Processa Pharmaceuticals

Applying FDA's Project Optimus to the Development of Next Generation Chemotherapy Treatment of Rare Cancers

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President and CEO
Processa Pharmaceuticals, Inc

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NASDAQ: PCSA

Forward Looking Statement and Disclosures

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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.

Company Overview

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Stakeholders' Goals

- Safer & More Effective Treatment
- Improve Likelihood of Success in a Short Time
- Significant Investment Upside with Low Risk

Processa Solution

- Develop Next Generation Chemotherapy (NGC) Drugs - Modifications of Widely Used Cancer Drugs with Proven Cancer Killing Molecules
- Increase Exposure to Cancer Killing Molecules & Decrease Side Effects
- Use Regulatory Science Approach & FDA's Project Optimus Initiative

Desired Outcome

- Decrease Side Effects & Improve Effective Treatment
- More Positive Treatment to More Patients Resulting in Greater Gross Sales
- Increase the Likelihood of Obtaining FDA Marketing Approval
- More Efficiently Develop Drugs for FDA Marketing Approval

Investor Highlights

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- Clinical stage drug development company with 3 Next Generation Chemotherapy (NGC) drugs ***potentially improving the side effect profile while enhancing the effectiveness***
- ***Greater likelihood of FDA approval*** given increased exposure of cancer cells to proven cancer-killing molecules and demonstrated ability to obtain FDA approvals using Process's Regulatory Science Approach and principles of FDA's Project Optimus
- ***More efficient development program following Processa Regulatory Science Approach***
- ***Multiple NGC milestones*** achievable in 2023 and 2024
- ***Greater than $1.0 B U.S. market potential for each NGC*** used across multiple types of cancer
- Potential to ***out-license or partner non-NGC*** drug candidates PCS12852 and PCS499
- Pro-forma cash of $12.9M at YE22 provides an ***operating runway into 2H24***

Processa Pharmaceuticals (NASDAQ: PCSA)	
Stock Price (as of 5/3/23)	$0.66
Shares Outstanding (as of 3/27/23)	24.6M
Market Capitalization	$16M
FD Shares Outstanding	~32M
Cash & Equivalents (pro-forma at 12/31/22)	$12.9M
Insider Ownership	23%

Processa's Differentiated NGCs Increase Cancer Cell Exposure to Proven Cancer-Killing Molecules

