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): August 17, 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 presenting on August 17th at the 2023 Sidoti Micro-Cap Virtual Conference. The presentation, titled "Next Generation Chemotherapy: Improved Treatment for More Patients" will be presented during Track 2 at 11:30 AM Eastern by David Young, Pharm.D., Ph.D., Processa Pharmaceuticals' President, Research and Development.

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.

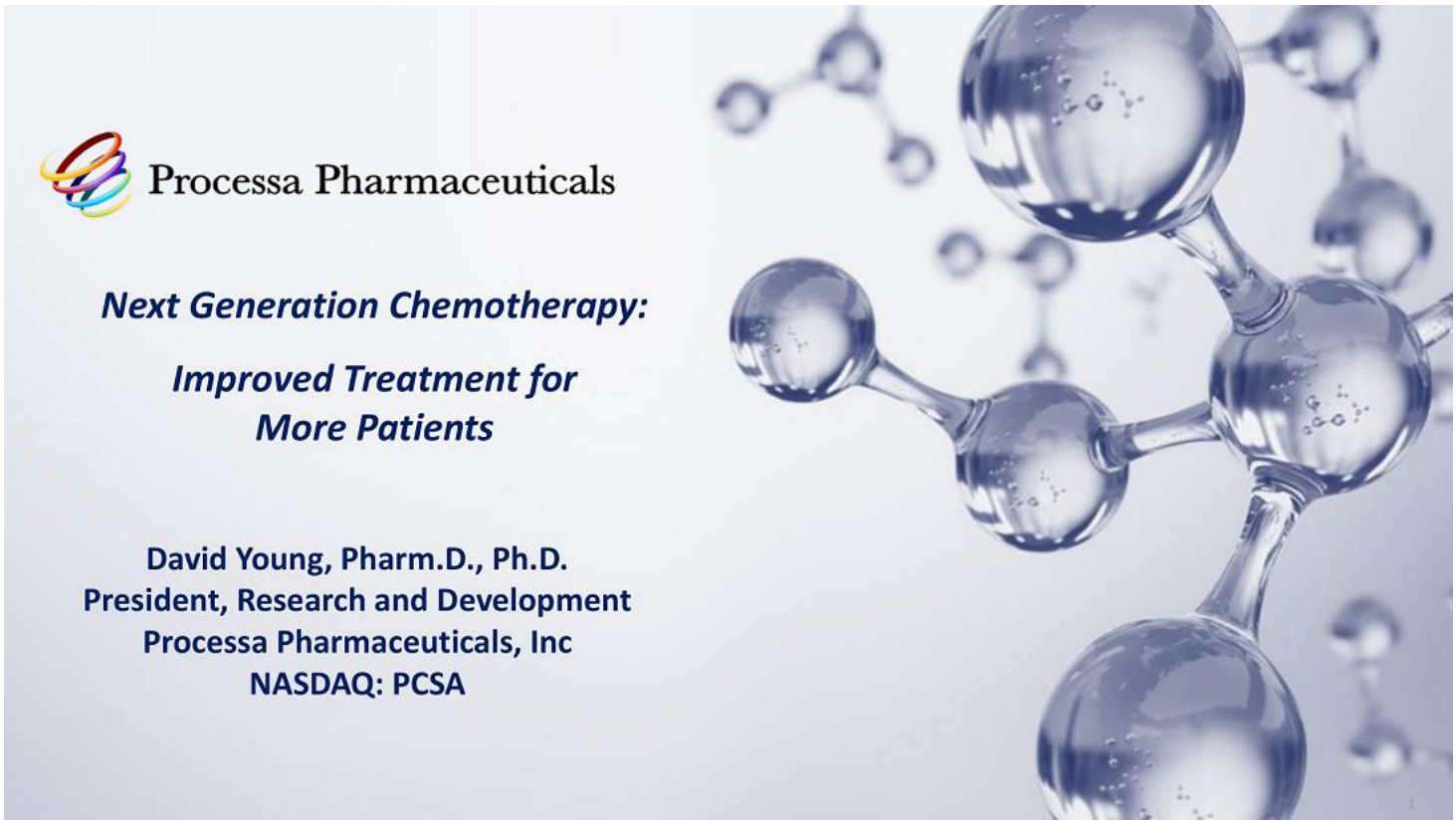
Exhibit No.	Exhibit Description
99.1	Processa Pharmaceuticals Presentation dated August 17, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document)

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 August 17, 2023.

