Processa Pharmaceuticals

Next-Generation Cancer Therapy
August 2024

Nasdaq: PCSA

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; (ii) our ability to maintain and enforce our intellectual property rights and related license agreements; (iii) our ability to succeed in any current or future litigation; (iv) our ability to successfully implement our strategic plans, including reliance on our lead product candidate; (v) our clinical development and related FDA regulatory approval of product candidates; (vi) clinical results for product candidates and unexpected costs related to applicable clinical development and trials; (vii) our ability to realize value from product candidates and preclinical programs being developed and anticipated to be developed; (viii) our reliance on collaborators and research and development partners; and (ix) our cybersecurity and data privacy.

These and other risks and uncertainties are more fully described in our 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, 2023, as amended, 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 information contained herein, including forward looking statements, to reflect any change in our expectations or any change in events, conditions, or circumstances on which any such statements are based.

About Processa Pharmaceuticals

Processa Pharmaceuticals

De-Risked Strategy for New Cancer Therapy

- Improving the distribution and/or metabolism of existing, proven anti-cancer agents as NCEs
  - Reducing side effects
  - Increasing efficacy
  - Increasing potency
- Three anti-cancer NCEs with multiple near-term catalysts
  - Two in clinical development
  - One near clinic-ready
  - All show significantly increased concentration in tumors and decreased concentration in healthy tissues.
  - Initial Phase 2 data expected mid-2025
- Experienced Team:
  - >30 indications approved by FDA to date using proprietary Regulatory Science Approach advancing drugs through the regulatory process
  - Approach includes defining the optimal dosage regimen that provides an FDA acceptable benefit-risk profile of efficacy and toxicity

Regulatory Science Approach

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Defining and Obtaining the Non-Clinical and Clinical Evidence Needed to Make Regulatory Decision

- Originated from collaboration between the FDA, Dr. Young and other faculty at the Univ. of MD, resulting in 4 FDA Guidance's
- Drs. Young and Bigora have refined their Regulatory Science approach over the last 30+ years
- The approach includes trying to understand what evidence FDA requires as well as the FDA evaluation process when evaluating benefit vs risk of a drug for approval
- Using the Processa Regulatory Science approach increases the likelihood of approval by aligning ourselves more closely to the FDA thought process
- For example, one major objective of Processa's Regulatory Science approach has been to determine the optimal dosage regimen of the drug
  - The Regulatory Science approach for oncology drugs, therefore, follows the principles of FDA's Oncology Project Optimus Initiative and Optimal Dosage Regimen Draft Guidance

Large Market Opportunity in Oncology

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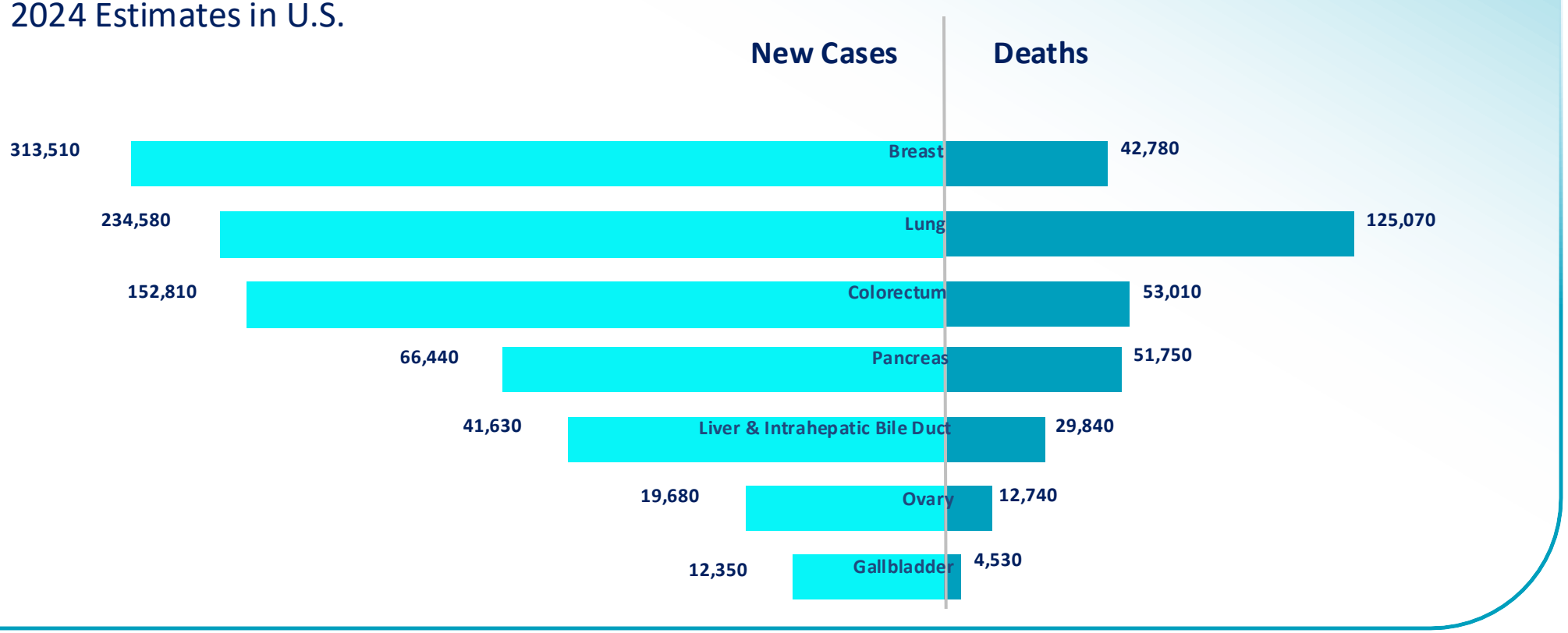
Cancer is the Second Leading Cause of Death in the U.S.

