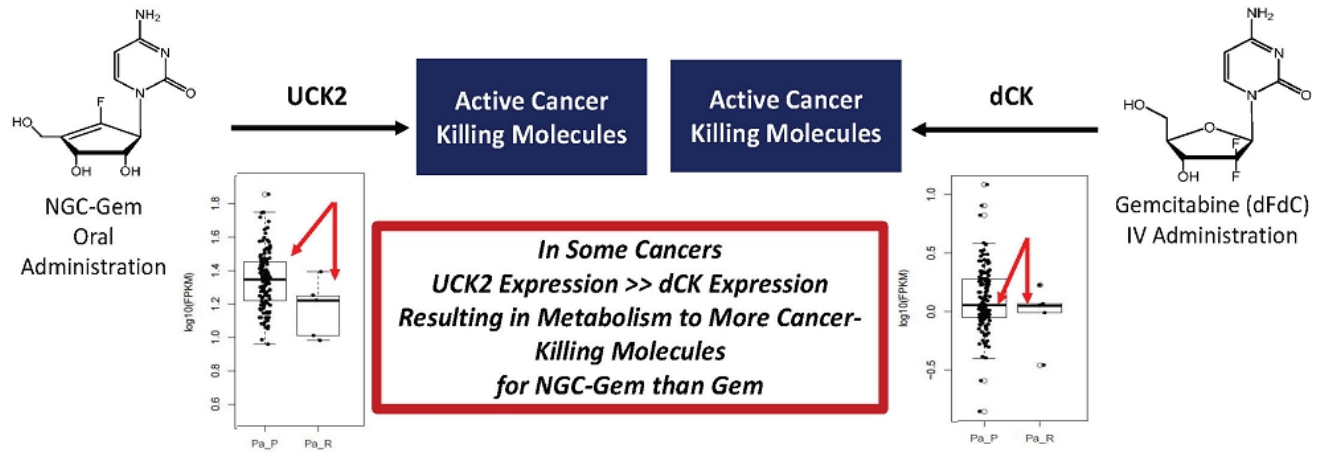
PCS3117 / Next Generation Gemcitabine (NGC-Gem)



Oral Drug with Same MOA as Gemcitabine

	NGC-Gem
Efficacy	<ul style="list-style-type: none">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	<ul style="list-style-type: none">Side effect profile similar to Gemcitabine
Clinical Development	<ul style="list-style-type: none">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

NGC-Gem (Oral): Increase Metabolism to Cancer-Killing Molecules Given Different Metabolizing Enzyme than Gemcitabine (IV)



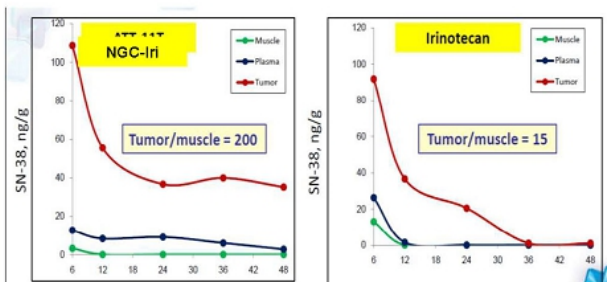
55% - 85% of Patients Inherently Resistant to Gemcitabine or Acquire Resistance

PCS11T / Next Generation Irinotecan (NGC-Iri)

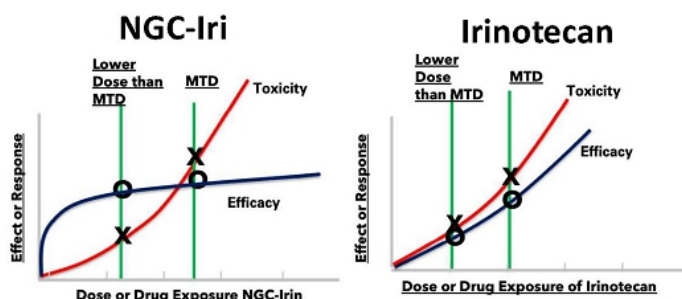
	NGC-Iri
Efficacy	<ul style="list-style-type: none">• Active molecule SN-38 is same active molecule in Irinotecan• Distributes SN-38 differently, entering the cell membrane of cancer cells preferentially over normal cells, improving cancer-killing effect
Side Effects	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Expand pre-clinical analysis with additional ongoing pre-clinical efficacy study• Evaluating sites to manufacture PCS11T• Pre-IND enabling toxicology studies and CMC studies to be completed prior to IND submission

