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): December 5, 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.

Dr. David Young, President R&D for Processa Pharmaceuticals, Inc. ("***Processa***") will present virtually at the MedInvest Oncology Investor Conference being held on December 5, 2023 in Palo Alto, CA. Dr. Young's presentation titled "Next Generation Chemotherapy: Improved Treatment for More Patients" will be held on December 5, 2023 at 1:35 PM PT/4:35 PM ET. George Ng, CEO will be attending the meeting in person and will be available for questions and one-on-one meetings.

During the session, Processa's presentation will be uploaded into a portal, which is furnished as Exhibit 99.1 and is incorporated herein by reference. The presentation 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.

Exhibit No.	Exhibit Description
99.1	Processa Pharmaceuticals Presentation dated December 5, 2023.

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 December 5, 2023.

PROCESSA PHARMACEUTICALS, INC.
Registrant

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

Exhibit 99.1


Processa Pharmaceuticals
Next Generation Chemotherapy:
Improved Treatment for More Patients
David Young, Pharm.D., Ph.D.
President, Research & Development
&
George Ng
Chief Executive Officer
Processa Pharmaceuticals, Inc (NASDAQ: PCSA)
MedInvest Oncology Investor Conference
December 2023

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

Developing the Next-Generation Chemotherapies (NGCs) Designed to Improve Survival and Quality of Life for More 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 obtaining > 30 FDA approvals for indications across FDA Divisions** using our proven Regulatory Science Approach and focusing on defining the Optimal Dosage Regimen (ODR) to improve the efficacy-safety profile
- **Actively advancing three anti-cancer NCEs**, two with INDs and one near clinic-ready, that are better versions of three of the most widely used existing chemotherapy drugs
- **Potential to out-license or partner** non-NGC and select NGC drug candidates

Processa Pharmaceuticals (NASDAQ: PCSA)	
Stock Price (as of 11/30/23)	$0.64
Shares Outstanding (as of 11/1/23)	24.6M
Market Capitalization	$15.8M
Cash & Equivalents (at 9/30/23)	$6.9M
Insider Ownership	23.2%

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

Each Next Generation Chemotherapy (NGC): Potential Annual Sales of > $500M - $1B

Processa Pharmaceuticals

	Present Chemotherapy (Approx % Pts)	NGC (Expected %)
Patients Experiencing Side Effects That Require Dose Reduction or Discontinuation	35% - 70%	
Patients Receiving Full Course Prescribed Chemo	30% - 65%	
Number of Patients Responding to Chemo	20% - 40%	
Patients Initially Treated with Chemo	20% - 80% of Cancer Patient	

How Do NGCs Improve the Safety-Efficacy Profile While Treating More Patients?

Processa Pharmaceuticals

- Each NGC **Mechanism of Killing Cancer Cells Remains the Same as Existing FDA-Approved Drug**
- **Alter Metabolism/Distribution** of FDA-Approved Cancer Drug or Active Molecules Results in **More Exposure of Cancer Cells to Cancer-Killing Molecules**
- **Define the Optimal Dosage Regimen (ODR) for NGCs** with Processa's Regulatory Science Approach **Applying FDA's Project Optimus Oncology Initiative**

- **Improve Safety**
- **Improve Efficacy**
- **Treat More Patients**

Processa Pharmaceuticals

Our NGCs Differ from Current Chemotherapy

Standard of Care Problem	Potential Patient Benefits with Our NGCs
Capecitabine – High side effect profile resulting in dose reduction, treatment discontinuation, and less response	By changing metabolism and distribution of cancer-killing molecules, **AEs may be reduced, efficacy improved, and the number of patients treated expanded**
Gemcitabine –High drug resistance and/or acquired resistance; administered as IV	**Oral therapy** that increases metabolism to cancer-killing molecules, **increases the exposure to** cancer-killing molecules, and **decreases 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's NGC Pipeline

