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): March 14, 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.

Processa Pharmaceuticals, Inc. ("***Processa***") will be virtually presenting at the Oppenheimer 33rd Annual Healthcare Conference at 12:00 PM Eastern on March 14, 2023. During these meetings, 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 March 14, 2023.
104	Cover Page Interactive Data File - The cover page XBRL tags are 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 March 14, 2023.

PROCESSA PHARMACEUTICALS, INC.
Registrant

By: */s/ David Young*
David Young
Chief Executive Officer

Processa Pharmaceuticals

Development of Next Generation Chemotherapy Using Regulatory Science and Project Optimus

David Young, PharmD, PhD
President and CEO

Oppenheimer 33rd Annual Healthcare Conference
March 14, 2023

Disclaimer: Forward Looking Statements

The following summary is provided for informational purposes only and does not constitute an offer or solicitation to acquire interests in the investment or any related or associated company.

The information contained here is general in nature and is not intended as legal, tax or investment advice. Furthermore, the information contained herein may not be applicable to or suitable for an individual's specific circumstances or needs and may require consideration of other matters. The Company and its directors, officers, employees and consultants do not assume any obligation to inform any person of any changes or other factors that could affect the information contained herein.

These materials may include forward-looking statements including financial projections, plans, target and schedules on the basis of currently available information and are intended only as illustrations of potential future performance, and all have been prepared internally.

Forward-looking statements, by their very nature, are subject to uncertainties and contingencies and assume certain known and unknown risks. Since the impact of these risks, uncertainties and other factors is unpredictable, actual results and financial performance may substantially differ from the details expressed or implied herein. Please refer to the documents filed by Processa Pharmaceuticals with the SEC, specifically the most recent reports on Forms 10-K and 10-Q, which identify important risk factors which could cause actual results to differ from those contained in the forward-looking statements. The Company does not assume any obligation to release updates or revisions to forward-looking statements contained herein.

Developing Cancer Drugs in 2023 and Beyond

Goal: Treat Each Cancer Patient with the "Right" Drug at the "Right" Dose

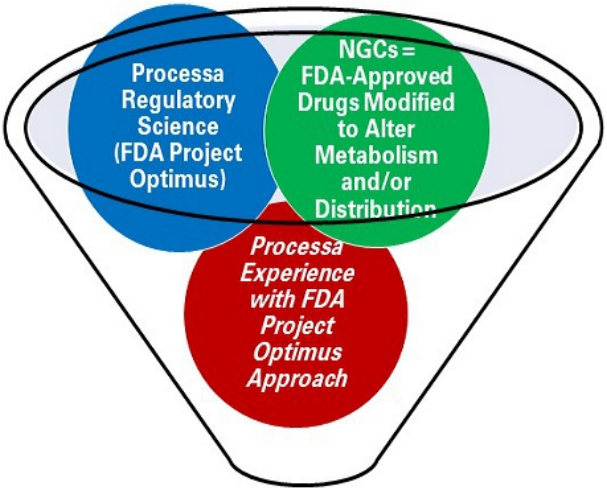
- FDA goal is to ensure that the benefit of the therapy outweighs the risks associated with therapy and the cancer itself.
- To achieve their goal, FDA has a new oncology initiative (Project Optimus) and a draft guidance on finding the "optimal" dosage regimen for oncology drugs.

- The side effects are less severe and/or there are fewer side effects.
- The response of an individual patient to treatment is more significant.

- More patients respond to treatment.
- Less patients have side effects that lead to discontinuation of treatment or a decrease in the dose.

Advantages of Processa's Regulatory Science Approach & Next Generation Chemotherapies (NGCs)

Why is Processa Different than Other Oncology Biotech Companies?