PROCESSA PHARMACEUTICALS, INC.
Registrant

By: */s/ James Stanker*
James Stanker
Chief Financial Officer



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.

Present Chemotherapy Profile vs Desired Chemotherapy Profile

Processa Pharmaceuticals

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

How Can Processa Provide the Desired Chemotherapy?

Processa Pharmaceuticals

Processa Two-Part Solution

1. **Use Processa's Regulatory Science Approach & FDA's Project Optimus Oncology Initiative to Increase the Probability of Approval and Define an Optimal Dosage Regimen**
2. **Develop Next Generation Chemotherapy (NGC) Drugs – Improve Cancer Exposure to Widely Used FDA-Approved Cancer Killing Molecules (Proven History of Therapeutic Success) by Modifying Metabolism and/or Distribution of these Molecules**

Anticipated Outcome

1. **Provide Patients with Safer & More Effective Treatment**
2. **Improve Likelihood of FDA Approval**
3. **Provide Significant Investment Upside with Low Risk**
4. **Differentiate NGCs from Existing Chemotherapy with the Same Active Molecules**

Processa Senior Management

Processa Pharmaceuticals

George Ng
Chief Executive Officer

Joined Processa 2023

Former Roles:

- COO & Director, Calidi Biotherapeutics
- Partner, PENG Life Science Ventures
- Founder and President, Scilex Pharmaceuticals
- JD, University of Notre Dame; BASc, University of California, Davis

David Young, Pharm.D, Ph.D.
President, Research and Development

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

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, Hesperos
- 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

Investor Highlights

Processa Pharmaceuticals

- ***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
- Management Team involved with ***Billion-Dollar exits***
- ***3 Next Generation Chemotherapy (NGC) drugs with a greater likelihood of FDA-approval and potentially better safety-efficacy profiles (***2 NGCs in clinical stage)
- ***Greater than $500M - $1.0B U.S.*** market potential for each NGC used across multiple types of cancer
- ***Multiple NGC milestones*** achievable in 2023 and 2024
- Pro-forma ***cash of $8.7M at 2Q23 provides an operating runway into 2H24***
- ***Potential to out-license or partner*** non-NGC drug candidates PCS12852 and PCS499

Processa Pharmaceuticals (NASDAQ: PCSA)	
Stock Price (as of 8/11/23)	$0.40
Shares Outstanding (as of 8/15/23)	24.5M
Market Capitalization	$9.8M
FD Shares Outstanding	~32M
Cash & Equivalents (pro-forma at 6/30/23)	$8.7M
Insider Ownership	22%

How Can Processa Provide the Desired Chemotherapy?

Processa Pharmaceuticals

Processa Two-Part Solution

1. Use ***Processa's Regulatory Science Approach & FDA's Project Optimus Oncology Initiative*** to Increase the Probability of Approval and Define an Optimal Dosage Regimen
2. Develop ***Next Generation Chemotherapy (NGC) Drugs*** – Improve Cancer Exposure to Widely Used FDA-Approved Cancer Killing Molecules (Proven History of Therapeutic Success) by Modifying Metabolism and/or Distribution of these Molecules

Role of Regulatory Science and Project Optimus (Determining the Optimal Dosage Regimen)

Processa Pharmaceuticals

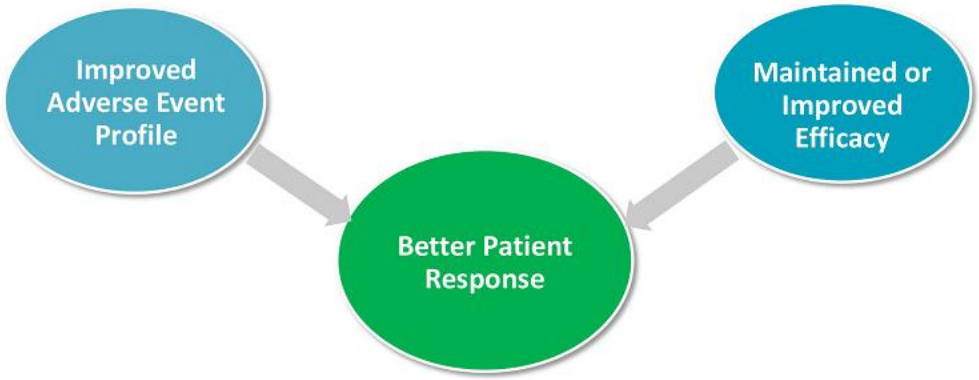
Processa Develops NGCs Using its Regulatory Science Approach and FDA's Project Optimus Oncology Initiative

