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 30, 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	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 2.02 Results of Operations and Financial Condition.

On March 30, 2023, Processa Pharmaceuticals, Inc. (the "Company") issued an earnings release announcing its financial results for the year ended December 31, 2022. A copy of the earnings release is furnished as Exhibit 99.1 to this Current Report on Form 8-K (this "Report").

The information in this Item 2.02 and Exhibit 99.1 hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any of the Company's filings under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act.

Item 7.01 Regulation FD Disclosure.

Corporate Presentation

On March 30, 2023, the Company posted an updated corporate presentation to its website at https://www.processapharmaceuticals.com/, which the Company may use from time to time in communications or conferences. A copy of the corporate presentation is attached as Exhibit 99.2 to this Report.

The information in this Item 7.01 and Exhibits 99.2 shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Exhibit 99.2 hereto contains forward-looking statements within the meaning of the federal securities laws. These forward-looking statements are based on current expectations and are not guarantees of future performance. Further, the forward-looking statements are subject to the limitations listed in Exhibit 99.2 and in the other reports of the Company filed with the Securities and Exchange Commission, including that actual events or results may differ materially from those in the forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Exhibit Description
99.1	Earnings release, dated March 30, 2023 announcing Processa Pharmaceuticals, Inc. financial results for the year ended December 31, 2022
99.2	Corporate Presentation, dated March 30, 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 March 30, 2023.

PROCESSA PHARMACEUTICALS, INC.
Registrant

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

Exhibit 99.1

Processa Pharmaceuticals Provides Corporate Update and Announces Year End 2022 Financial Results

- **Company focused on the development of Next Generation Chemotherapy drugs in 2023 and out-licensing/business development efforts for non-oncology assets.**
- **Dose escalations continue for Next Generation Capecitabine with no observed adverse events associated with the catabolites of capecitabine.**
- **FDA discussions mid-April on Next Generation Capecitabine Phase 2B trial and overall development following Project Optimus initiative**

HANOVER, MD., March 30, 2023 (GLOBE NEWSWIRE) — Processa Pharmaceuticals, Inc. (Nasdaq: PCSA) ("Processa" or the "Company"),a developer of Next Generation Chemotherapy drugs that provide a better safety-efficacy profile than their widely used
FDA-approved counterparts, today provided an update on their clinical programs and announced financial results for the year ended December 31, 2022.

Dr. David Young, President and CEO of Processa, commented, "We completed a successful Phase 2A trial of PCS12852 in patients with gastroparesis, positioning the asset well for potential out-licensing or business development opportunities. Today, we are focusing our energy and efforts on the Next Generation Chemotherapies (NGCs) that can reshape the landscape of chemotherapy.

Our first NGC to move into Phase 2B will be Next Generation Capecitabine (NGC-Cap). Since 50-70% of the patients on capecitabine typically have dose-limiting side effects, one major benefit of NGC-Cap is to significantly decrease or potentially eliminate these side effects, so patients do not need to reduce their dose or discontinue treatment entirely. As a safer and potentially more efficacious version of the presently used capecitabine, the target population for NGC-Cap includes patients with such cancers as colorectal, breast, pancreatic, and many other solid tumor cancers. These cancers have more than 200,000 newly diagnosed cases per year in the U.S. We look forward to meeting with the FDA in mid-April to discuss our NGC-Cap Phase 2B trial and hope to initiate the Phase 2B trial in colorectal cancer in the second half of 2023. Given we are working with an approved established cancer-killing molecule, and we will be following the principles of Project Optimus, we anticipate efficiencies in the development of NGC-Cap that we believe will confer better odds of success, while providing better and safer drugs to hundreds of thousands of patients in need of better treatment options."