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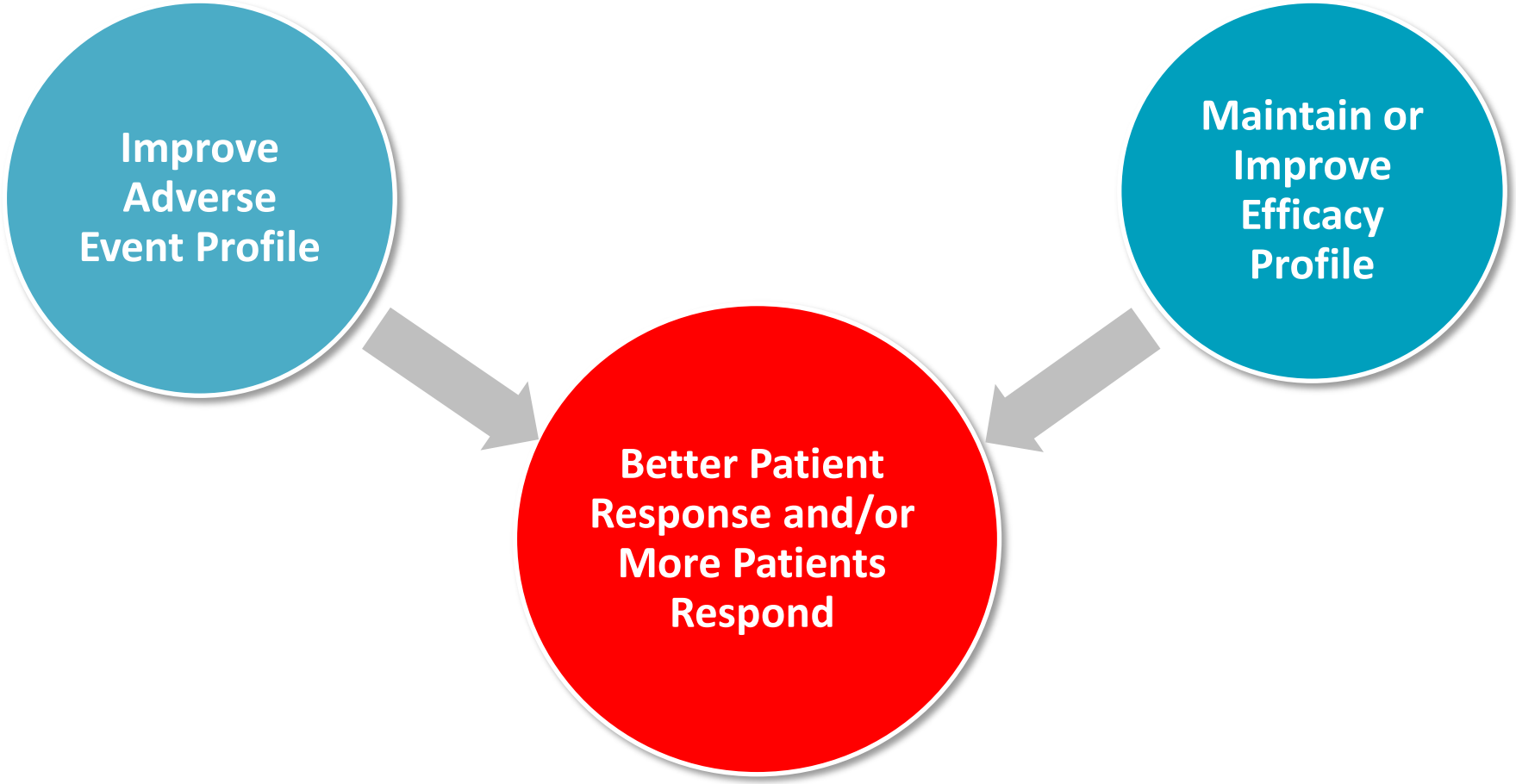
Unique Next Generation Oncology Drugs

Alter Metabolism and/or Distribution of FDA-Approved Cancer Drugs or Their Active Metabolites While ***Maintaining Existing Mechanism of Killing Cancer***



Ultimate Goal of Cancer Drug Development – Treat Each Patient with the Right Drug at the Right Dose

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

- ***Optimal Dosage Regimen (ODR) to be determined as required by Project Optimus based on the dose- or exposure-response relationships for side effects and efficacy***
- ***Benefits of defining the ODR and use of Processa Regulatory Science Approach***:
  - Fewer side effects
  - More significant response to treatment
  - Provide more positive treatment to more patients
  - More efficient development/approval process
- Drs. Young and Bigora, two of the Processa Founders, collaborated with the FDA to develop the concept of Regulatory Science.
  - Processa's Regulatory Science Approach was further developed and refined resulting in >30 FDA approvals for multiple indications over the last 30 years
  - Evaluates factors influencing FDA's Risk-Benefit analyses including the ***ODR***

Project Optimus & Our Regulatory Science Approach Recognize the Need to Evaluate the Exposure-Response Relationships