- **Processa Regulatory Science Approach defines the "best" FDA acceptable way to determine the balance between safety and efficacy**
  - Processa Founders have developed their Regulatory Science Approach to drug development over the last 35 years with >30 approvals for multiple indications across FDA
- **Optimal Dosage Regimen (ODR) as defined by FDA's Project Optimus creates a better balance** between side effects and patient response
  - Determination and justification for ODR now required by FDA
  - Fewer side effects
  - Greater effect on the cancer
  - More efficient approval process

NGCs Enhance the Potential to Kill Cancer Cells by Altering the Metabolism of the Drug and/or the Distribution to Cancer Cells

Processa Pharmaceuticals

- NGCs use different scientific approaches to **Alter Metabolism and/or Distribution** of FDA-Approved cancer drugs or their active metabolites while maintaining existing mechanisms of killing cancer
- Pre-clinical and clinical studies provide preliminary evidence that the safety-efficacy profile is also improved



Processa's Pipeline of Drugs

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			Complete Phase 1B		
Next Generation Gemcitabine (PCS3117)	Pancreatic, Gall Bladder, Non-Small Cell Lung, & Other Solid Tumor Cancers			Proj. Opt. Phase 2 Re-Analysis		
Next Generation Irinotecan (PCS11T)	Pancreatic, Ovarian, Lung, Colorectal, Gastric, Cervical & Other Cancers		Proj. Opt. Pre-Clin Re-Analysis			
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					

Highlights of all NGCs

Processa Pharmaceuticals

	NGC Drugs
Development, Commercial	• More likely to obtain FDA approval given cancer-killing molecules are in existing chemotherapy & implementation of Regulatory Science Approach • More efficient development program expected than new types of oncology drugs • > 200,000 newly diagnosed patients/year in U.S. with cancers treated using each of the present FDA-approved versions • Market potential for each NGC in all presently treated cancers > $500M - $1.0B
Side Effects	• Side effect profile in patients better for NGC-Cap than Cap; similar for NGC-Gem & Gem • Side effect profile in animals better for NGC-Irin than Irin
Efficacy	• Active molecule same as FDA-approved cancer drugs for 2 of the NGCs and slight modification for 3rd • Cancer cells exposed to more active cancer-killing molecules for all 3 NGCs
Safety-Efficacy Profile	• Determining the Optimal Dosage Regimen (ODR) using FDA's Project Optimus Oncology Initiative being implemented

Summary of Milestones in 2023

Processa Pharmaceuticals

NGC-Cap Milestone		Approx. Date
****Complete Phase 1B MTD Trial Enrollment, Analyze Data to Assist in Phase 2 Design**	Ongoing	**2H2023**
****Define Reg. Paths to Approval & ODR Phase 2 Design with FDA**	Ongoing	**2023**
Begin ODR Phase 2 Trial Prep. (e.g., Writing Protocol, CRO Selection, Site Interviews)	Ongoing	2Q2023
Submit ODR Phase 2 Protocol to IND, Begin Initiating Sites		4Q2023
NGC-Gem Milestone		**Approx. Date**
****Re-analyze Clinical Cancer Data Using Project Optimus Approach**	Ongoing	**Mid-2023**
****Define Reg. Paths to Approval & ODR Phase 2&3 Designs with FDA Including Combo Treatment**	Ongoing	**2H2023**
Submit ODR Phase 2 Protocol to IND, Begin Initiating Sites		2H2023

NGC-Irin Milestone		Approx. Date
****Re-analyze Animal Cancer Data Using Project Optimus Approach**	Ongoing	**Mid-2023**
Define Drug Development "Roadmaps" for Potential Population Targets	Ongoing	Mid-2023
Select Drug Substance & Drug Product Manufacturing Sites		2H2023
Initiate Study Start-up for IND Enabling Toxicology Studies		2H2023

**** Key 2023 Valued Adding Catalyst**

Investor Summary

Processa Pharmaceuticals

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Processa's Pipeline of Drugs