Two million new cancer cases expected in 2024 and approximately 611,720 deaths

Select Cancer Indications

2024 Estimates in U.S.



American Cancer Society 2024
Colorectum includes appendix
Male and Female breast cancer combined

Chemotherapy is a Large and Growing Market

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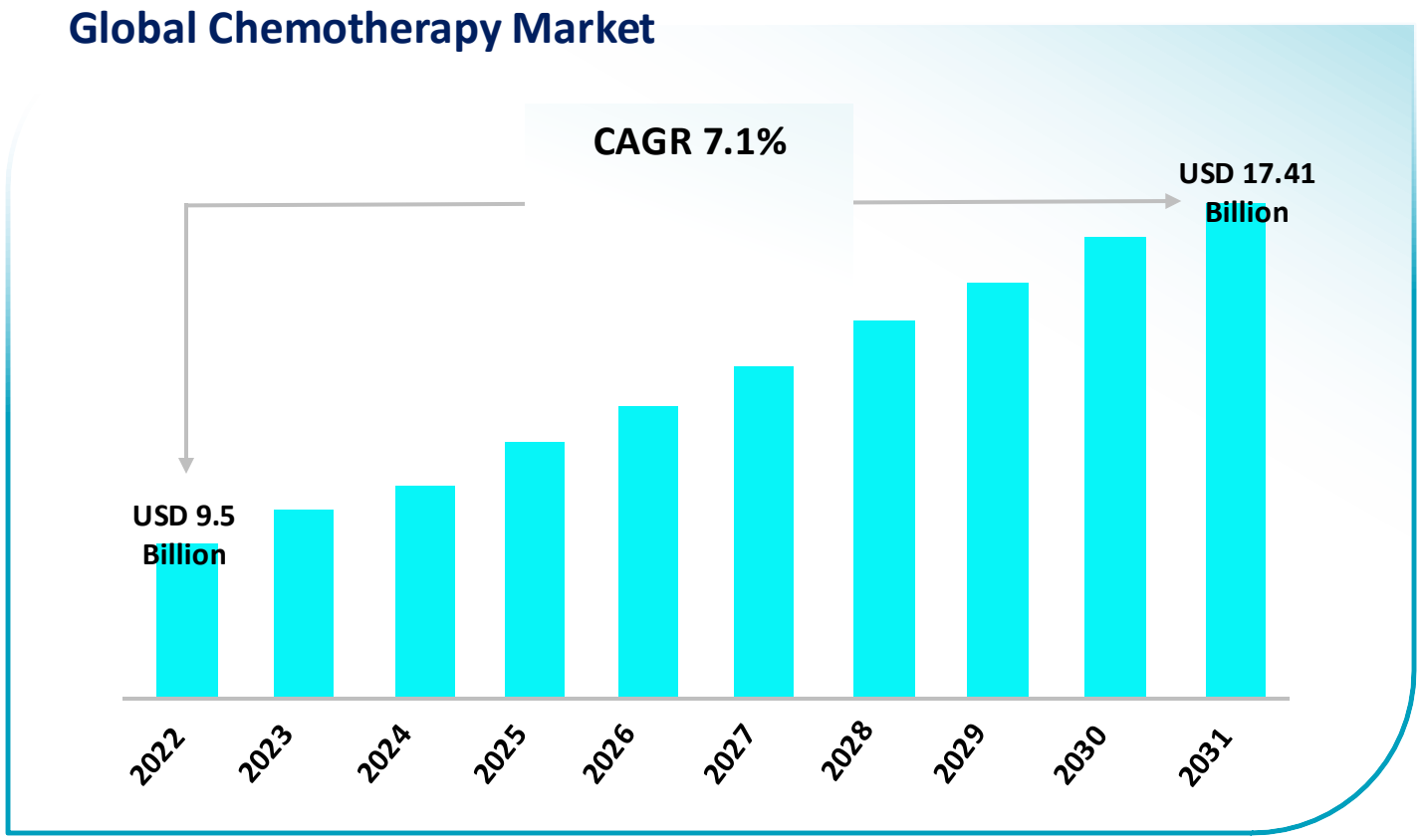
Chemotherapy Remains a Foundation of Cancer Therapy

Market is expected to grow as better, less toxic technologies enter the market



https://straitsresearch.com/report/chemotherapy-market

Our Approach to Next-Generation Chemotherapy

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Excellent Risk-Reward: Improving drugs that we know already work

- Industry's Approach:
  - Search for novel or different ways to treat cancer - exciting, novel technology (gets headlines)
  - High failure rate in clinic and market (often patients fail to complete treatment regimen due to side effects)
- Our NGC Approach:
  - Target heavily used current drugs where benefit is often limited due to toxicity (e.g., capecitabine, gemcitabine, irinotecan)
  - Improve how the body metabolizes these drugs to their active cancer-killing metabolites and how these active metabolites distribute to the cancer
    - Reduce toxicity while keeping the cancer-killing mechanism of action
- NGC compounds will potentially improve efficacy and toxicity by altering distribution and/or metabolism of known cancer killing molecules
  - Goal to demonstrate improvement over standard of care
  - Regulatory Science development process aligns with FDA's Oncology Project Optimus initiative to determine and justify the selection of the ODR[1]
- Improved treatment would expand market to additional patient populations
  - Fewer patients require dose modification, including dose reduction or discontinuation
  - Expanded use in elderly and pediatric patients