Financial Results for the Year Ended December 31, 2022

Our cash balance on December 31, 2022, was $6.5 million. Subsequent to year-end, we raised net proceeds of $6.4 million from the sale of 8,432,192 shares of our common stock through a combination of financing vehicles, including a registered direct offering to accredited investors. Based on our current plans, we believe the cumulative $12.9 million will be adequate to fund our operations into the third quarter of 2024.

Our net loss for the year ended December 31, 2022 was $27.4 million, or $1.70 per share, compared to a net loss of $11.4 million, or $0.75 per share for the same period of 2021. The increase in our net loss was primarily due to a one-time non-cash impairment of an intangible asset for $7.3 million, along with increased stock-based compensation and clinical trial costs.

For the year ended December 31, 2022, we incurred $11.5 million in research and development costs, compared to $6.9 million for the same period in 2021. Our general and administrative expenses totaled $8.8 million for the year ended December 31, 2022 compared to $4.7 million for the same period in 2021. The increase was primarily due to stock-based and other compensation costs. During the year ended December 31, 2022, we allocated $8.8 million of total non-cash compensation costs between our R&D and G&A costs, with the majority being recorded as G&A.

We used cash of $9.6 million during the year ended December 31, 2022 to fund our three clinical trials and operations versus $8.8 million of cash we used in 2021. Our operating cash flow is significantly less than our net loss primarily due to non-cash expenses.

As of March 27, 2022, we had 24.6 million common shares outstanding.

Conference Call Information

To participate in this event, please log-on or dial-in approximately 5 to 10 minutes before the beginning of the call.

Date: March 30, 2023
Time: 4:30 p.m. ET
Toll Free: 888-506-0062
International: 973-528-0011
Entry Code: 382258
Live Webcast: https://www.webcaster4.com/Webcast/Page/2572/47882

Conference Call Replay Information

Toll-free: 877-481-4010
International: 919-882-2331
Replay Passcode: 47882
Replay Webcast: https://www.webcaster4.com/Webcast/Page/2572/47882

About Processa Pharmaceuticals, Inc.

The mission of Processa is to develop the Next Generation Chemotherapies (with existing clinical evidence of safety and efficacy) for cancer patients who need better cancer drugs to extend survival and/or improve their quality of life. The Company uses its Regulatory Science Approach and the principles of the FDA's Project Optimus Oncology initiative to provide an efficient development program, increase the probability of approval, and provide a safer and better cancer treatment that can be easily differentiated from what is presently on the market and in development. Processa is developing three Next Generation Chemotherapy oncology treatments: Next Generation Capecitabine (PCS6422 and capecitabine to treat metastatic colorectal, gastrointestinal, breast, pancreatic, and other cancers), Next Generation Gemcitabine (PCS3117 to treat pancreatic, lung, ovarian, breast, and other cancers), and Next Generation Irinotecan (PCS11T to treat lung, colorectal, gastrointestinal, pancreatic, and other cancers).

For more information, visit the company's website at www.processapharma.com.

Forward-Looking Statements

This release contains forward-looking statements. The statements in this press release that are not purely historical are forward-looking statements which involve risks and uncertainties. Actual future performance outcomes and results may differ materially from those expressed in forward-looking statements. 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.

For More Information:

Michael Floyd
301-651-4256
mfloyd@processapharma.com

Patrick Lin
(925) 683-3218
plin@processapharma.com

Processa Pharmaceuticals

2022 Earnings Conference Call

Development of Next Generation Chemotherapy Using Regulatory Science and Project Optimus

David Young, PharmD, PhD
President and CEO

March 30, 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.

