# 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): June 21, 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, (Address of Principal Executive C	
•	
(443) 776-3 (Registrant's Telephone Numb	
(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 230.42	5)
□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-1	2)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act	t (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act	(17 CFR 240.13e-4(e))
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 the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).	Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of
Emerging growth company $\Box$	
If an emerging growth company, indicate by check mark if the registrant has elected not accounting standards provided pursuant to Section 13(a) of the Exchange Act. $\Box$	to use the extended transition period for complying with any new or revised financial

#### Item 7.01. Regulation Disclosure.

Dr. David Young of Processa Pharmaceuticals, Inc. ("*Processa*") will present at the MedInvest Oncology Investor Conference being held on June 21-22 in Boston, MA. Dr. Young's presentation titled "Next Generation Chemotherapy to Improve Treatment of Cancer while Treating More Patients" will be held on June 21, 2023 at 12:00 PM ET.

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 <a href="https://www.processapharmaceuticals.com">https://www.processapharmaceuticals.com</a>.

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.

Exhibit No.	Exhibit Description
99.1 104	Processa Pharmaceuticals Presentation dated June 21, 2023.  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 June 21, 2023.

PROCESSA PHARMACEUTICALS, INC. Registrant

By: /s/ David Young

David Young Chief Executive Officer



#### **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.

NASDAO: PCSA

# Present Chemotherapy vs. Expectations of Next Generation Chemotherapy



	Present Chemotherapy (Approx %)
Patients Presenting with Cancer Initially Treated with Chemo	20% - 80% of Cancer Patient
Patients Experiencing Side Effects That Require Dose Reduction or Discontinuation	35% - 70% of Patients Treated
Patients Receiving Full Course Prescribed Chemo	30% - 65% of Patients Treated
Patients Responding to Chemo	20% - 40% of Patients Treated
Patients Not Responding to Chemo	60% - 80% of Patients Treated
NASDAQ: PCSA	

# Present Chemotherapy vs. Expectations of Next Generation Chemotherapy



	Present Chemotherapy (Approx %)	Next Generation Chemotherapy (Expected %)
Patients Presenting with Cancer Initially Treated with Chemo	20% - 80% of Cancer Patient	Greater Than Present Chemo
Patients Experiencing Side Effects That Require Dose Reduction or Discontinuation	35% - 70% of Patients Treated	Less Than Present Chemo
Patients Receiving Full Course Prescribed Chemo	30% - 65% of Patients Treated	Greater Than Present Chemo
Patients Responding to Chemo	20% - 40% of Patients Treated	Greater Than Present Chemo
Patients Not Responding to Chemo	60% - 80% of Patients Treated	Less Than Present Chemo
NASDAO: PCSA		

#### **Next Generation Chemotherapy Overview**



#### **Processa Solution**

- Develop Next Generation Chemotherapy (NGC) Drugs Improving Cancer Exposure to Widely Used FDA Approved Cancer Killing Molecules with a Proven History of Therapeutic Success
- Use Processa Regulatory Science Approach & FDA's Project Optimus Oncology Initiative to Define the
  Optimal Dosage Regimen (ODR) for Each NGC as Required by FDA
- NGCs create new opportunities to improve treatment and/or impact the side effect profile



#### **Desired Outcome**

- Safer & More Effective Treatment
- Improved Likelihood of FDA-Approval in a Short Time
- Significant Investment Upside with Low Risk
- Differentiation from Existing Chemotherapy with the Same Active Molecules

MACDAO: BCCA

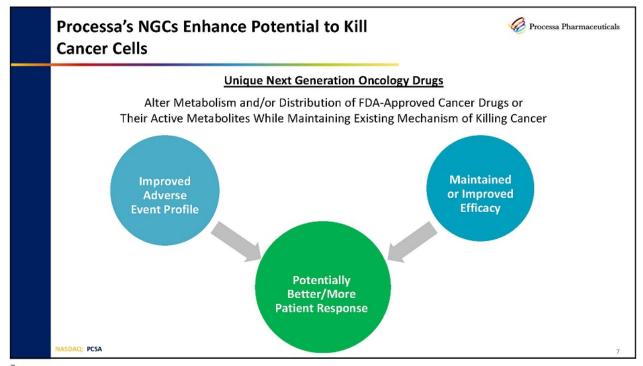
#### **Investor Highlights**



- Clinical stage drug development company with 3
   Next Generation Chemotherapy (NGC) drugs with a
   greater likelihood of FDA approval in a more
   efficient development program
- Multiple NGC milestones achievable in 2023 and 2024
- Greater than \$1.0B U.S. market potential for each NGC used across multiple types of cancer
- Potential to out-license or partner additional non-NGC drug candidates PCS12852 and PCS499
- Pro-forma cash of \$10.7M at 1Q23 provides an operating runway into 2H24