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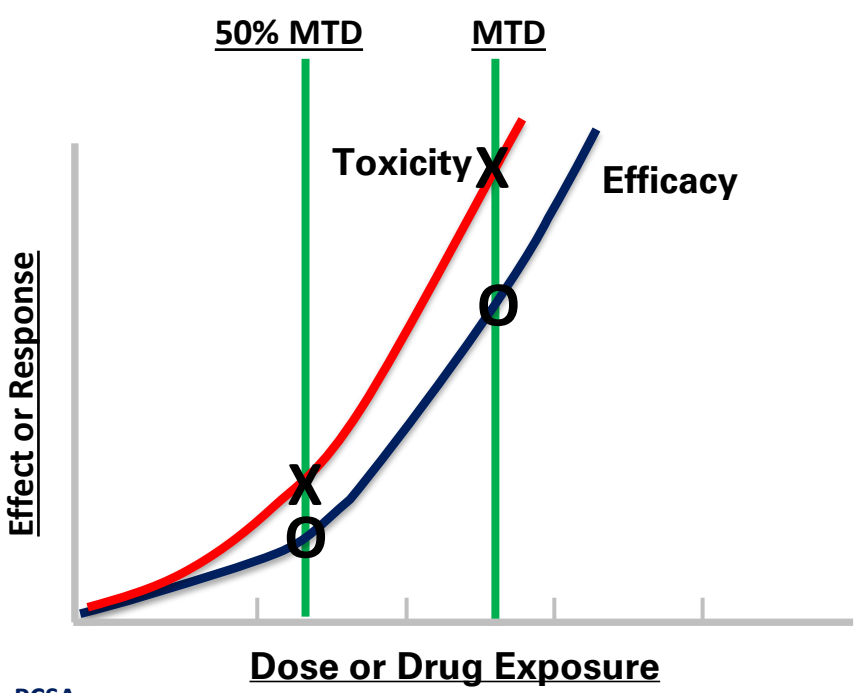
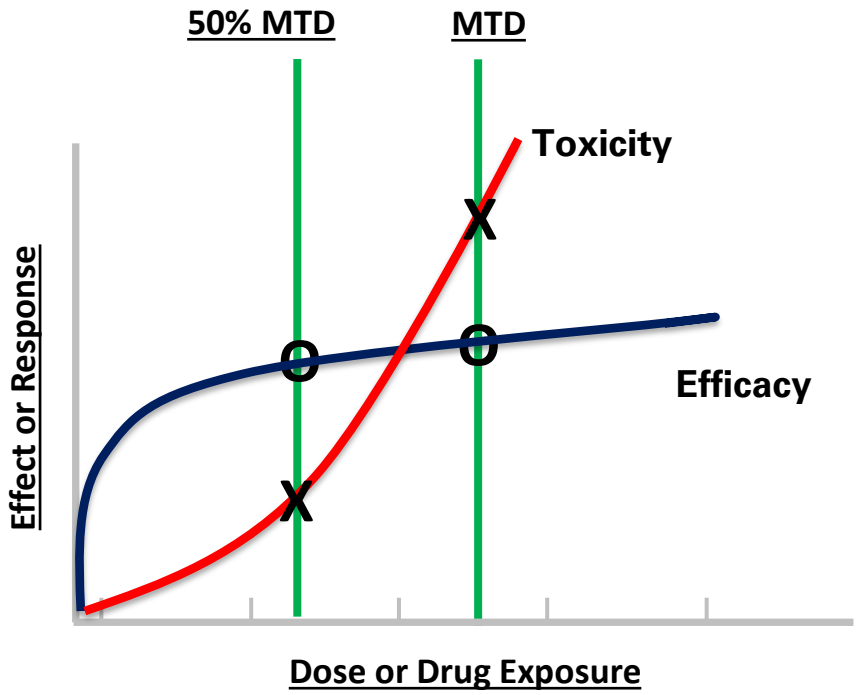
- ***Assumption Using Prior Maximum Tolerated Dose Approach to Define the Optimal Dosage Regimen (ODR) (Left Figure):*** Dose- or exposure-response relationships for toxicity and efficacy follow a similar pattern
- ***New FDA Oncology Drug Requirements Under Project Optimus:***
  - Answers the question "Does dose- or exposure-response relationship follow the left or right Figure?"
  - Project Optimus requires Companies to determine the relationship for both toxicity and efficacy in order to determine the ***ODR***



or



NGC-IRIN Dose-Response for Safety and Efficacy Follow Different Patterns in Animal Cancer Models, Irinotecan Follows Same Pattern