[1] https://www.fda.gov/about-fda/oncology-center-excellence/project-optimus

Pipeline

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Next-Generation Chemotherapies Improving Safety and Efficacy

Stage of Development

Drug	Target / Indications	Preclinical	Phase 1	Phase 2	Next Milestone
NGC-Cap (PCS6422) ***Capecitabine***	Breast, Colorectal, Hepatocellular, Pancreatic, Gastric, & Other Solid Tumor Cancers		Phase 1b Enrollment Completed		**3Q24:** Begin enrolling and dosing patients in Phase 2 trial in advanced or metastatic breast cancer
NGC-Gem (PCS3117) ***Gemcitabine***	Pancreatic, Gall Bladder, Non-Small Cell Lung, & Other Solid Tumor Cancers			Phase 2a Completed	**4Q24-1Q25:** Meet with the FDA to define the ODR Phase 2 protocol.
NGC-Iri (PCS11T) ***Irinotecan***	Lung, Pancreatic, Ovarian, Colorectal, Gastric, Cervical & Other Cancers	Preclinical			**2025:** Expand preclinical analysis with additional ongoing preclinical efficacy study; Evaluating sites to manufacture PCS11T; Conduct CMC and Pre-IND enabling toxicology studies

NGC-Cap: What Is Capecitabine?

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Commonly Used Anticancer Drug with Significant Side Effects

- Capecitabine
  - Oral prodrug of 5-fluorouracil (5-FU)
  - Capecitabine and 5-FU are among the most widely used cancer chemotherapy agents
    - Breast, Gastric and Colorectal
- Low treatment response with high side-effect profile
  - Therapeutic dose determined by side effects from catabolites (non-cancer killing molecules) and anabolites (cancer killing molecules)
  - Approximately 35% - 70% of patients have dose-limiting side effects from catabolites requiring a change in therapy
- Only 20%-40% of patients respond to Capecitabine
- Medicare doses (2021): ~9,200,000

Source: Xeloda product label and Talbot Br J Cancer 86, 1367, 2002.

NGC-Cap: How We Improve Capecitabine Therapy

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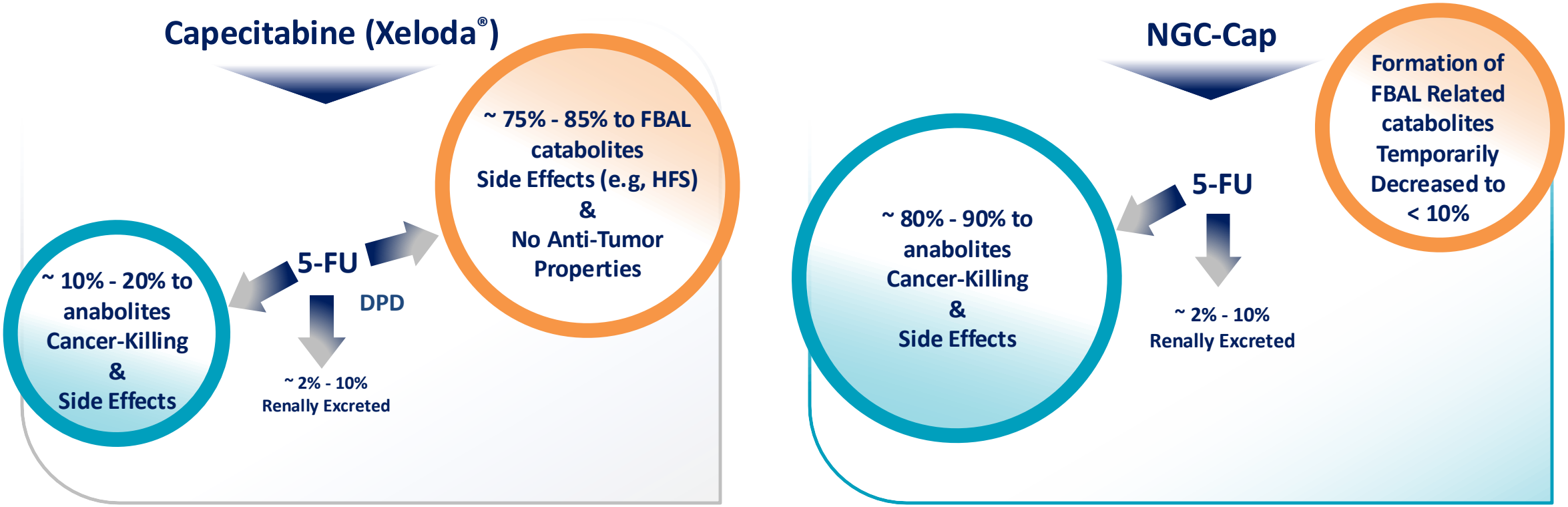
Increased cancer-killing anabolites in tumor; Reduced catabolites (side effects) outside tumor



- NGC-Cap is the combination of PCS6422 and Capecitabine
- The mechanism of killing cancer cells is the same as Cap/5-FU
- Formation of catabolites almost non-existent
- ***Exposure profile of the cancer cells to cancer-killing anabolites is GREATER than existing FDA-approved*** Cap even though the amount of Cap administered is 10% of FDA-approved Cap
- Therapeutic dose to be determined solely by exposure profile of anabolites