Processa Pharmaceuticals

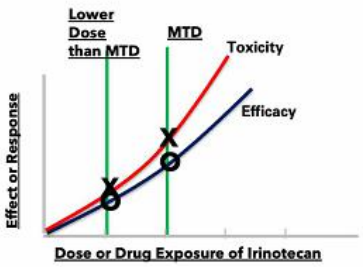
Next Generation Chemotherapies Improving Safety and Efficacy						
		Development Stage				
Drug	**Cancer Indications**	**Preclin**	**Phase 1**	**Phase 2**	**Phase 3**	**NDA**
Next Generation Capecitabine (PCS6422)	Hepatocellular, Pancreatic, Colorectal, Breast, Gastric, & Other Solid Tumor Cancers		Phase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

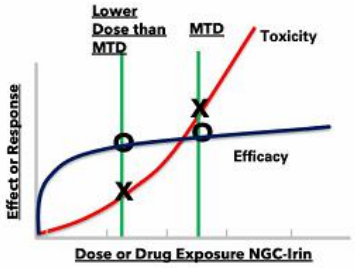
Optimizing NGC Cancer Treatment

Processa Pharmaceuticals

Processa Develops NGCs Using its Regulatory Science Approach and FDA's Project Optimus Oncology Initiative

- **Optimal Dosage Regimen (ODR) creates a better balance between side effects and patient response** with potentially
  - Fewer side effects, Greater effect on the cancer
  - More efficient development/approval process
- ODR approach is required by FDA Project Optimus Initiative and ODR Draft Guidance
  - **Management team with Regulatory Science Approach to define the Optimal Dosage Regimen (ODR) to improve the efficacy-safety profile**