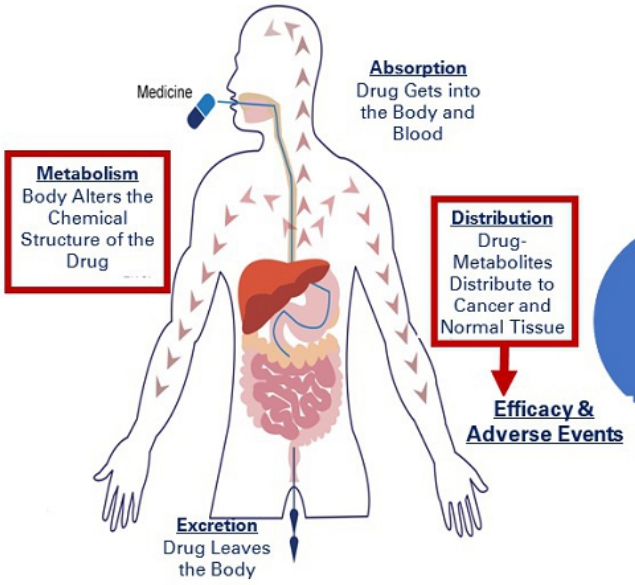
Efficiently Develop Drugs

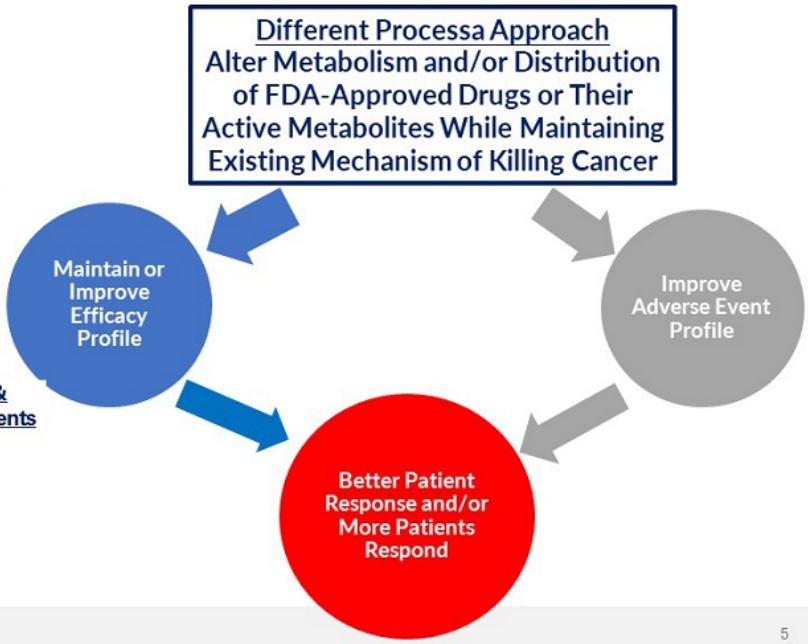
Increase Probability of FDA Approval

Better Therapy Than Existing FDA-Approved Drugs

Next Generation Chemotherapies Act on Established Targets

Most Oncology Companies Specialize in Drug Delivery or New Targets (eg, Immuno-Oncology, Gene Tx)



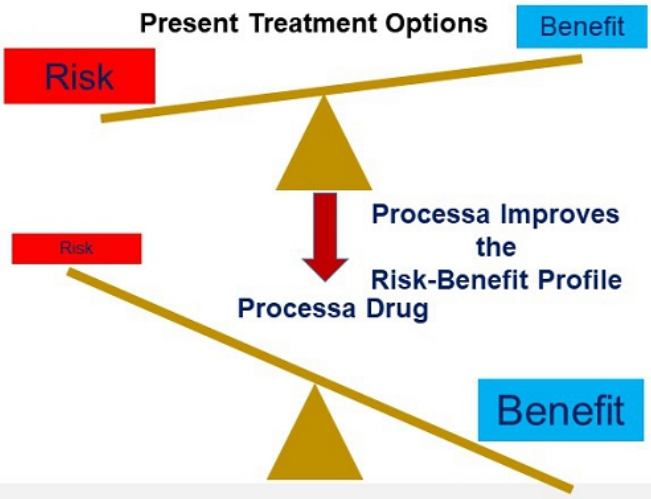


Processa's Regulatory Science Approach Improves Development and Product Differentiation