Processa Pharmaceuticals (NASDAQ: PCSA)		
Stock Price (as of 6/12/23)	\$0.73	
Shares Outstanding (as of 5/9/23)	24.5M	
Market Capitalization	\$18M	
FD Shares Outstanding	~32M	
Cash & Equivalents (pro-forma at 3/31/23)	\$10.7M	
Insider Ownership	23%	

NASDAQ: PCSA



#### **Optimizing Cancer Treatment**



# 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 Project Optimus Initiative
- Processa Founders have developed their Regulatory Science Approach to drug development based on an extensive history of successful drug development with >30 FDA approvals for multiple indications since the early 1990s

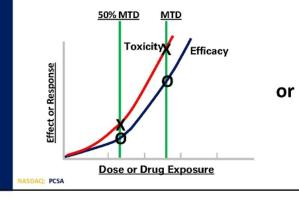


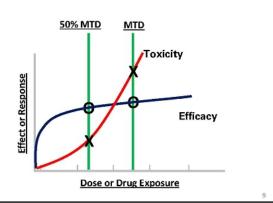
NASDAQ: PCSA

#### Regulatory Science Approach Utilizes Evaluation of the Exposure-Response Relationship Between Drug and Patient

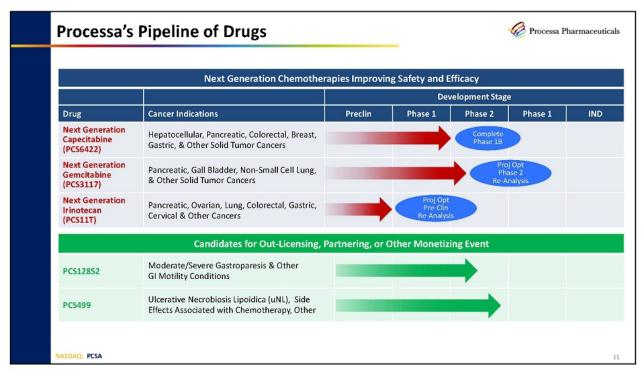


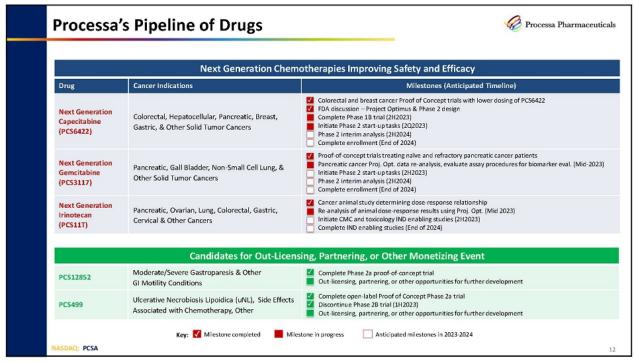
- Maximum Tolerated Dose (MTD) approach assumes the Optimal Dosage Regimen (ODR) is the MTD and the dose- or exposure-response relationships for toxicity and efficacy follow a similar pattern
- Project Optimus and Processa Regulatory
   Science approach determines the dose- or exposure–response relationships for toxicity and efficacy in order to determine the ODR

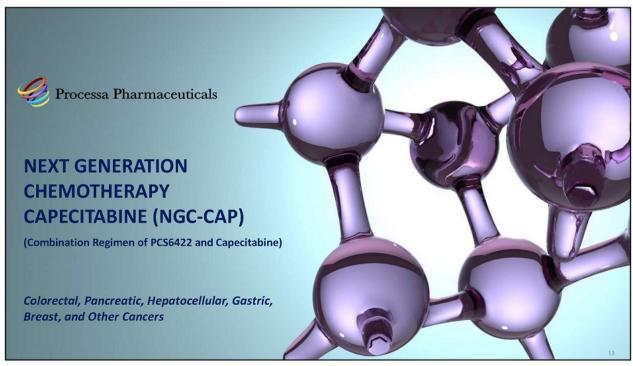




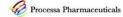
#### Case Study: NGC-Irin Dose-Response for Safety and Processa Pharmaceuticals **Efficacy Differs from Irinotecan in Animal Cancer Models** NGC-Irin Irinotecan Lower Dose than MTD Dose or Drug Exposure NGC-Irin Decreasing the dose of Irinotecan below MTD Decreasing the dose of NGC-Irin below MTD decreases the severity and/or number of adverse decreases the severity and/or number of adverse events AND ALSO decreases Irinotecan's ability to events but does NOT significantly change NGCinhibit cancer Irin's ability to inhibit cancer Tumor Growth Inhibition (Efficacy) Dose Irinotecan NGC-Irin MTD 85% 100% ½ MTD 64% 100% ¼ MTD 53% 100% ASDAQ: PCSA