Processa Pharmaceuticals

Next Generation Chemotherapies Improving Safety and Efficacy		
Drug	**Cancer Indications**	**Milestones (Anticipated Timeline)**
Next Generation Capecitabine (PCS6422)	Colorectal, Hepatocellular, Pancreatic, 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	☑ Proof-of-concept trials treating naïve and refractory pancreatic cancer patients ■ Pancreatic cancer Project Optimus data re-analysis (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 Project Optimus (Mid 2023) ☐ Initiate CMC and toxicology 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

NASDAQ: PCSA

Processa Pharmaceuticals

Develop NGCs Using Processa's Regulatory Science Approach and FDA's Project Optimus

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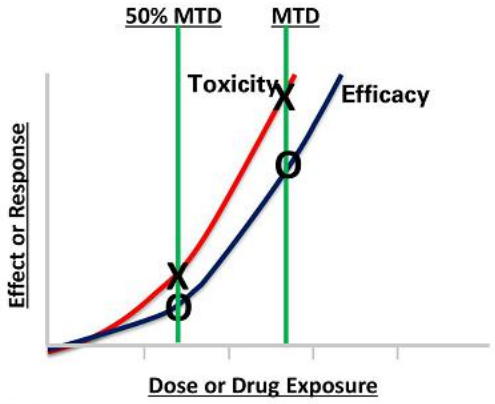
Regulatory Science Approach Utilizes Evaluation of the Exposure-Response Relationship Between Drug and Patient

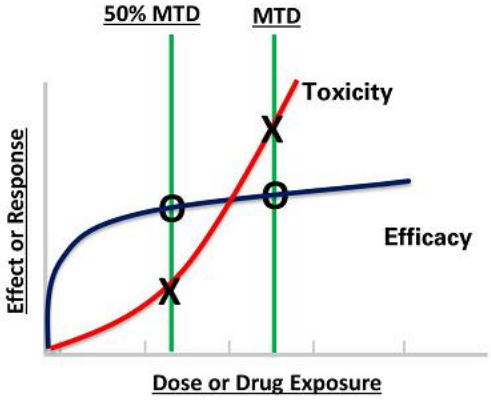
Processa Pharmaceuticals

- ***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



or

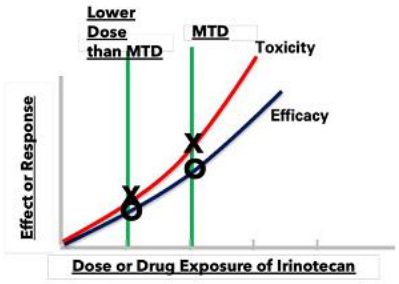
- ***Project Optimus and Processa Regulatory Science*** approach determines the dose- or exposure–response relationships for toxicity and efficacy in order to determine the ***ODR*** without prior assumptions



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

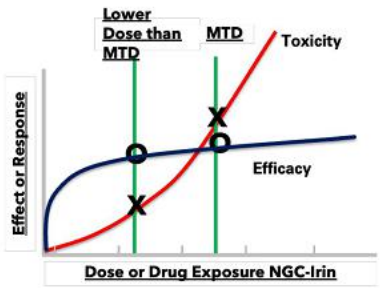
Processa Pharmaceuticals

Irinotecan



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

NGC-Irin



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***

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

Processa Pharmaceuticals

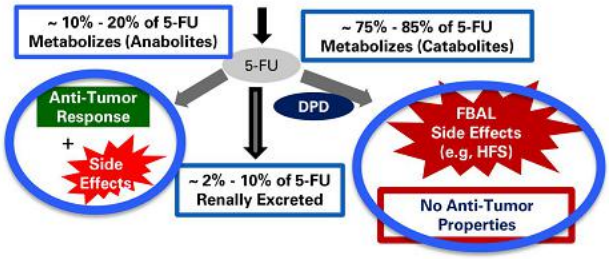
Next Generation Chemotherapy Drugs (NGCs)

Alter Metabolism and/or Distribution of FDA-Approved Drugs or their Cancer-Killing Molecules

NGC-Cap: Decrease *Metabolism* of Capecitabine* (Oral Pro-Drug of 5-FU) to Metabolites Only Causing Side Effects and Increase *Distribution* of Cancer-Killing Molecules to Cancer Cells