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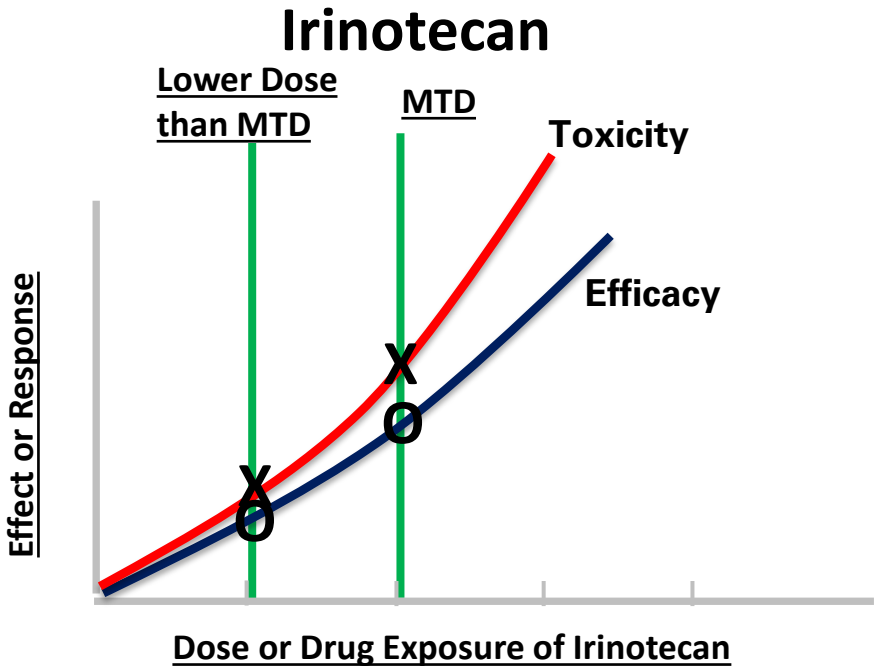

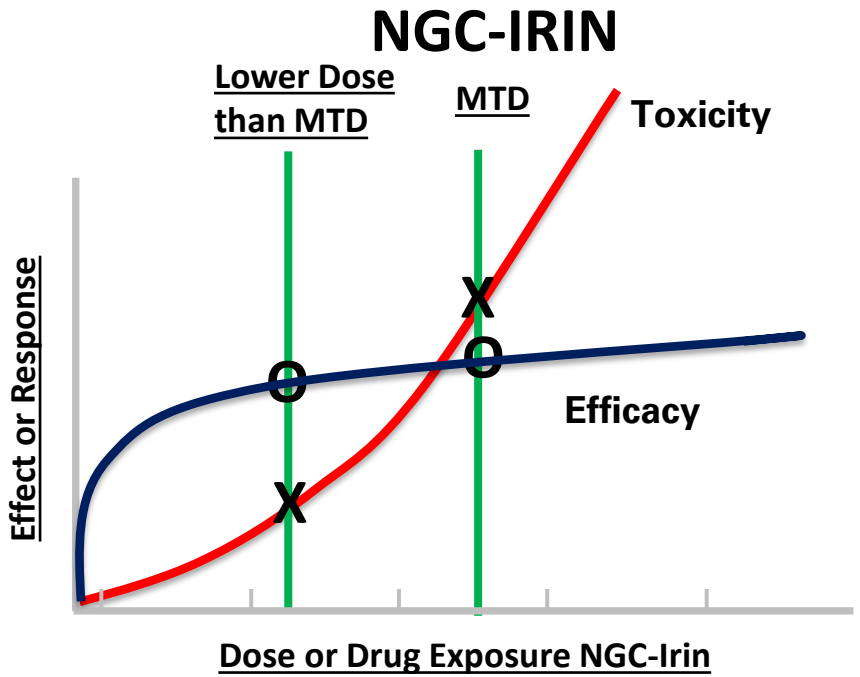

Decreasing the dose of Irinotecan to a lower dose than MTD ***decreases the severity and/or number of adverse events*** and ***decreases Irinotecan's ability to inhibit cancer***