NGC-Cap: Study Design

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Determining the NGC-Cap dosage regimens with a safety profile better than capecitabine monotherapy

- Patients with advanced, progressive GI cancer even after multiple types of treatment including 5-FU or capecitabine (n=18)
- NGC-Cap is the combination of a single dose of PCS6422 administered 12-24 hours prior to receiving 7 days of capecitabine followed by 7 capecitabine-free days
- Doses of capecitabine in NGC-Cap ranged from 75mg QD to 225mg BID, versus the 1,600 - 2,500mg BID for FDA-approved capecitabine
- Primary objective to determine the Recommended Dose Range for Phase 2, including the Maximum Tolerated Dose (MTD)

NGC-Cap: Study Results To Date

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Better Tolerated than Capecitabine with Preliminary Positive Efficacy

- 5-10x greater exposure to its 5-FU cancer treatment metabolite than capecitabine
  - Better tolerated than capecitabine even with greater exposure
  - One patient with mild case of hand-foot-syndrome: 6% versus expected ~50% based upon published data
- Although patients had advanced, progressive cancer entering the study, some patients responded to NGC-Cap
  - Positive preliminary efficacy in patients' refractory to other cancer treatments, including 5-FU or capecitabine
  - Partial response or stable disease was observed in 66.7% (8 out of 12) of evaluable patients
  - Progression-free survival was approximately 5 - 11 months in these relapse and refractory patients

NGC-Cap Product Profile

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Efficacy

- Alters metabolism to increase formation and distribution of 5-FU and cancer-killing molecules to cancer cells while reducing the metabolites that only cause side effects
- Active molecule same as Capecitabine but provides improved treatment

Side Effects

- Better side-effect profile

Intellectual Property

- Current patent protection until 2030; potential patent protection from additional filings until ~2044

Clinical Development

- Recommended Dose Range for Project Optimus evaluation identified in Phase 1b study
- Phase 1b study completed with final data analysis pending
- Received IND clearance to initiate a Phase 2 trial for advanced or metastatic breast cancer expected to commence 3Q24

NGC-Gem: What is Gemcitabine?

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Standard of care drug with known resistance

- Gemcitabine is widely used in pancreatic, gall bladder, lung, and other solid tumor cancers
- Approximately 20% - 40% of patients respond to Gemcitabine across solid tumor cancers
- Resistance to Gemcitabine a key problem with 55% - 85% of patients inherently resistant or acquire resistance
- Enzyme metabolizing NGC-Gem to cancer-killing metabolite is more abundant than enzyme metabolizing Gemcitabine
- NGC-Gem oral therapy rather than IV as with Gemcitabine
- Medicare doses (2021): ~840,000

Source: Gemcitabine product label.

NGC-Gem: Improves Metabolism of Gemcitabine

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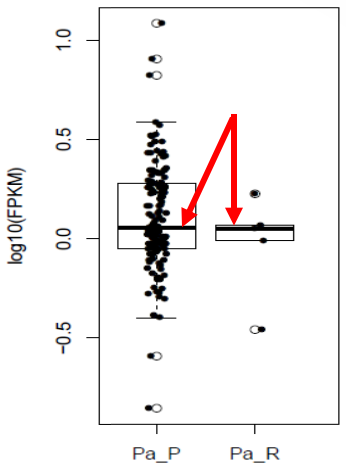
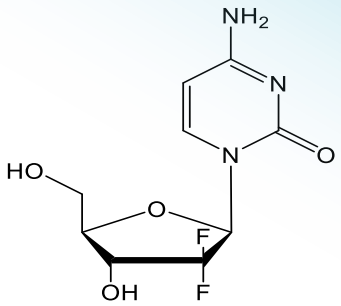
New Oral Formulation Increasing Expression Through a Novel Enzyme Pathway

dCK



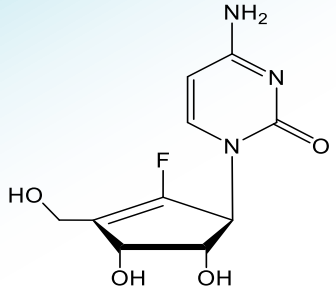


Gemcitabine (dFdC)
IV Administration

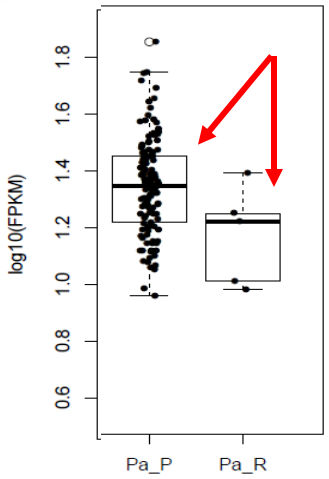
Active Cancer Killing Molecules

In some cancers
dCK Expression < UCK2 Expression
resulting in metabolism to more cancer-killing molecules for NGC-Gem than Gem

UCK2



NGC-Gem
Oral
Administration



Increase metabolism to cancer-killing molecules given different metabolizing enzyme than Gemcitabine (dCK being one of the major causes for resistance)