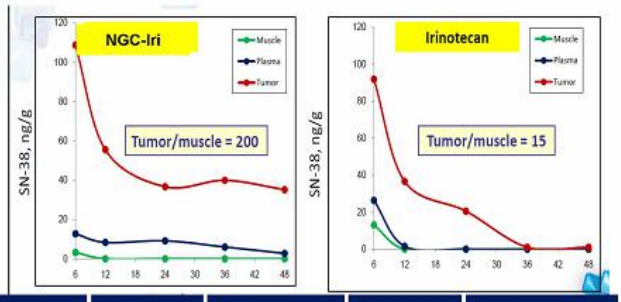




Project Optimus Example: Next Generation Irinotecan

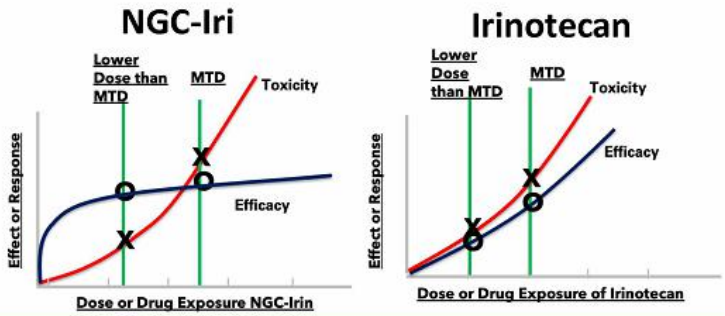
Processa Pharmaceuticals

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



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

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



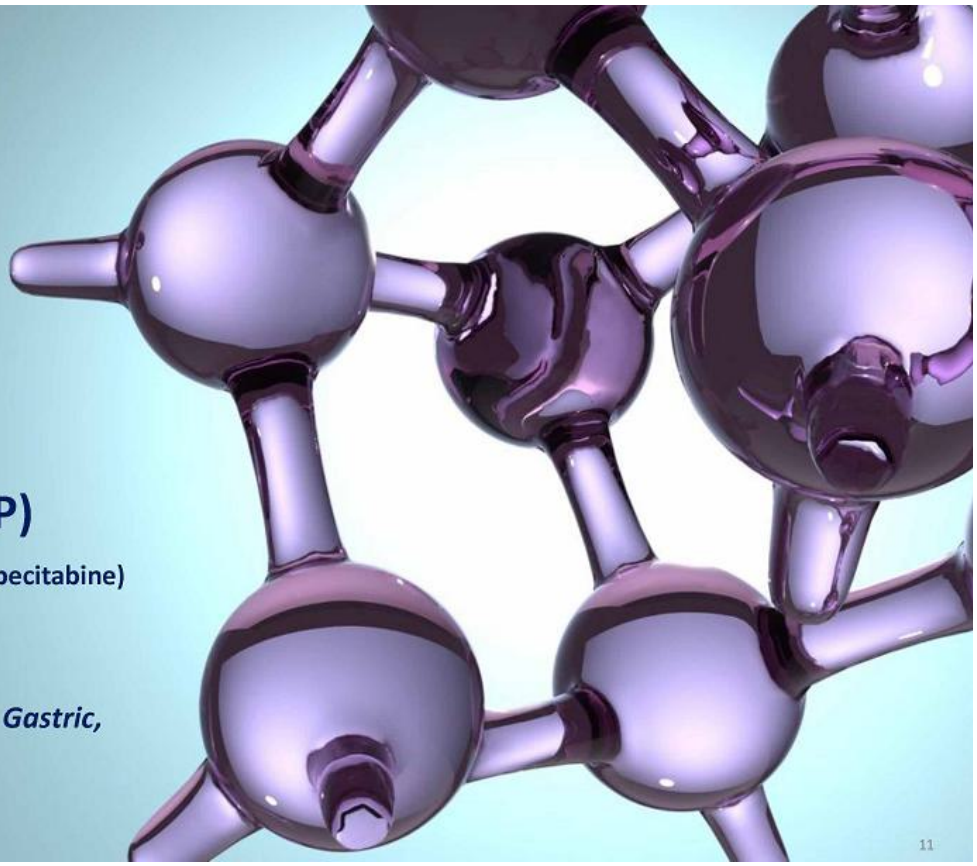
Dose	Tumor Growth Inhibition (Efficacy)	
	NGC-IRI	NGC-Irin
MTD	100%	85%
½ MTD	100%	64%
¼ MTD	100%	53%

Processa Pharmaceuticals

NEXT GENERATION CHEMOTHERAPY CAPECITABINE (NGC-CAP)

(Combination Regimen of PCS6422 and Capecitabine)

Colorectal, Pancreatic, Hepatocellular, Gastric, Breast, and Other Cancers



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

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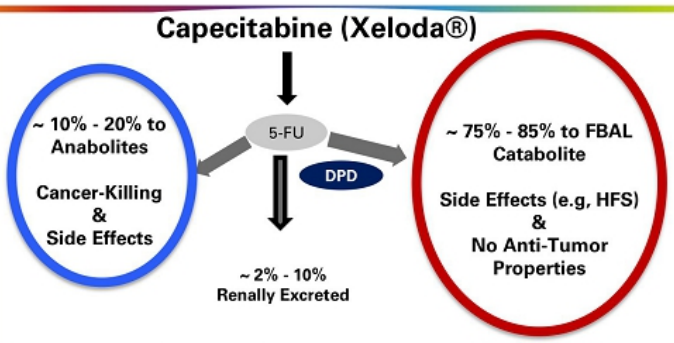
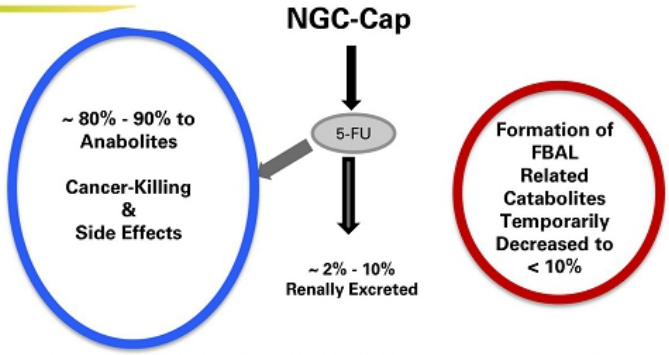