- **PCSA Regulatory Science approach:**
  - **was conceived from 2 FDA contracts in the 1990s.**
  - **evaluates the factors influencing FDA's Risk-Benefit analyses.**
  - **has resulted in > 30 FDA approvals for indications across FDA.**
  - **includes the principles of FDA's Project Optimus oncology initiative and Draft FDA Guidance.**

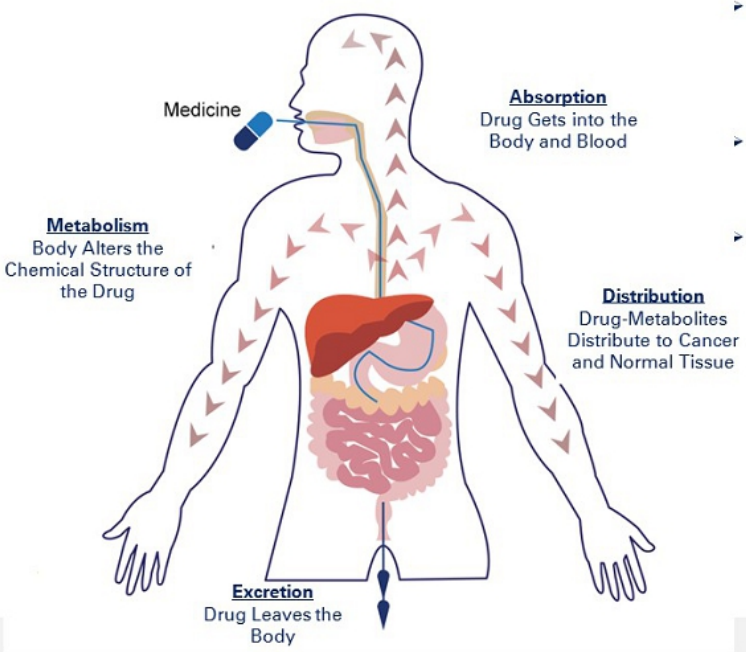
What Influences the Risk/Benefit Balance?

- **Existing Therapy (On-Label & Off-Label)**
- **Clinical Study Design for Best Risk-Benefit Outcome**
- **Regulators' View of Clinical Design & Results**
- **Regulators' View of Acceptable Risk/Benefit Balance**



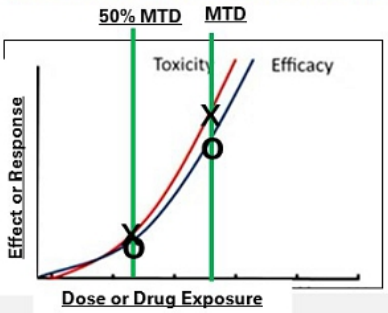
Prior TO FDA Project Optimus Initiative
Previous 30 Years of Oncology Clinical Drug Development

What Happens to Oncology Drugs in Patients?



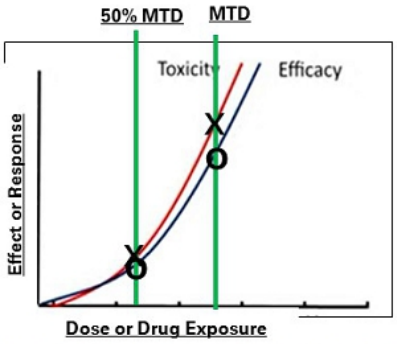
Previous Maximum Tolerated Dose (MTD) Approach