NGC-Gem: Phase 2 Safety and Efficacy in Pancreatic Cancer

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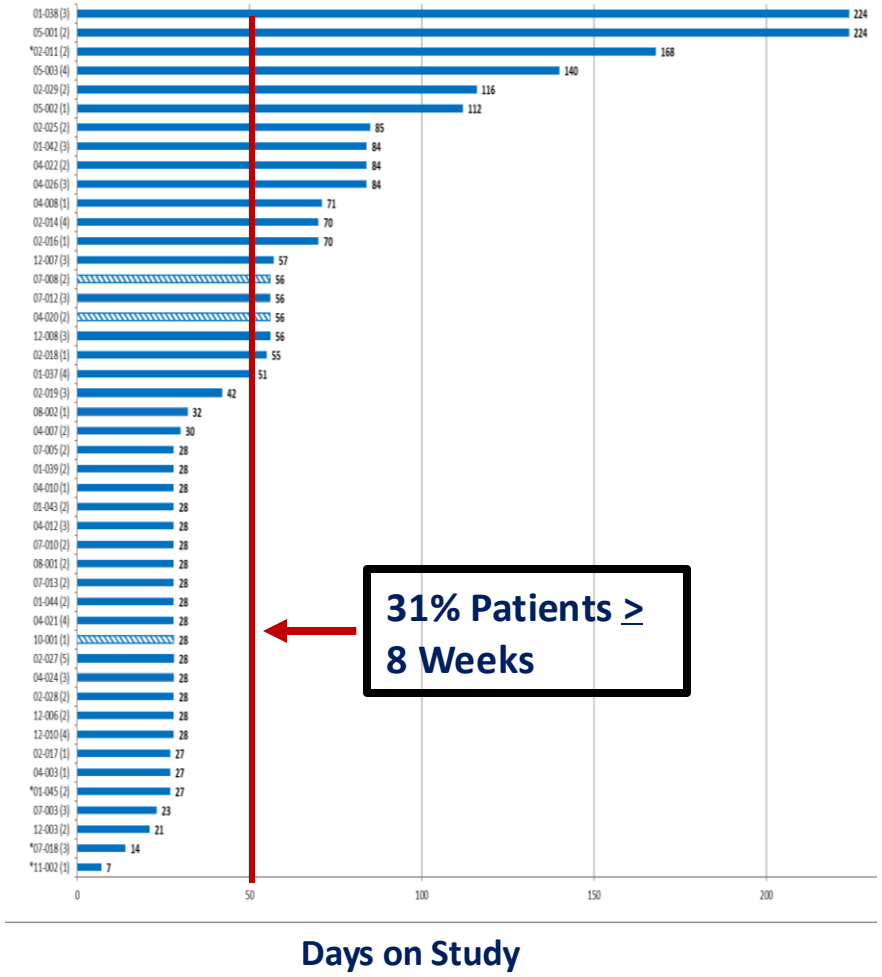
Phase 2 Trial in patients with progressive metastatic pancreatic cancer after previous therapies of chemotherapy, including 93% refractory to Gemcitabine



- 31% (14 patients) had progression-free survival for 8 weeks or more
- 12% (5 patients) had stable disease for more than 4 months
- One patient had a tumor reduction of 40% after 28 days of treatment
- Mild to moderate adverse events were reported with a better overall safety profile than Gemcitabine

NGC-Gem Product Profile

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Efficacy

- Positive results demonstrated in Phase 2a trial in pancreatic cancer patients
- Cancer cells exposed to more NGC-Gem cancer-killing molecules due to improved activating enzyme

Side Effects

- Side-effect profile similar to Gemcitabine

Intellectual Property

- Potential patent until 2036

Clinical Development

- Company to collaborate with FDA on the Phase 2 development program, including target population, design of the next safety-efficacy trial, dosage regimen(s), and comparator treatment arm within the trial

NGC-Iri: What is Irinotecan?

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Safer and More Effective Chemotherapy Without Black Box Warning

- Irinotecan is widely used in lung, pancreatic, ovarian, cervical & other solid tumor cancers
- Approximately 15-35% of patients respond to Irinotecan across the solid tumor cancers
- The major drawback of Irinotecan and its active metabolite SN-38 is the side-effect profile which includes a black box warning for diarrhea and myelosuppression
- SN-38 from NGC-Iri preferentially accumulates in the membrane of tumor cells and the tumor core more than normal cells compared with Irinotecan and Onivyde®
  - Potentially increasing the cancer-killing effect
  - Decreasing the Black Box warning side effects associated with Irinotecan
- Medicare doses (2021): ~1,800,000

Source: Irinotecan product label.