# Capecitabine (Oral Pro-Drug of 5-FU) and 5-FU Are Most Widely Used Cancer Chemotherapy Agents



# Capecitabine (Xeloda®) -- 10% - 20% of 5-FU Metabolizes (Anabolites) Anti-Tumor Response +- Side Effects -- 2% - 10% of 5-FU Renally Excreted No Anti-Tumor Properties

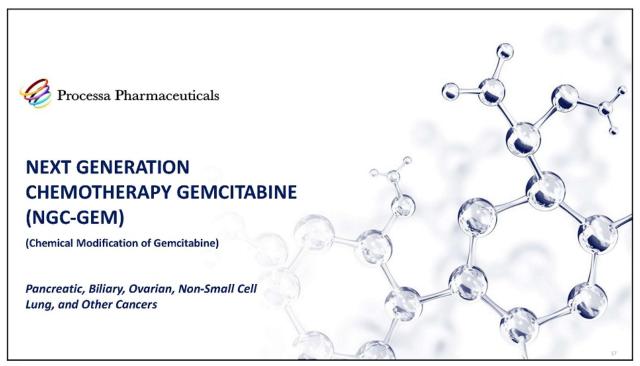
- Therapeutic dose determined by side effects from Catabolites (non-cancer killing molecules) and Anabolites (cancer killing molecules)
- 50% 70% of patients have dose-limiting side effects from Catabolites (non-cancer killing molecules) requiring a change in therapy
- Only 20%-40% of patients respond to Cap

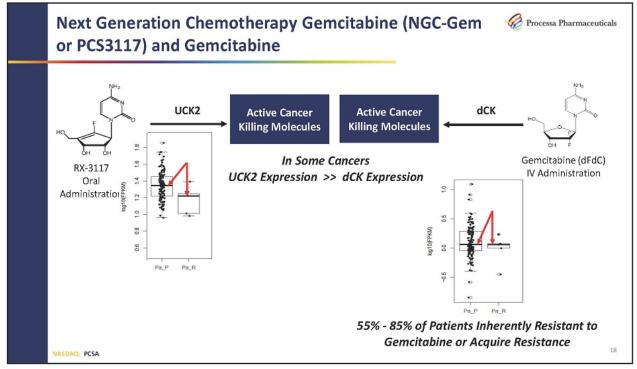
- Metabolism of 5-FU to Catabolites no longer occurs, eliminating those side effects
- Optimal Dosage Regimen to be determined by Project Optimus from only the side effects + antitumor response from Anabolites

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#### **Highlights of NGC-Cap** Processa Pharmaceuticals NGC-Cap · More likely to be FDA approved More efficient development program than new type of oncology drugs Development Develop using Project Optimus & Processa's Regulatory Science Approach Commercial > 200,000 newly diagnosed patients per year in U.S. with cancers treated with Cap U.S. market potential in Cap treated cancer > \$1.0B • Active molecule same as Cap but NGC-Cap may provide improved treatment over Cap Efficacy • Cancer cells exposed to more 5-FU & Anabolites after NGC-Cap even though dose approx. 5-10% of the typical Cap dose · No side effects from Catabolites in existing Phase 1b trial Side Effects • Side effects only related to Anabolites observed in Phase 1b trial even though dose is 5-10% of the typical Cap dose (cancer cells exposed to active molecules even with lower dose) Safety-Efficacy · Based on communications with FDA, Processa has initiated pre-study start-up tasks for the Profile Project Optimus Phase 2 safety-efficacy optimal dosage regimen trial

#### Next Milestones of NGC-Cap in 2023 Processa Pharmaceuticals Milestone Approx. Date Begin Phase 2 Trial Preparation (e.g., Writing Protocol, CRO Selection, Site Interviews, Drug 2Q2023 Manufacturing) Complete Enrollment of Phase 1b 2H2023 MTD Trial Submit Phase 2 Protocol to IND, Begin 4Q2023 **Initiating Sites** Evaluate Other Regulatory Paths to Approval 2023 (e.g., Fast Track) Prepare Additional Provisional Patent(s) 2023 NASDAQ: PCSA