- **Inherent Assumption: Decreasing dose or drug exposure decreases not only the toxicity (adverse events) but also decreases efficacy in a similar manner.**
- **Step 1: Determine what the dose-limiting adverse events are and the dose of the drug that causes these dose-limiting toxicities (DLTs).**
- **Step 2: Determine the MTD that in most patients will not cause the DLTs.**
- **Step 3: Evaluate the efficacy and the safety of the drug at the MTD.**

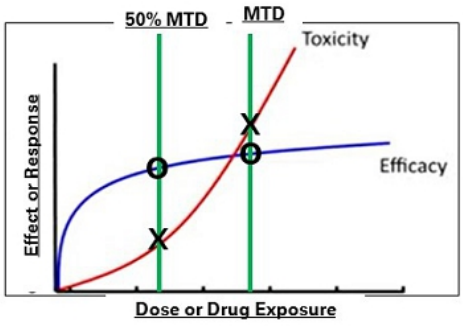


FDA Project Optimus:
Clinical Effect/Response May Not Follow the Same Pattern for All Oncology Drugs

- **Prior assumption that decreasing dose or drug exposure decreases not only the toxicity (adverse events) but also decreases efficacy in a similar manner may not be correct for all drugs (See Left vs Right Figures).**
- **Project Optimus defines the need to identify the optimal dosage regimen based on clinical response vs drug dose/exposure relationships.**
- **Processa has experience using the principles of Project Optimus in obtaining FDA approval for non-oncology drugs.**



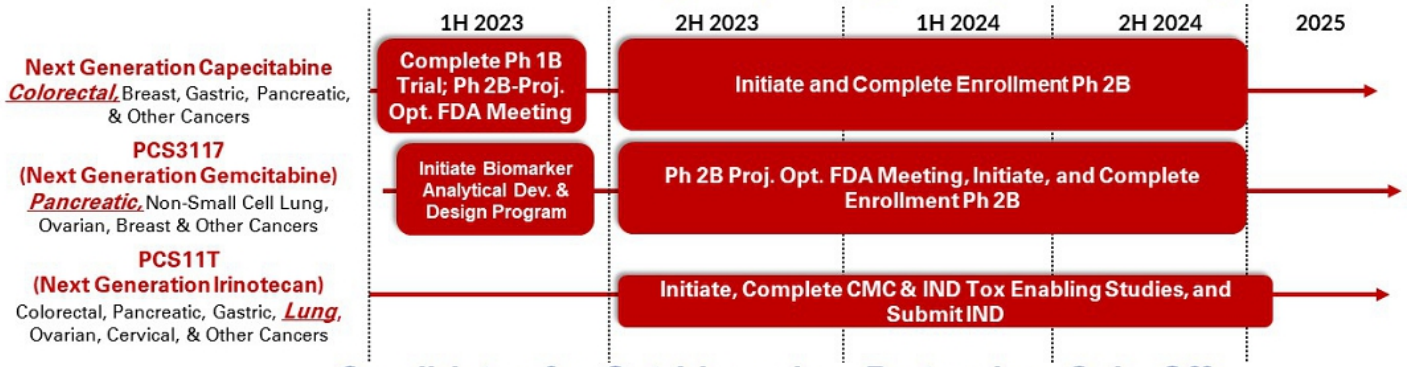
Example: ***Toxicity and efficacy vs exposure of irinotecan*** **(presently FDA-approved and widely used) follow the parallel path relationship in cancer animal models**