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

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

Processa's Pipeline of Drugs

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Next Generation Chemotherapies Improving Safety and Efficacy						
		Development Stage				
Drug	Cancer Indications	Preclin	Phase 1	Phase 2	Phase 1	IND
Next Generation Capecitabine (PCS6422)	Hepatocellular, Pancreatic, Colorectal, Breast, Gastric, & Other Solid Tumor Cancers					
Next Generation Gemcitabine (PCS3117)	Pancreatic, Gall Bladder, Non-Small Cell Lung, & Other Solid Tumor Cancers					
Next Generation Irinotecan (PCS11T)	Pancreatic, Ovarian, Lung, Colorectal, Gastric, Cervical & Other Cancers					
Candidates for Out-Licensing, Partnering, or Other Monetizing Event						
PCS12852	Moderate/Severe Gastroparesis & Other GI Motility Conditions					
PCS499	Ulcerative Necrobiosis Lipoidica (uNL), Side Effects Associated with Chemotherapy, Other					

Processa's Pipeline of Drugs

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Next Generation Chemotherapies Improving Safety and Efficacy		
Drug	**Cancer Indications**	**Milestones (Anticipated Timeline)**
Next Generation Capecitabine (PCS6422)	Hepatocellular, Pancreatic, Colorectal, Breast, Gastric, & Other Solid Tumor Cancers	☑ Colorectal and breast cancer Proof of Concept trials with lower dosing of PCS6422 ☑ FDA discussion – Project Optimus & Phase 2 design ■ Complete Phase 1B trial (2H2023) ■ Initiate Phase 2 start-up tasks (2Q2023) ☐ Phase 2 interim analysis (2H2024) ☐ Complete enrollment (End of 2024)
Next Generation Gemcitabine (PCS3117)	Pancreatic, Gall Bladder, Non-Small Cell Lung, & Other Solid Tumor Cancers	☑ Treatment naïve and treatment refractory Proof of Concept pancreatic cancer trials ■ Re-analysis of pancreatic cancer data using Proj. Opt. (Mid-2023) ☐ Initiate Phase 2 start-up tasks (2H2023) ☐ Phase 2 interim analysis (2H2024) ☐ Complete enrollment (End of 2024)
Next Generation Irinotecan (PCS11T)	Pancreatic, Ovarian, Lung, Colorectal, Gastric, Cervical & Other Cancers	☑ Cancer animal study determining dose-response relationship ■ Re-analysis of animal dose-response results using Proj. Opt. (Mid 2023) ☐ Initiate IND enabling studies (2H2023) ☐ Complete IND enabling studies (End of 2024)
Candidates for Out-Licensing, Partnering, or Other Monetizing Event		
PCS12852	Moderate/Severe Gastroparesis & Other GI Motility Conditions	☑ Complete Phase 2a proof-of-concept trial ■ Out-licensing, partnering, or other opportunities for further development
PCS499	Ulcerative Necrobiosis Lipoidica (uNL), Side Effects Associated with Chemotherapy, Other	☑ Complete open-label Proof of Concept Phase 2a trial ☑ Discontinue Phase 2B trial (1H2023) ■ Out-licensing, partnering, or other opportunities for further development

Key: ☑ Milestone completed ■ Milestone in progress ☐ Anticipated milestones in 2023-2024