Processa Mission – Next Generation Chemotherapy

Mission Statement When Company Formed

To Develop Products to Improve the Survival and/or Quality of Life for Patients Who Have an Unmet Medical Need Condition

Mission Statement in 2023 and Beyond

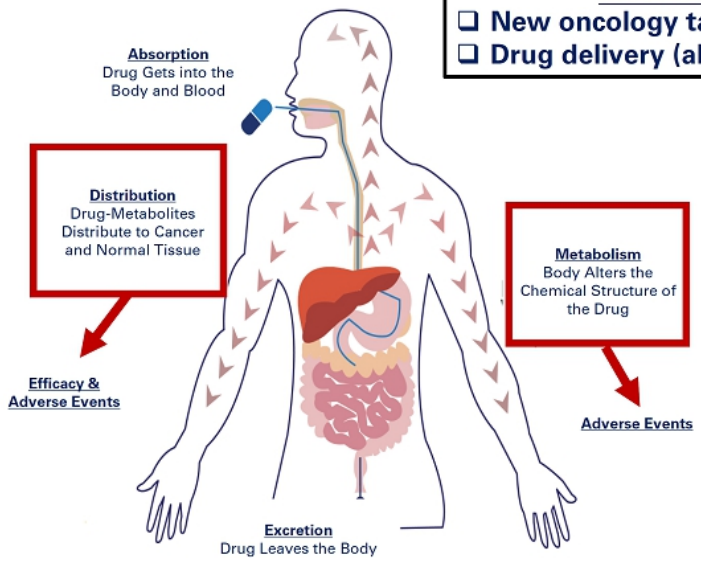
To Develop the Next Generation Chemotherapies to Improve the Survival and/or the Quality of Life of Patients with Cancer

Chemotherapy Remains the Backbone of Cancer Treatment

Next Generation Chemotherapy (NGC): Alter How the Existing Chemotherapy Drugs are Metabolized and/or Distributed in the Body (Capecitabine, Gemcitabine, Irinotecan)

- ❑ Capecitabine, Gemcitabine, and Irinotecan used in all types of cancers
  - 30%-70% of the patients who start treatment have side effects requiring the patient to decrease their dose to suboptimal doses or discontinue therapy.
  - Only approx. 20-40% of the patients have a positive response.
- ❑ NGCs
  - Patients in clinical studies and animals in preclinical studies have less severe and fewer side effects.
  - Fewer patients may have side effects that lead to discontinuation of NGCs or a decrease in the dose of NGCs.
  - Cancer response to NGCs for an individual patient may be more significant with more patients likely responding to NGCs.

Next Generation Chemotherapies (NGCs) – Modifications of Most Widely Used Existing Cancer Drugs



Most Oncology Companies Specialize in

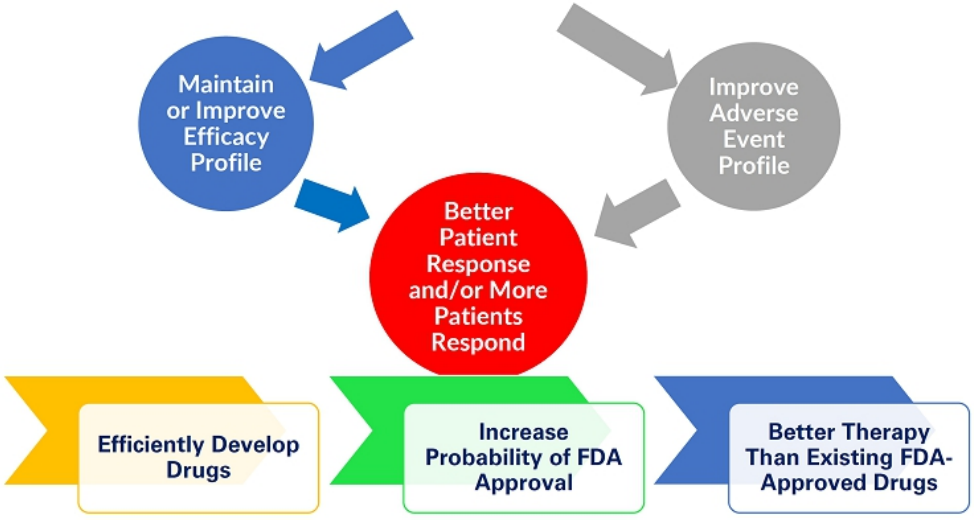
- ❑ New oncology targets or
- ❑ Drug delivery (altering the administration of a drug)