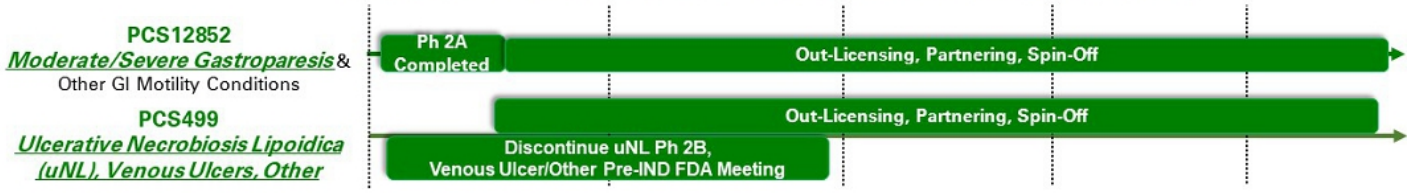
Example: ***Toxicity and efficacy vs exposure of Processa Next Generation Irinotecan*** **does not follow the parallel path relationship but instead large changes in dose result in large changes in toxicity but very small changes in efficacy**

Processa Pipeline of Drugs, Each with > $1B Market

Next Generation Chemotherapy Improving Safety and Efficacy



Candidates for Out-Licensing, Partnering, Spin-Off



Processa Senior Management

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**

Financial Highlights and Capital Structure

- Cash on September 30, 2022 was $9.1 million.
- On February 9, 2023 we closed an offering for net proceeds of $5.7 million from the sale of 7.8 million shares.
- Our current cash balance, include offering proceeds in 2023 provides a cash runway into the third quarter of 2024.
- Overhead only cash burn, including salaries, is expected to be approximately $5 million in 2022.
- For the six members of our C-Suite, cash compensation for all six will be a total of approximately $1.0 M in 2023.
- Current shares outstanding is approximately 24.5 million and fully diluted shares total approximately 32 million.
- 23% of our current outstanding common stock is held by officers and directors.
- Currently have 15 full and part-time employees.
- Our cash is maintained at the Bank of America and Merrill Lynch
- Research Analyst Reports:
  - Francois Brisebois, Oppenheimer; Naz Rahman, Maxim;
  - Robert Wasserman, Benchmark; Hogan Mullaly, Encode Ideas

Processa Pharmaceuticals

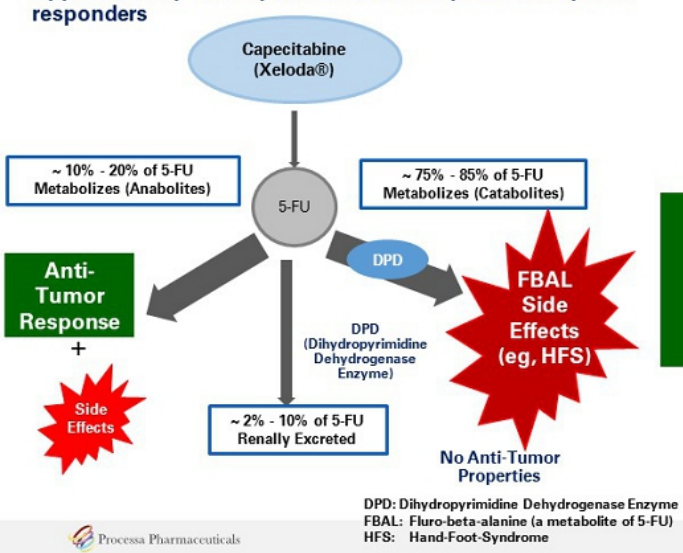
Next Generation Chemotherapy Capecitabine (NGC-Cap) (Combination Regimens of PCS6422 and Capecitabine)