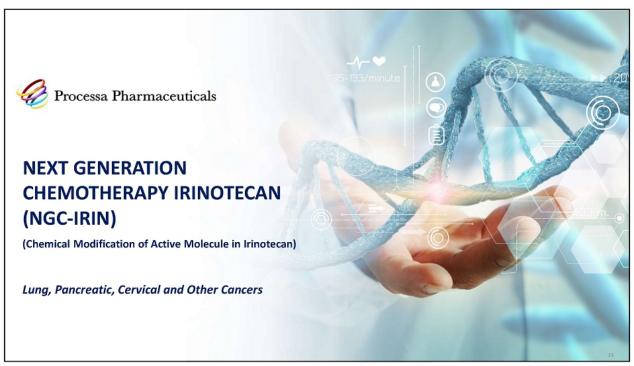


## Highlights of NGC-Gem



	NGC-Gem
Development Commercial	<ul> <li>Oral administration rather the intravenous as with Gem</li> <li>More likely to be FDA approved</li> <li>More efficient development program than new type of oncology drugs</li> <li>Developed using Project Optimus &amp; Processa's Regulatory Science Approach</li> <li>&gt; 200,000 newly diagnosed patients per year in U.S. with cancers treated with Cap</li> <li>U.S. market potential in Cap treated cancer &gt; \$1.0B</li> </ul>
Efficacy	<ul> <li>Active molecule similar to Gem but there is usually more NGC-Gem activating enzymes (UCK2) than Gem activating enzymes (dCK) potentially resulting in NGC-Gem being more effective than Gem</li> <li>Cancer cells exposed to more NGC-Gem cancer-killing molecules given more activating enzyme</li> <li>Working on analytical development of a biomarker assay to identify patients who would respond more to NGC-Gem</li> </ul>
Side Effects	Side effect profile similar to Gem
Safety-Efficacy Profile	<ul> <li>Phase 2 completed trials resulted in safety-response profile similar to Gem in pancreatic cancer patients as well as patient response in Gem resistant patients</li> <li>Identify which cancer patients are resistant to Gem and most likely to respond to NGC-Gem to be differentiated from Gem</li> </ul>
NASDAQ: PCSA	19

Next Milestones of NGC-Gem in	n 2023	Processa Pharmace
Milestone	Approx. Date	
Evaluate Assay Procedure to Measure Potential Biomarkers (Ongoing)	Mid-2023	
Re-analyze Clinical Cancer Data Using Project Optimus Approach (Ongoing)	Mid-2023	
Meet with FDA to Discuss Phase 2 Trial	2H2023	
Submit Phase 2 Protocol to IND, Begin Initiating Sites	2H2023	
NASDAQ: PCSA		



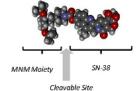
#### Next Generation Chemotherapy-Irinotecan (NGC-Irin): Pro-Drug of SN-38 (Active Metabolite of Irinotecan)



- Cancer killing metabolite of Irinotecan is SN-38
- · Irinotecan sales prior to generics > \$1B
- In NGC-Irin, SN-38 linked to Nano-Motor Transporting molecule allowing for more SN-38 to accumulate in the membranes of cancer cells than in normal cells







#### Irinotecan

Tissue	Exposure	Tumor/ Organ ratio
Tumor	1,153	1
Plasma	172	6.70
Muscle	78	15

#### NGC-Irin

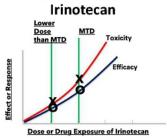
Tissue	Exposure	Tumor/organ ratio
Tumor	3,855	1
Plasma	403	9.57
Muscle	19.2	200

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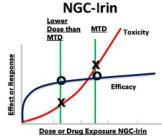
ASDAQ: PCSA

# Case Study: NGC-Irin Dose-Response for Safety and Efficacy Differs from Irinotecan in Animal Cancer Models





Decreasing the dose of Irinotecan below MTD decreases the severity and/or number of adverse events AND ALSO decreases Irinotecan's ability to inhibit cancer



Decreasing the dose of NGC-Irin below MTD decreases the severity and/or number of adverse events but does *NOT significantly change NGC-Irin's ability to inhibit cancer* 

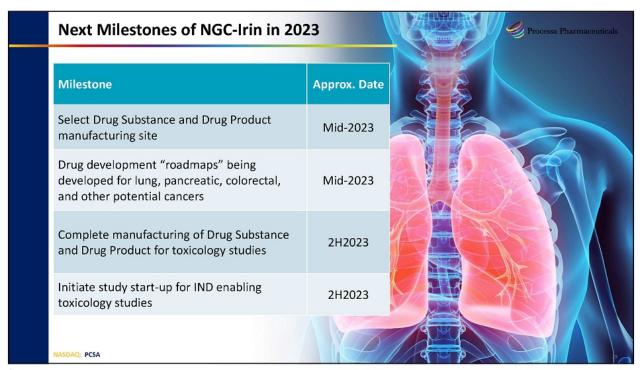
	Tumor Growth Inhibition (Efficacy)	
Dose	Irinotecan	NGC-Irin
MTD	85%	100%
½ MTD	64%	100%
1/4 MTD	53%	100%