Processa Approach is Different

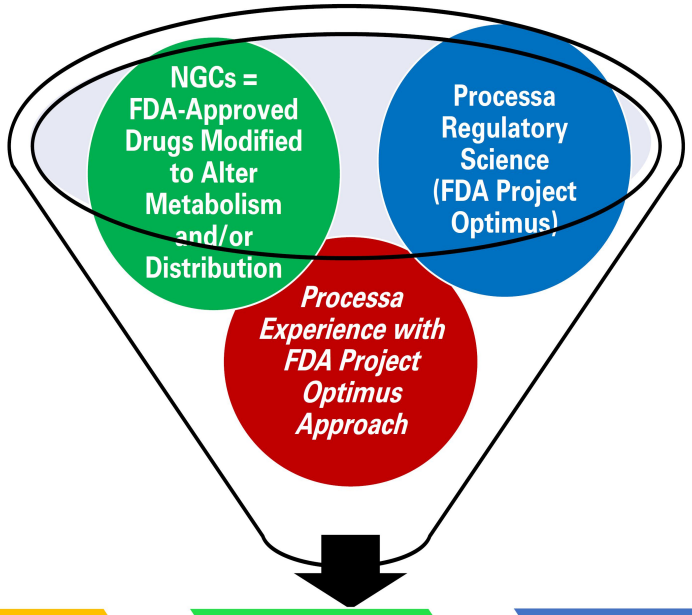
- ❑ NGCs of FDA-approved drugs or their active metabolites.
- ❑ NGCs alter the metabolism and/or distribution of chemotherapy drugs.
- ❑ Maintain existing mechanisms of killing cancer.
- ❑ Potential new patients targeted each year is > 200,000 for each Next Generation Chemotherapy drug.

Advantages of Next Generation Chemotherapy (NGC) Drugs

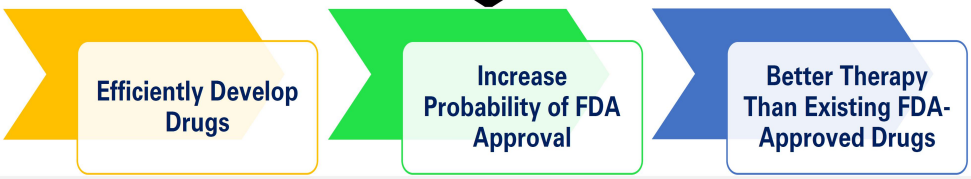
- ❑ Fewer patients may have side effects that lead to discontinuation of NGCs or a decrease in the dose of NGCs.
- ❑ Cancer response to NGCs for an individual patient may be more significant with more patients likely responding to NGCs.
- ❑ Potential new patients targeted each year is > 200,000 for each Next Generation Chemotherapy drug.



Processa Different than Other Biotech and Pharma Companies



- To obtain FDA-approval oncology drugs must now justify dosage regimen using principles of Project Optimus and Regulatory Science.
- Processa experienced in using the principles of Project Optimus for FDA approvals of non-oncology drugs.



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Next Generation Chemotherapy Capecitabine (NGC-Cap)

- ❑ Capecitabine - oral pro-drug of 5-FU widely used in many types of cancer including Colorectal, Gastric, Breast, Pancreatic, and Other Cancers (Incidence > 200,000)
- ❑ NGC-Cap - combination treatment of PCS6422 (which alters capecitabine metabolism and distribution) and capecitabine

NGC-Capecitabine: Results Show Metabolism and Distribution of Key Metabolites of Capecitabine Positively Altered for Safer NGC-Cap

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)	TBD	TBD
5-FU Exposure Level E (NGC Regimen E)	2/5 (Exposure Limiting)	0/5

- ❑ Metabolism and distribution of Capecitabine has been altered in NGC-Cap.
- ❑ NGC-Cap eliminates dose-limiting side effects (DLTs) associated with Capecitabine catabolites (usually occurring in 50%-70% of patients presently treated with Capecitabine).
- ❑ Identified regimens & exposures that will cause and those that will not cause DLTs.