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

5-FU & Capecitabine - Most Widely Used Cancer Chemotherapy Agents

Capecitabine

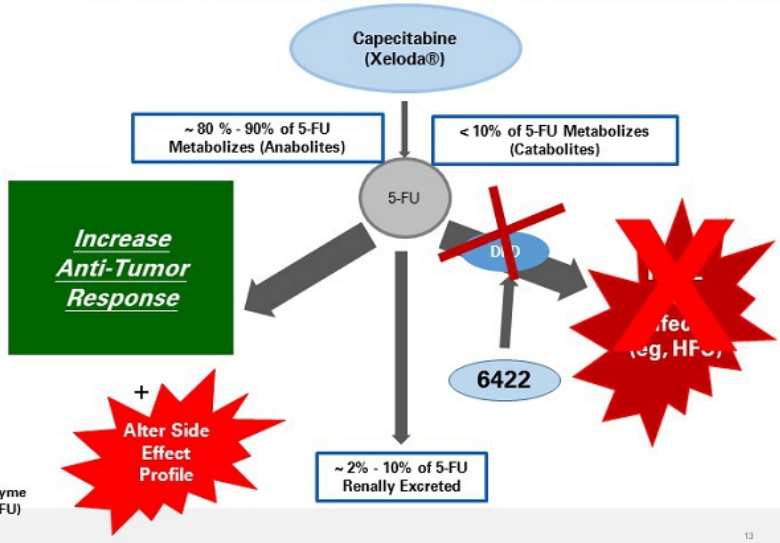
- The Maximum Tolerated Dose (MTD) for Cap is determined from AEs associated with Catabolites and Anabolites
- 50% - 70% of patients on capecitabine have dose-limiting side effects requiring a change in therapy
- Approximately 60% of patients do not respond or are partial responders



DPD: Dihydropyrimidine Dehydrogenase Enzyme
FBAL: Fluro-beta-alanine (a metabolite of 5-FU)
HFS: Hand-Foot-Syndrome

Next Generation Chemotherapy-Capecitabine

- For NGC-Cap (i.e., combining PCS6422 regimen (irreversibly inhibiting DPD) with capecitabine regimen), the 5-FU formed is predominately metabolized to Anabolites
- The MTD for NGC-Cap is different than MTD Capecitabine because NGC-Cap MTD is determined from the AEs associated with Anabolites

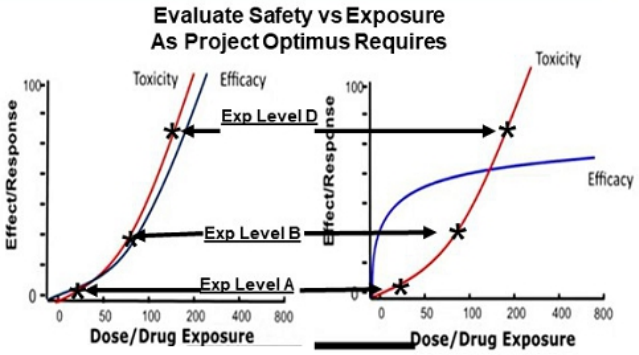


Next Generation Chemotherapy-Capecitabine (NGC-Cap)

	NGC-Cap Vs Cap
Absorption, Metabolism, Distribution	• No change in absorption of NGC-CAP compared to Cap • Less metabolism of NGC-Cap to catabolites • More metabolism of NGC-Cap to anabolites • More distribution of NGC-Cap to cancer cells
Side Effects	• NGC-Cap AEs caused by anabolites while Cap AEs caused by catabolites and anabolites • NGC-Cap has fewer dose-limiting AEs than Cap
Efficacy	• Mechanism of killing cancer cells same as Cap • Lower dose of NGC-Cap needed to kill cancer cells
Safety-Efficacy Profile	• MTD of NGC-Cap is significantly less than Cap • Fewer patients will need dose modification on NGC-Cap • Efficacy dosage regimen to be determined in Phase 2B • Proj. Opt. approach required for NGC-Cap while MTD approach was used for Cap

NGC-Cap Project Optimus: Evaluating Safety as a Function of Drug Exposure and 6422 Regimens in Phase 1B Trial

Phase 1B Trial	DLTs from Anabolites (e.g., Neutropenia)	AEs, DLTs from Catabolites (e.g., HFS)
5-FU Exposure Level A (NGC Regimen A)	0/1	0/1
5-FU Exposure Level B (NGC Regimen B)	0/6	0/6
5-FU Exposure Level C (NGC Regimen C)	TBD	TBD
5-FU Exposure Level D (NGC Regimen D)	2/5 (Exposure Limiting)	0/5