NGC Irinotecan: Higher Amounts & Lower Required Dose

Tumor-Bearing Mice Had 200x Higher Drug In Tumor vs Muscle Compared To 15x With Irinotecan



Efficacy Maintained at Lower Doses of NGC-Iri When Compared to Irinotecan in SW620 Colorectal Cancer Xenograft Model



Tissue	NGC-Iri AUC (ng/g*hr)	NGC-Iri Tumor/Tissue Ratio	Irinotecan AUC (ng/g*hr)	Irinotecan Tumor/Tissue Ratio
Tumor	3,855	1	1,153	1
Plasma	403	9.57	172	6.7
Muscle	19.2	200	78	15

NASDAQ: PCSA

Dose	Tumor Growth Inhibition (Efficacy)	
	NGC-Iri	Irinotecan
MTD	100%	85%
½ MTD	100%	64%
¼ MTD	100%	53%

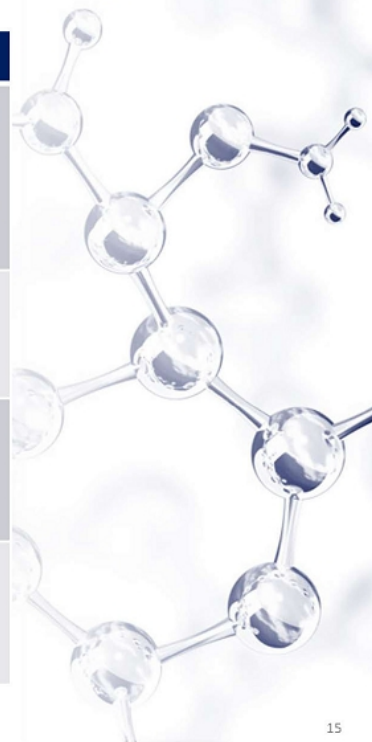
Summary of Activities/Milestones

Milestone	Approx. Date
NGC-Cap: Cohort review committee meeting to determine if Phase 1B MTD trial enrollment completed	January 2024 ✓
NGC-Cap: Finish defining regulatory paths to approval and ODR Phase 2 design based on FDA communications	1Q2024
NGC-Cap: Submit Phase 2 protocol to IND, begin initiating sites	1H2024
NGC-Gem: Define regulatory paths to approval and ODR Phase 2 and 3 designs with FDA	2Q-3Q2024
NGC-Gem: Submit ODR Phase 2 or 3 protocol to IND and begin study preparation	2H2024
NGC-Iri: Preclinical toxicity study preparation	1H2024

Company Summary

Company is Positioned for Success

Strategic transition to oncology-focused company:	<ul style="list-style-type: none">• Multiple oncology assets in clinical and pre-clinical development• Partnering (i.e. out-licensing) non-oncology drug products for non-dilutive funding for development of oncology drug products
Track record of drug development through regulatory approval:	<ul style="list-style-type: none">• Experienced development team with 30 FDA regulatory approvals to date using its proprietary Regulatory Science approach
Innovative clinical development programs addressing issues with standard of care:	<ul style="list-style-type: none">• Phase 2 study anticipated in first line metastatic breast cancer based on an encouraging Phase 1b dose escalation study
Strong financial position to support progress:	<ul style="list-style-type: none">• Cash runway into 2025:<ul style="list-style-type: none">– \$11.1M pro forma cash as of December 31, 2023





Processa Pharmaceuticals



NASDAQ: PCSA

Investor & Media Relations:
CORE IR
IR@processapharma.com