ASDAQ: PCSA

## Highlights of NGC-Irin



NGC-Irin
<ul> <li>More likely to be FDA approved</li> <li>More efficient development program than new type of oncology drugs</li> <li>Developed using Project Optimus &amp; Processa's Regulatory Science Approach</li> <li>&gt; 200,000 newly diagnosed patients per year in U.S. with cancers treated with Cap</li> <li>U.S. market potential in Cap treated cancer &gt; \$1.0B</li> </ul>
<ul> <li>Active molecule of NGC-Irin (i.e., SN-38) is same active molecule in Irinotecan</li> <li>Cancer cells exposed to more SN-38 in NGC-Irin because of the MNM-SN38 membrane transporter in NGC-Irin</li> </ul>
Given MNM-SN38 specificity for cancer cells over normal cells, it is unlikely that NGC-Irin will have diarrhea and myelosuppression BlackBox
<ul> <li>Pre-clinical animal model results suggest that the MTD approach to defining the Optimal         Dosage Regimen probably is not the correct approach to defining the Optimal Dosage Regimen,         further supporting the Project Optimus approach</li> </ul>



Mid-2023

2H2023

2H2023

#### **Summary of Potential Milestones in 2023** Processa Pharmaceuticals NGC-Cap Milestone Approx. Date Begin Phase 2 Trial Preparation (e.g., Writing Protocol, CRO Selection, Site Interviews, Drug Manufacturing) 2Q2023 2H2023 Complete Enrollment of Phase 1b MTD Trial Submit Phase 2 Protocol to IND, Begin Initiating Sites, 4Q2023 Evaluate Other Regulatory Paths to Approval (e.g., Fast Track) 2023 Prepare Additional Provisional Patent(s) 2023 NGC-Gem Milestone Approx. Date Mid-2023 Evaluate Assay Procedure to Measure Potential Biomarkers (Ongoing) Re-analyze Clinical Cancer Data Using Project Optimus Approach (Ongoing) Mid-2023 2H2023 Meet with FDA to Discuss Phase 2 Trial Submit Phase 2 Protocol to IND, Begin Initiating Sites 2H2023 NGC-Irin Milestone Approx. Date Select Drug Substance and Drug Product manufacturing site Mid-2023

Drug development "roadmaps" being developed for lung, pancreatic, colorectal, other potential cancers

Complete manufacturing of Drug Substance and Drug Product for toxicology studies

Initiate study start-up for IND enabling toxicology studies

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#### **Processa Senior Management**





David Young, Pharm.D, Ph.D. President & CEO

#### Joined Processa 2018

#### Former Roles:

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



Patrick Lin Chief Business & Strategy Officer

#### Joined Processa 2018

#### 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



Sian Bigora, Pharm.D. Chief Development Officer

#### Joined Processa 2018

#### Former Roles:

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



James Stanker, CPA Chief Financial Officer

#### Joined Processa 2019

#### 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



Michael Floyd Chief Operating Officer

#### Joined Processa 2020

#### Former Roles:

- · President & CEO, Elion Oncology
- U.S. Project Lead, Gentium
- President, Arpida
- BSBA, Georgetown University



Wendy Guy Chief Administrative Office

#### Joined Processa 2018

#### Former Roles:

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

NASDAQ: PCSA

#### **Investor Summary** Processa Pharmaceuticals · Clinical stage drug development company with a robust pipeline of 3 Next Generation Chemotherapy (NGC) drug candidates with the potential to improve the treatment of patients with multiple types of · Number of Key Milestones achievable over the next 12 months · Management with significant drug development experience that is aligned with FDA's Project Optimus Oncology Initiative to define the Optimal Dosage Regimens for each cancer drug · Given an improved safety and efficacy profile, more patients should benefit from NGCs and more patients should be treated providing a U.S. market potential of >\$1.0B for each NGC · Management Team Involved With Billion-Dollar Exits (Questcor - \$5.7B & Gentium - \$1.0B) Potential to out-license or partner non-NGC drug candidates PCS12852 and PCS499 · Pro-forma cash of \$10.7M at 1Q23 provides an operating runway into 2H24