- 50%-70% of patients on FDA-approved Capecitabine have dose-limiting adverse events from FBAL resulting in discontinuation of treatment or a decrease in dose.
- Evaluating relationship between dose-limiting toxicities (DLTs)/adverse events and 5-FU exposure; present exposures/doses of Capecitabine in NGC-Cap have not caused DLTs or severe adverse events related to FBAL.
- Evaluating timeline of maintaining the potency of NGC to ~ 50-times greater than approved Capecitabine.
- **Safe 5-FU exposure levels (and NGC-Cap regimens) identified for evaluation in the Phase 2B safety/efficacy study; exposure levels and NGC-Cap regimens that cause DLTs have also been identified; meeting with FDA to discuss regimens and Phase 2B design.**

Next Milestones of NGC-Cap in 2023-2024

- NGC-Cap Cohort 3 (300 mg Cap per day x 7 days) is enrolling for evaluation of Adverse Event-Exposure relationship; no DLTs with one dose of 6422 and 150 mg Cap per day x 7 days.
- Potential 5-FU exposures and NGC regimens have been identified for a Phase 2B trial which will provide the exposure range required for FDA's Project Optimus Oncology Initiative.
- FDA meeting will be in April 2023 to discuss the development program, Project Optimus, and Phase 2B trial design.
- PCSA will initiate and complete patient enrollment of Phase 2B trial.
- PCSA is evaluating additional regulatory approaches (eg, fast track) to expedite development.
- PCSA is preparing provisional patent(s).

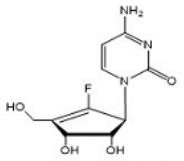
Initiate Phase 2B Trial in 2H2023 & Complete Enrollment in 2024, Subject to Funding

Processa Pharmaceuticals

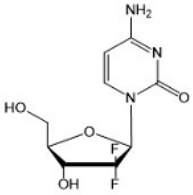
Next Generation Chemotherapy Gemcitabine (PCS3117)

Pancreatic Cancer - Recurrent Pancreatic Cancer after Surgery and Adjuvant Therapy, Biliary Cancer, Non-Small Cell Lung, and Other Cancers

PCS3117: Next Generation Chemotherapy – Gemcitabine (NGC-Gem)



NGC-Gem (PCS3117)
Oral Administration
(Cytosine + Ribose Analog)



Gemcitabine (dFdC)
IV Administration
(Cytosine + F,F-Deoxyribose)

- Gemcitabine is the most widely used chemotherapy agent used to treat pancreatic, non-small cell lung, biliary cancer.
- U.S. pancreatic cancer Gemcitabine sales are ~ $1 B; U.S. market for all cancer/indications is > $1.5 B.
- 55% - 85% of patients are inherently resistant to Gemcitabine or acquire resistance.
- NGC-Gem has a similar structure to Gemcitabine but is metabolized to the activate cancer-killing metabolite through a different pathway.
- NGC-Gem is more efficacious than Gemcitabine with a similar safety profile.
- NGC-Gem has FDA Orphan Designation for the treatment of pancreatic cancer.
- Initial target indications are:
  - First-line therapy for post-surgical recurrent pancreatic cancer after FOLFIRINOX adjuvant chemotherapy.
  - If biomarkers can be identified, first-line treatment in pancreatic cancer patients.

NGC-Gem Milestones in 2023-2024

- PCSA will complete the assay for possible biomarkers in pancreatic cancer patients (potential biomarkers to identify potential non-responders to Gemcitabine and responders to NGC-Gem).
- PCSA will meet with FDA to discuss pancreatic cancer development program and Phase 2B study design in mid-2023.
- PCSA will submit Phase 2B protocol to existing IND 2H2023.
- PCSA will initiate and complete patient enrollment of Phase 2B trial.