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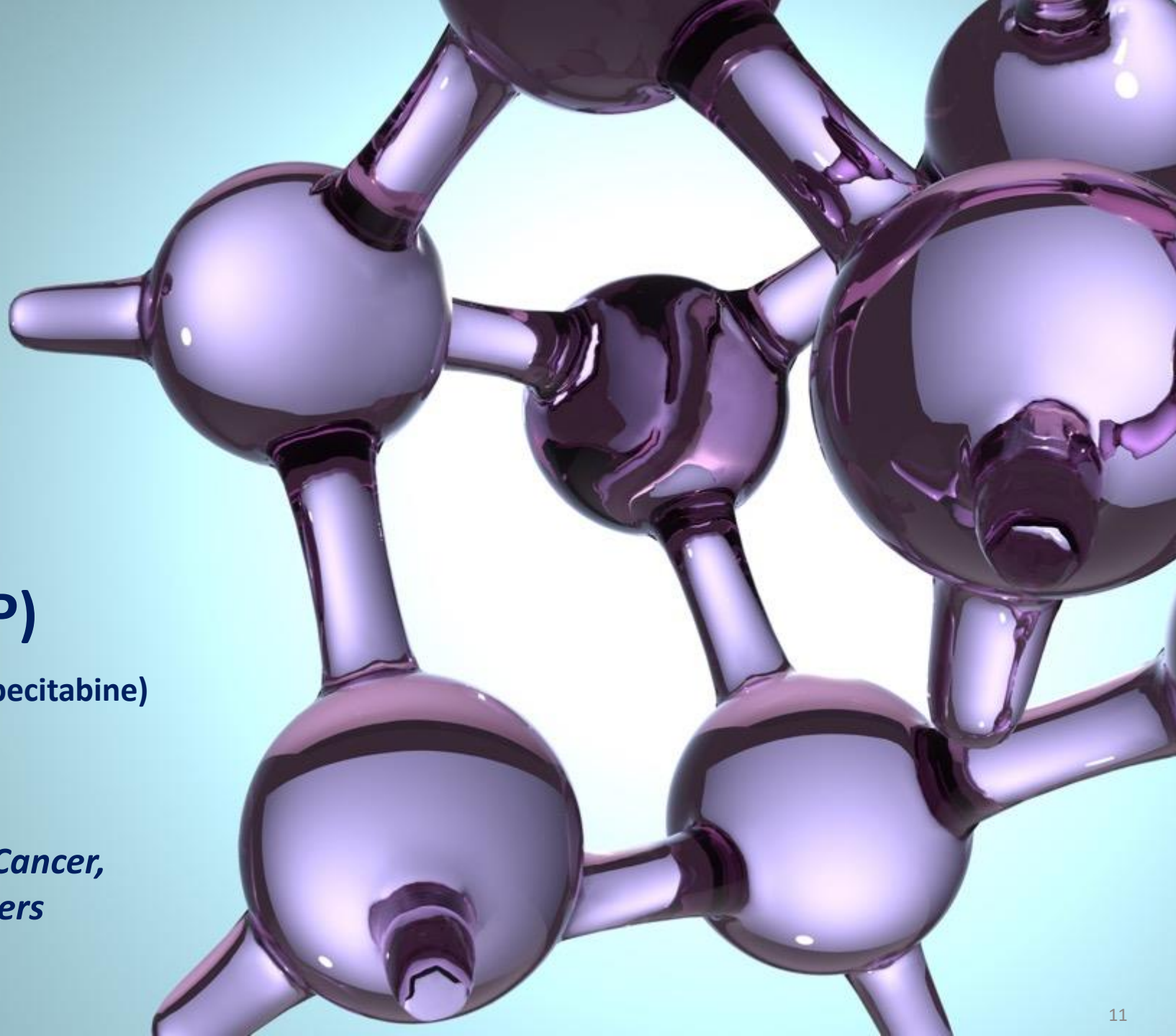
NEXT GENERATION CHEMOTHERAPY CAPECITABINE (NGC-CAP)

(Combination Regimen of PCS6422 and Capecitabine)