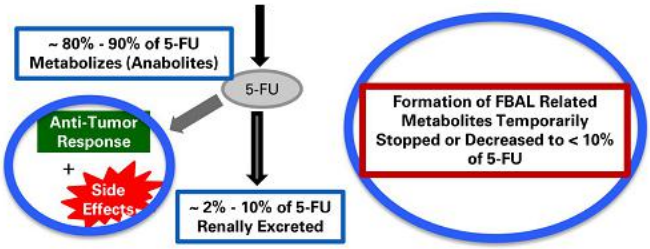
Processa Pharmaceuticals

Capecitabine (Xeloda®)



- Therapeutic dose determined by side effects from Catabolites (not cancer-killing molecules) and Anabolites (cancer-killing)
- **50-70% of patients have dose-limiting side effects from Catabolites requiring a change in therapy**
- Only **20%-40% of patients respond to Cap**

NGC-Cap (PCS6422+Cap)



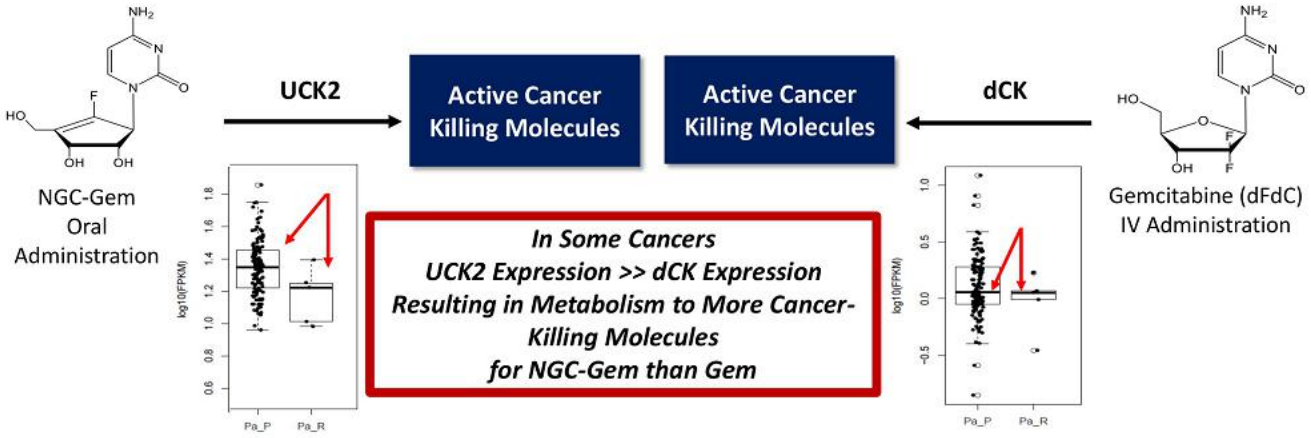
- With the administration of NGC-Cap, **metabolism of 5-FU to Catabolites no longer occurs and side effects from Catabolites are eliminated in Phase 1B trial**
- More **5-FU is available to distribute to cancer**
- **ODR to balance safety-efficacy to be determined in our Project Optimus designed Phase 2 trial**

NASDAQ: PCSA

* Capecitabine and 5-FU are 2 of the most widely used cancer drugs in U.S. and worldwide

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

Processa Pharmaceuticals



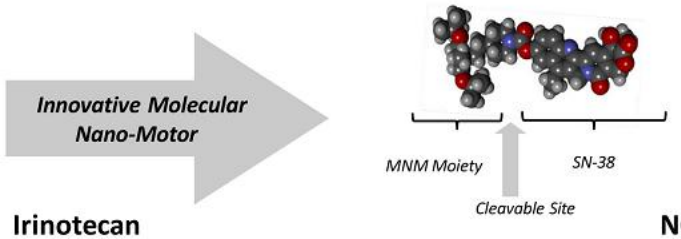
55% - 85% of Patients Inherently Resistant to Gemcitabine or Acquire Resistance

NASDAQ: PCSA

NGC-Irin: *Increase Distribution* of Cancer-Killing Molecule to Cancer Cells

Processa Pharmaceuticals

- Cancer-killing metabolite of Irinotecan is SN-38
- 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
- ***Extends half-life of SN-38 and increases SN-38 distribution to cancer 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