NGC-Iri: Higher Amounts & Lower Required Dose

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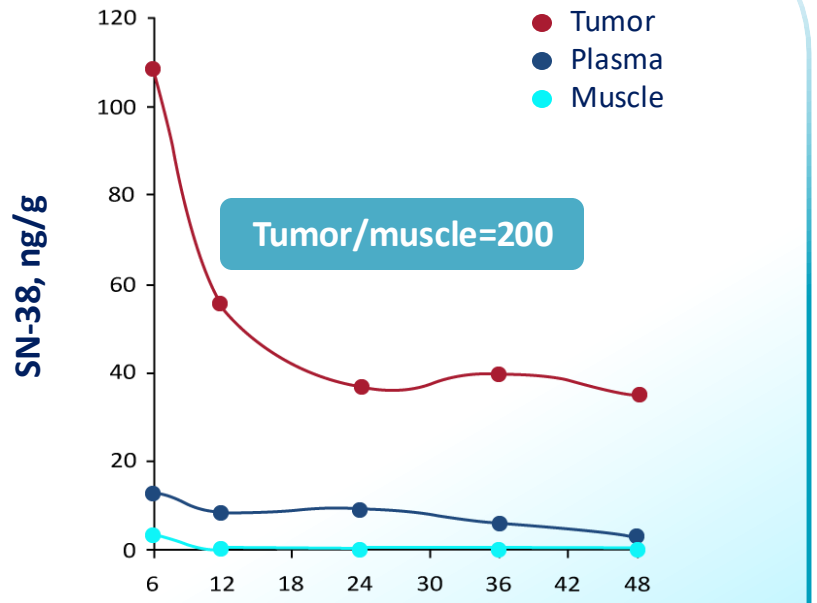
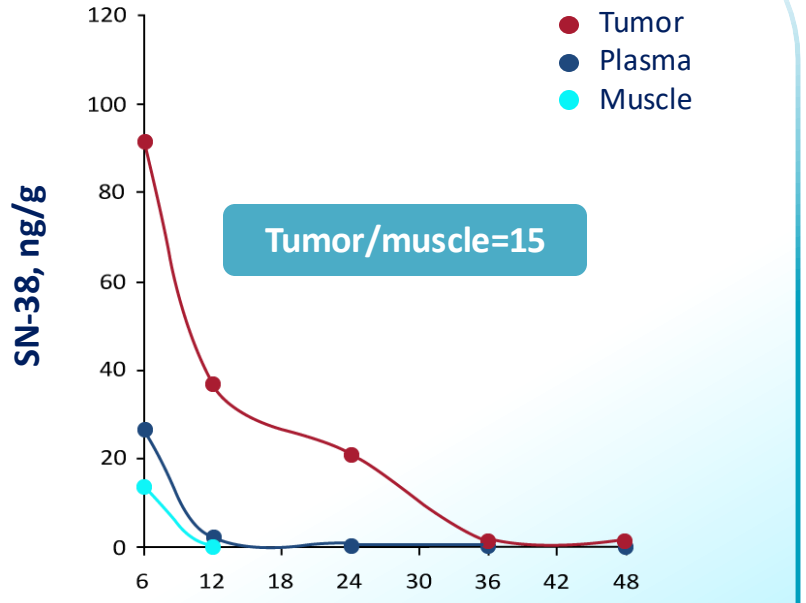
Tumor-Bearing Mice had 200x Higher Drug in Tumor Versus Muscle Compared to 15x with Irinotecan

NGC-Iri



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

NGC-Iri: Higher Amounts & Lower Required Dose

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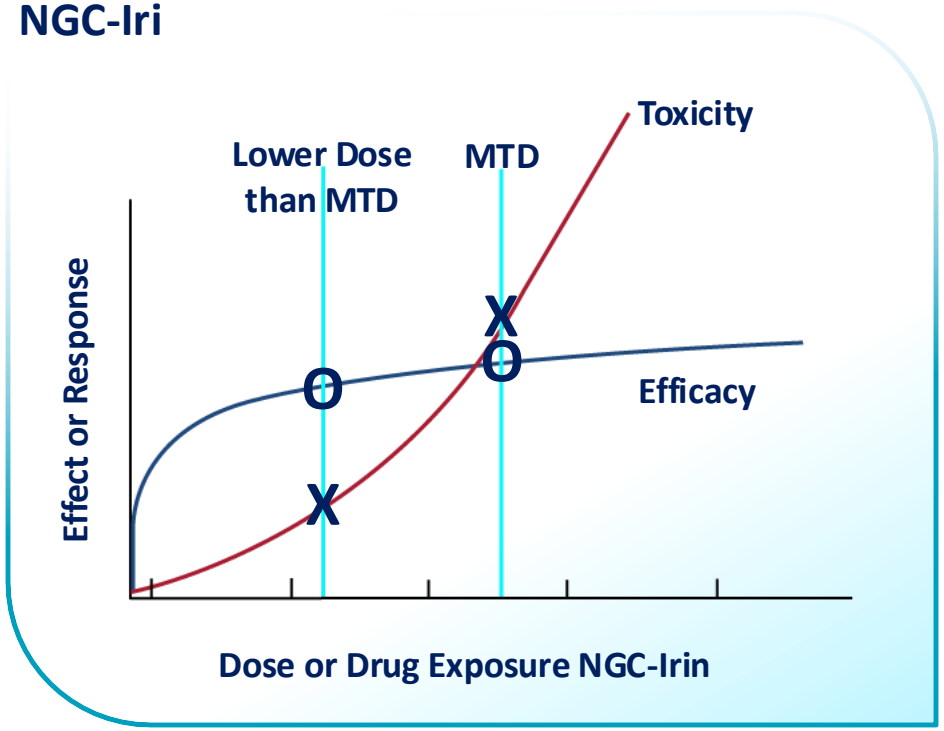
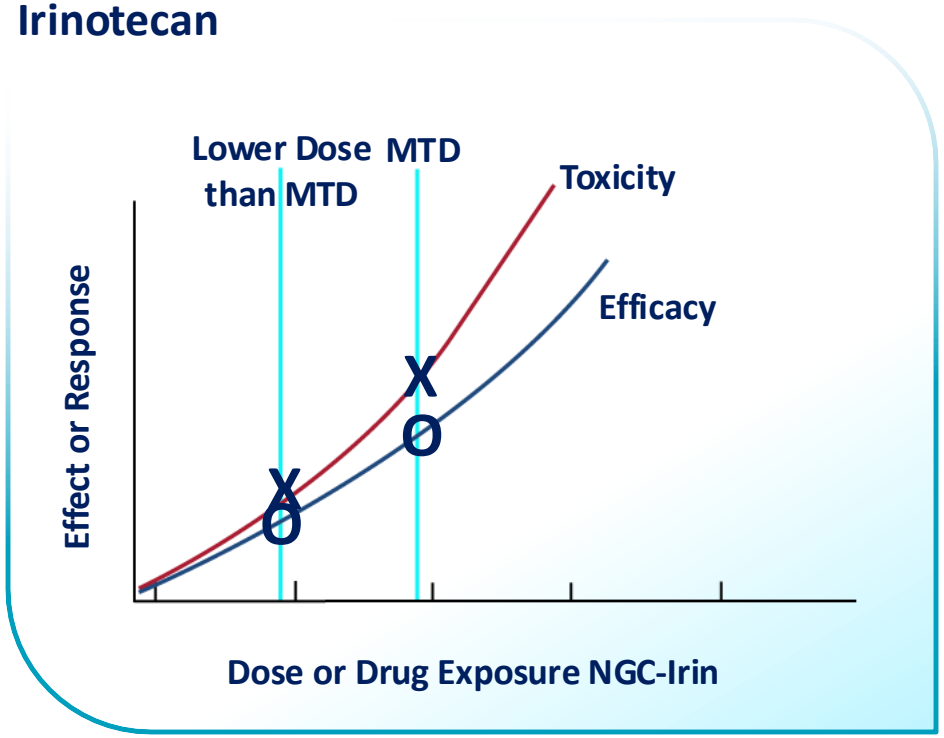
Efficacy Maintained at Lower Doses of NGC-Iri When Compared to Irinotecan in SW620 Colorectal Cancer Xenograft Model