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



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

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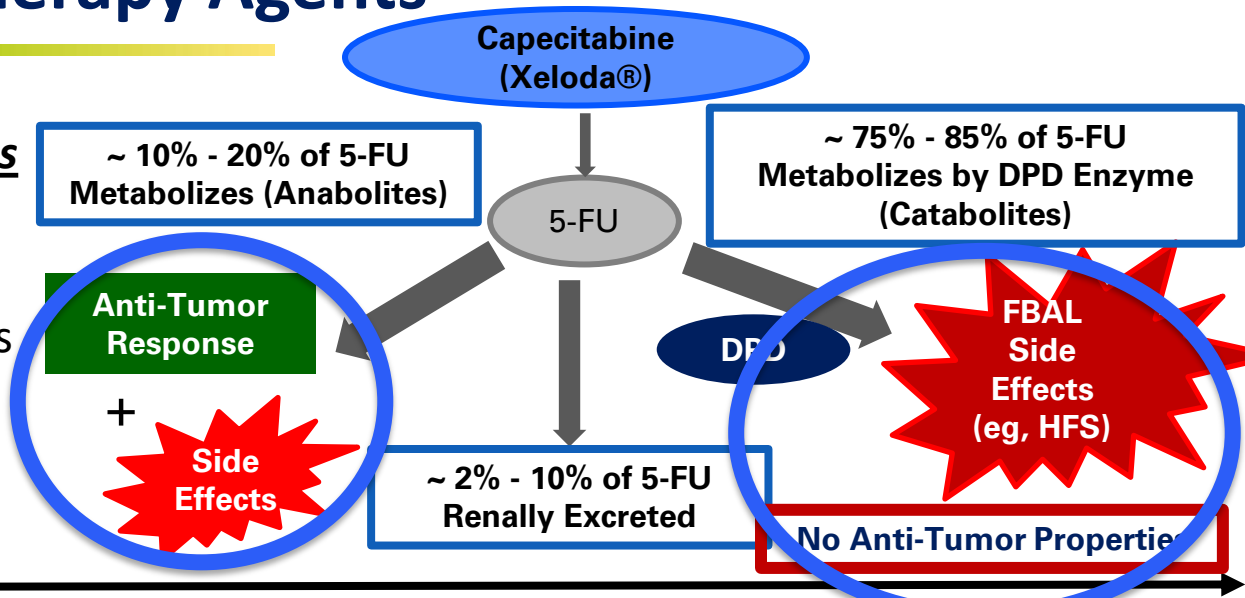
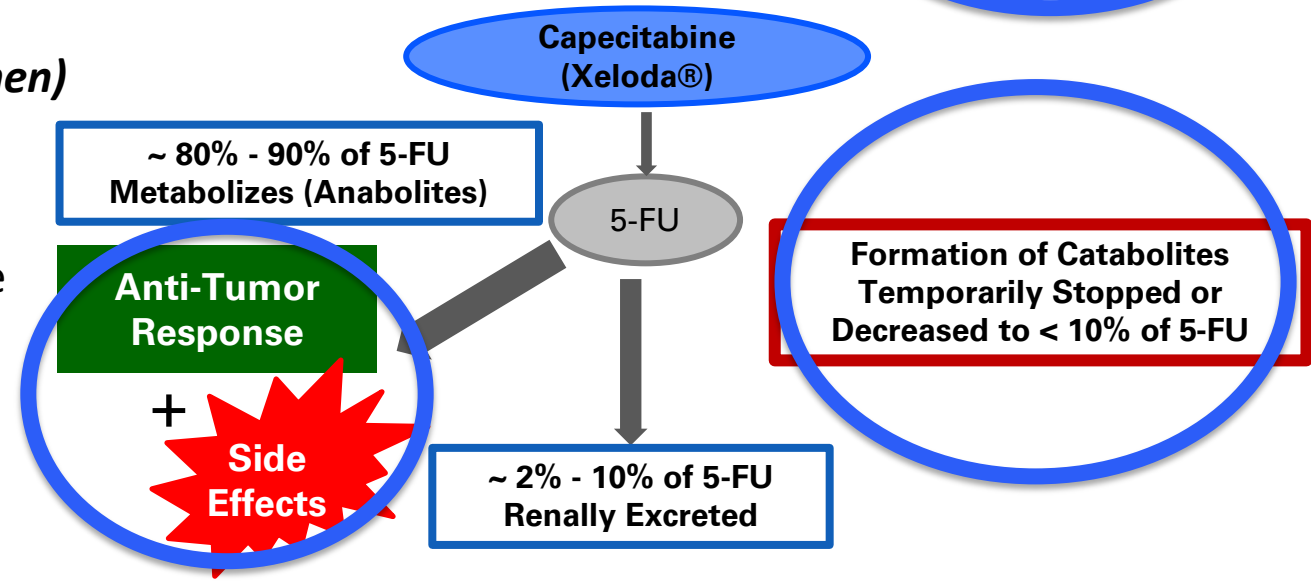
Capecitabine