Initiate Phase 2B Trial in 2H2023 & Complete Patient Enrollment in 2024, Subject to Funding

Processa Pharmaceuticals

Next Generation Chemotherapy Irinotecan (PCS11T)

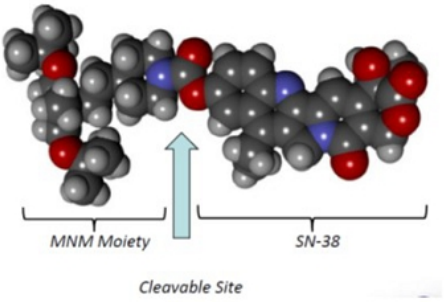
Colorectal, *Lung*, Pancreatic, Cervical and Other Cancers

Next Generation Chemotherapy-Irinotecan (PCS11T): Lipophilic Prodrug of SN-38 (Irinotecan Active Metabolite)

- Pro-drug of SN-38 linking SN-38 to a molecular nano-motor (MNM), a proprietary compound, which interacts with cell membranes **preferentially accumulating in the membrane of tumor cells and the tumor core more than normal cells.**

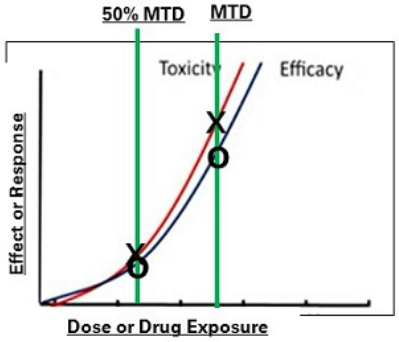
- Given the PCS11T specificity for cancer cells, upon approval it is **unlikely that PCS11T will have the BlackBox diarrhea warning that Irinotecan has.**

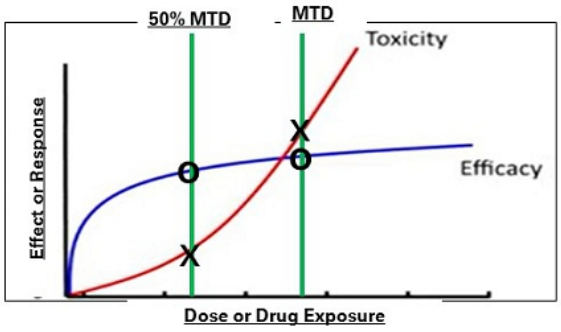
- **Irinotecan sales prior to generics was > $1B.**



NGC-Irin Clinical Effect/Response Do Not Follow the Same Pattern In Animal Cancer Model

- **Efficacy is maintained at lower doses of NGC-Irin compared to Irinotecan in colorectal cancer xenograft model**
- **SN38 had 200-times greater uptake in cancer cells vs muscle after NGC-Irin compared to only 15-times greater uptake after irinotecan.**





Toxicity and efficacy vs exposure of irinotecan **(presently FDA-approved and widely used) follow the parallel path relationship in cancer animal models**

Toxicity & efficacy vs exposure of Processa Next Generation Irinotecan **does not follow the parallel path relationship but instead large changes in dose result in large changes in toxicity but very small changes in efficacy**

At MTD	At ½ MTD	At ¼ MTD
Tumor Growth Inhibition	Tumor Growth Inhibition	Tumor Growth Inhibition
100% CPT-11	64% CPT-11	53% CPT-11
100% PCS11T	100% PCS11T	100% PCS11T

NGC-Irin Milestones in 2023-2024

- Drug Substance manufacturing site has been selected and Drug Product manufacturing sites are being evaluated.
- Drug development "roadmaps" are being developed for lung, pancreatic, colorectal, and other potential cancers.
- PCSA will complete manufacturing of Drug Substance and Drug Product.
- PCSA will complete IND enabling studies.

Initiate and Complete IND Enabling CMC and Toxicology Studies in 2023-2024, Subject to Funding