NGC-Iri



Irinotecan



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

NGC-Iri: Comparing NGC-Iri to Irinotecan and Onivyde

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- Accumulation of SN-38 in the tumor compared with other tissues, such as muscle, was greater after NGC-Iri administration than after irinotecan or Onivyde® administration, as demonstrated by the tumor-to-muscle ratio of approximately 200 for NGC-Iri and less than 15 for irinotecan and Onivyde® ;
- More SN-38 accumulated in the tumor after NGC-Iri administration than after irinotecan or Onivyde® administration, as demonstrated by the tumor-to-plasma ratio being approximately 10 for NGC-Iri and less than 7 for irinotecan and Onivyde® ; and
- Less SN-38 accumulated in non-cancer tissues, such as muscle, after NGC-Iri administration than after irinotecan or Onivyde® administration, as demonstrated by the muscle-to-plasma ration being less than 0.10 for NGC-Iri and greater than 0.4 for irinotecan and Onivyde® , supporting the potential for a better NGC-Iri safety profile.
- Despite the Black Box warning for severe side effects, in 2021 Medicare reported a total of more than 1.8M doses of irinotecan and Onivyde® .

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Efficacy

- Active molecule SN-38 is same active molecule in Irinotecan
- Distributes SN-38 differently, entering the cell membrane of cancer cells preferentially over normal cells, improving cancer-killing effect

Side Effects

- Given the specificity of NGC-Iri for cancer cells over normal cells, animal data suggests fewer side effects; likely that patients will have less diarrhea and less myelosuppression (a Black Box warning for Irinotecan)

Intellectual Property

- Potential patent protection until 2031; Evaluating potentially new intellectual property

Clinical Development

- Expand preclinical analysis with additional ongoing preclinical efficacy study
- Evaluating sites to manufacture PCS11T
- Pre-IND enabling toxicology studies and CMC studies anticipated to be conducted in 2025

Timeline of Milestones

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2023

In Jan. 2023, strategic transition to oncology-focused pipeline

NGC-Cap: In collaboration with FDA, determined upcoming Phase 2 indication in advanced/metastatic breast cancer patients

NGC-Cap: Cohort review committee determined Phase 1B trial enrollment completed

2024

NGC-Cap: Completed Phase 1b trial and received FDA IND clearance for Phase 2 trial in metastatic and advanced breast cancer

NGC-Cap: Enroll 1st patient in Phase 2 study to identify ODR

NGC-Gem: Request meeting with the FDA to define the ODR Phase 2 protocol

2025

NGC-Cap: Interim analyses of Phase 2 efficacy-safety across doses

NGC-Gem: Initiate Phase 2 study sites

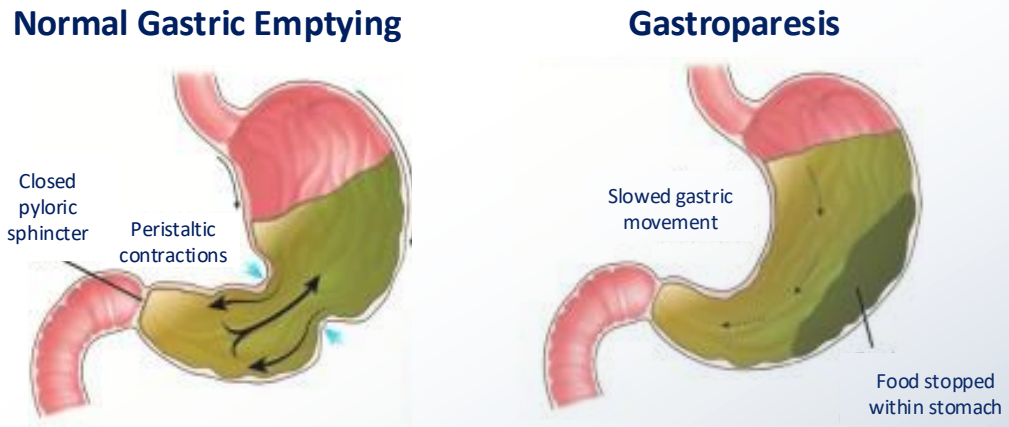
NGC-Iri: Preliminary results from initial toxicology studies