- Capecitabine (Oral Pro-Drug of 5-FU) and 5-FU Are Most Widely Used Cancer Chemotherapy Agents
- Therapeutic dose determined by side effects from Catabolites (non-cancer killing molecules) and Anabolites (cancer killing molecules)
- 35% - 70% of patients have dose-limiting side effects from Catabolites (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
- <u>Exposure profile of the cancer cells to cancer-killing Anabolites is GREATER than existing FDA-approved</u> Capecitabine even though the amount of Cap administered is 10% of FDA-Approved Cap
- Therapeutic dose to be determined solely by exposure profile of Anabolites

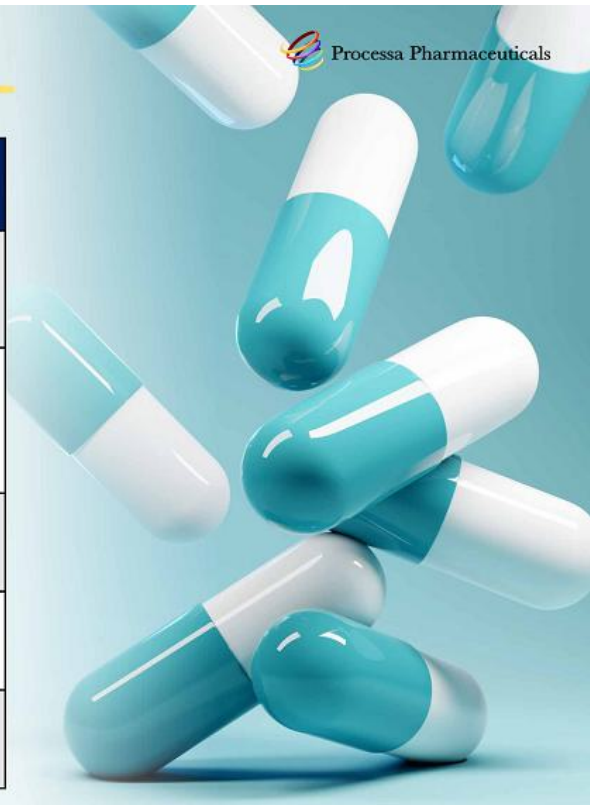
Highlights of NGC-Cap

Processa Pharmaceuticals

	NGC-Cap
Side Effects	• **Fewer Catabolites equals fewer catabolite related side effects in Phase 1b trial** • **Side effects related to Anabolites in Phase 1b trial** even though dose is 5-10% of the typical Cap dose (more efficient cancer cell exposure to Anabolites)
Efficacy	• **Cancer cells exposed to more 5-FU & Anabolites** after NGC-Cap
Safety-Efficacy Profile	• Based on existing communications with FDA, **Processa has initiated pre-study start-up tasks** for the Project Optimus Phase 2 safety-efficacy optimal dosage regimen trial • Meet with FDA in Dec. on Phase 2 dose (RP2D) and design of Phase 2 trial
Development Commercial	• **More likely to be FDA approved given established MOA and ODR evaluation** • **More efficient development program than new type of oncology drugs** • **> 200,000 newly diagnosed patients per year in U.S. have cancers treatable with Cap** • **U.S. potential annual sales in Cap treated cancer > $1.0B**