- ***Maximum Tolerated Dose (MTD) for Capecitabine is determined from AEs associated with 5-FU Catabolites and Anabolites***
- 50% - 70% of patients have dose-limiting side effects from Catabolites requiring a change in therapy
- 60% - 70% of patients do not respond or are partial responders



NGC-Capecitabine (Combining PCS6422 Regimen (Irreversibly Inhibiting DPD) with Capecitabine Regimen)

- For NGC-Cap, 5-FU formation of Catabolites temporarily stopped or decreased to < 10% of 5-FU
- MTD for NGC-Cap different from MTD Capecitabine
  - 75%-80% of the metabolism of 5-FU to Catabolites no longer occurs
  - ***NGC-Cap MTD is determined only from the Anabolite AEs***



Highlights of Next Generation Chemotherapy-Capecitabine (NGC-Cap)

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- NGC-Cap has fewer Catabolites formed and is safer than Capecitabine based on previous clinical trials and the ongoing Phase 1b trial where ***0% of the patients have Catabolite related side effects*** (Capecitabine Catabolite side effects typically occur in 50-70% of the patients)
- NGC-Cap provides more exposure to the Capecitabine cancer killing Anabolites in ongoing Phase 1b trial resulting in ***patients having Anabolite related side effects even with Capecitabine doses equal to 5-10% of the FDA-approved Capecitabine dose***
- ***Based on communications with FDA, Processa has initiated pre-study start-up tasks for the Project Optimus Phase 2 safety-efficacy optimal dosage regimen trial***
- NGC-Cap is more likely to be approved by FDA through a more efficient development program than new oncology drugs given the ***active molecule is already known to kill cancer, the NGCs should provide improved treatment over existing chemotherapy, and the use of Project Optimus and Processa's Regulatory Science Approach***

Next Milestones of NGC-Cap in 2023

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Milestone	Approx. Date
Begin Phase 2 Trial Preparation (e.g., Writing Protocol, CRO Selection, Site Interviews, Drug Manufacturing)	2Q2023
Complete Enrollment of Phase 1b MTD Trial	2H2023
Submit Phase 2 Protocol to IND, Begin Initiating Sites, Begin Screening Patients	4Q2023
Evaluate Other Regulatory Paths to Approval (e.g., Fast Track)	2023
Prepare Additional Provisional Patent(s)	2023

Initiate Phase 2 Patient Screening in 4Q2023,
Interim Analysis in 2024 &
Complete Enrollment in 2024

Corporate Summary

- Clinical stage drug development company with a ***robust pipeline of Phase 2-ready Next Generation Chemotherapy (NGC)*** drug candidates with the potential to significantly ***reduce the number and severity of many side effects*** compared to existing chemotherapy drugs ***while improving patient response***
- 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 > $1.0 B for each NGC***
- ***Potential to out-license or partner non-NGC*** drug candidates PCS12852 and PCS499
- Pro-forma cash of $12.9M at YE22 provides an ***operating runway into 2H24***

Processa Senior Management

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Approvals for Indications in Almost Every FDA Division
Two FDA Contracts Where Regulatory Science Was Conceived
Management Team Involved With Billion-Dollar Exits (Questcor - $5.7 B & Gentium - $1.0 B)

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

Joined Processa 2018

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 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

Michael Floyd
Chief Operating Officer

Joined Processa 2020

Former Roles:

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

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

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, Hersperos
- MBA, California State University; BS, San Jose University

Wendy Guy
Chief Administrative Officer

Joined Processa 2018

Former Roles:

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

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IR@processapharma.com

NASDAQ: PCSA