Product Partnering Opportunities

Processa Pharmaceuticals

PCS12852 to treat gastroparesis

- Best-in-class 5-HT4 receptor agonist for disease with high unmet medical need
- Completed P2a with positive results showing excellent safety and efficacy profile
- Outstanding safety profile and selectivity combine to provide first meaningful treatment for diabetic gastroparesis patients



PCS499 for rare nephropathies

- Safe and well-tolerated NCE with potential for development on multiple nephropathies
- Significant clinical exposure demonstrating safety benefit to legacy forms of pentoxifylline
- Extensive patent estate
- Potential indications in rare diseases:
  - Focal segmental glomerulosclerosis (FSGS)
  - Membranous nephropathy (MN)
  - IgA nephropathy (IGAN)

Processa Senior Management

Processa Pharmaceuticals

George Ng
Chief Executive Officer

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Track Record of Drug Development with more than 30 FDA approvals

Company Summary

Processa Pharmaceuticals

De-risked strategy to develop more effective chemotherapy options with improved tolerability for cancer patients through an efficient regulatory path

Track record of drug development through regulatory approval using proprietary Regulatory Science Approach

Innovative clinical development programs addressing limitations of standard of care with three active programs

Out-licensing opportunities for non-oncology drug candidates with potential for non-dilutive funding

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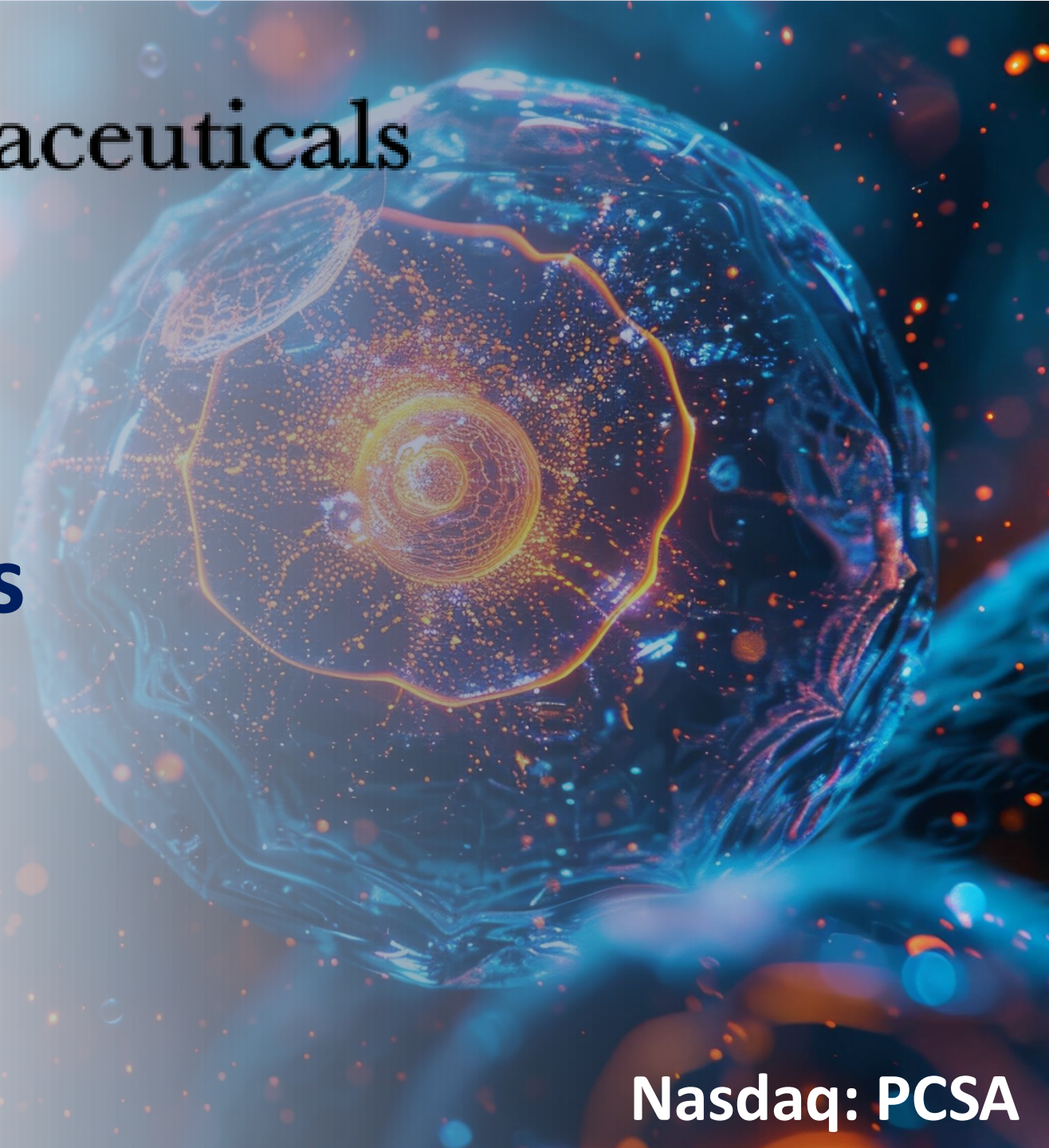

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