Next Milestones of NGC-Cap

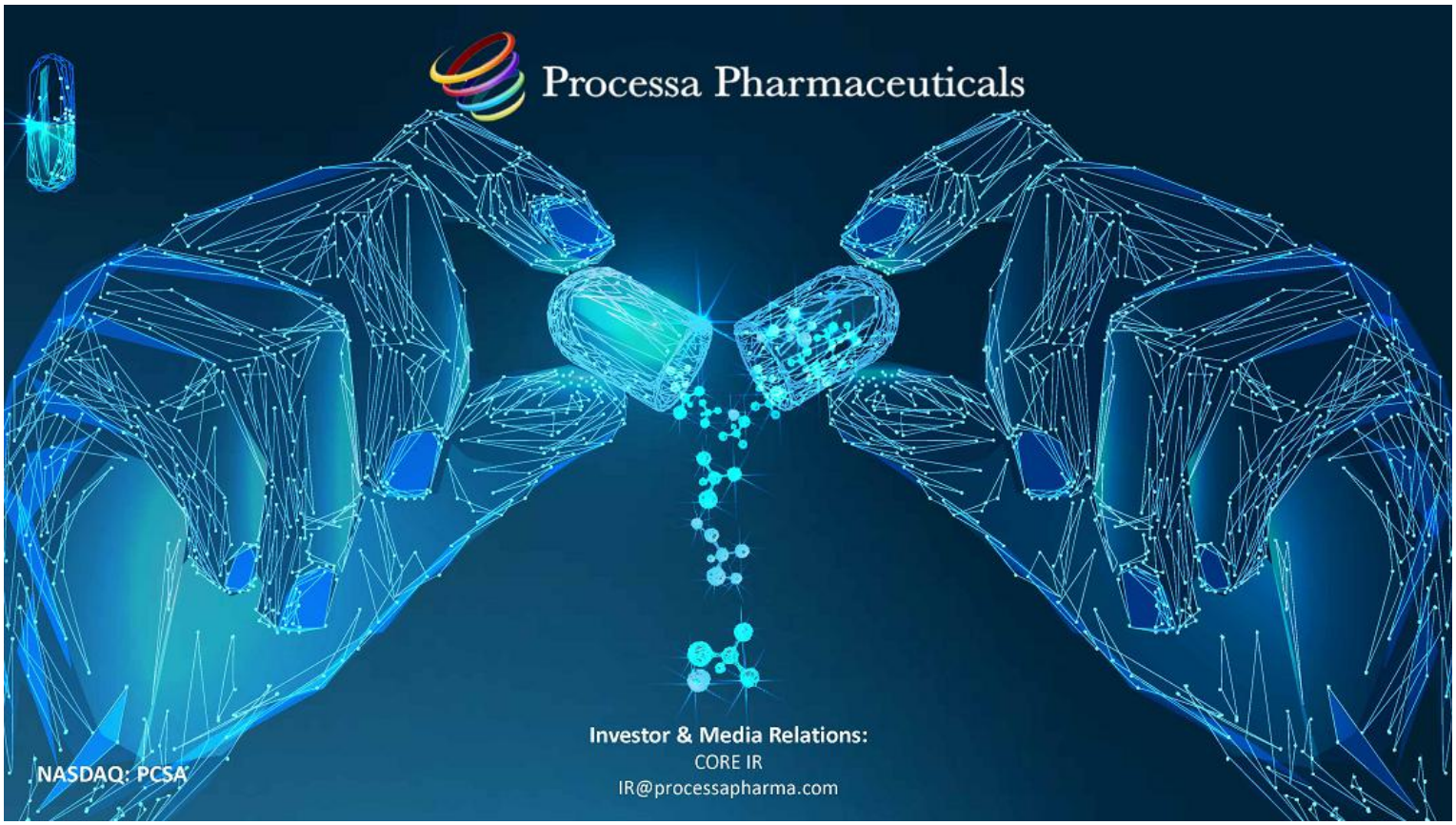
Milestone	Approx. Date
Determine Phase 2 Recommended Dose from Ongoing Phase 1b Trial	Ongoing
Phase 2 Trial Preparation (e.g., Writing Protocol, CRO Selection, Site Interviews, Drug Manufacturing)	Ongoing
Meet with FDA to Define Project Optimus Phase 2 Trial Design	Dec 2023
Submit Phase 2 Protocol to IND, Begin Initiating Sites	Mid-2024
Finalize Provisional Patent(s)	2023-2024



Why Processa Now?

Processa Pharmaceuticals

- **NGCs provide an improved safety and efficacy profile for FDA-approved cancer-killing molecules allowing more patients to benefit from the NGCs**
- **Each NGC has the potential of annual sales > $500M-$1B**
- Upcoming Catalysts/Milestones:
  - PCS6422/NGC-Cap
  - PCS3117/NGC-Gem
  - PCS11T/NGC-Iri
- **New CEO (August 2023) with extensive turnaround, BD track record, and significant oncology experience**
- **Team experienced in oncology and in obtaining FDA approvals in all FDA divisions**
- Potential non-core asset out-licensing transaction(s) to generate non-dilutive funds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