- ➢ FDA discussions mid-April on Phase 2B trial and regimens to be used for Project Optimus.
- ➢ Goal to initiate Phase 2B in 2H2023, interim analysis mid-2024, and complete enrollment 2024.

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Next Generation Chemotherapy Irinotecan (PCS11T)

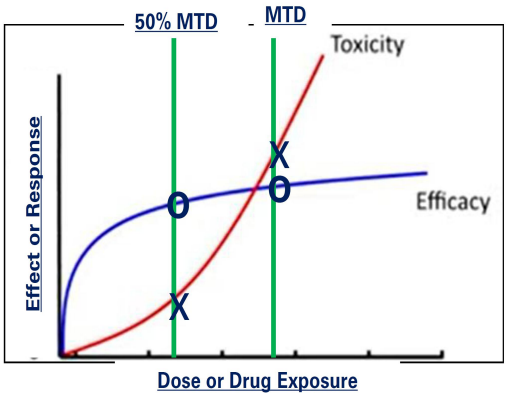
- Irinotecan – Use in many types of cancer including Colorectal, Lung, Pancreatic, Cervical, and Other Cancers (Incidence > 200,000)

NGC-Irinotecan: Results Show NGC-Irin Positively Alters Distribution

In our Project Optimus analysis, the efficacy of NGC-Irinotecan was maintained across a wide dose range (left Figure) while for FDA-approved Irinotecan (right Figure) efficacy across the dose range decreased as the dose decreased in Colorectal Xenograft Animals

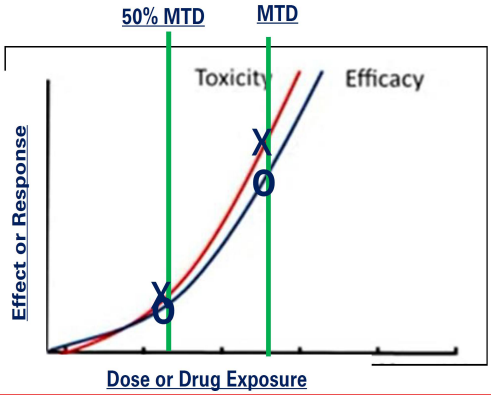
Next Generation Irinotecan

Safety-Dose and Efficacy-Dose Do Not Follow the Same Relationship



Irinotecan

Safety-Dose and Efficacy-Dose Follow the Same Relationship



- **Hope to initiate IND-enabling studies in 2023 with the goal to complete studies by end of 2024.**

Milestones in 2022

- **Next Generation Chemotherapy Milestones Provide Further Rationale for Implementing Project Optimus**
  - **Demonstrated NGCs altered the metabolism and/or distribution of the cancer drug or active metabolite compared to their FDA-approved counterparts.**
  - **Determined NGC-Cap drug exposure levels that cause DLTs and exposure levels that will not.**
  - **Defined the to be targeted cancer populations for NGC-Gem.**
  - **Determined NGC-Irin adverse event-exposure and efficacy-exposure relationships do NOT follow a similar pattern.**
- **Non-Oncology Drugs**
  - **Completed the Phase 2A PCS12852 Gastroparesis trial - PCS12852 had a positive effect on gastric emptying rate and larger effect than placebo on improving gastroparesis symptoms.**
  - **PCS499 was discontinued due to enrollment difficulties in ulcerative necrobiosis lipoidica; prevalence is different from the literature published prior to the study; evaluated other indications with larger populations for future licensee/partner.**

Milestones Goals in 2023

- **NGC-Capecitabine**
  - Meet FDA mid-April to discuss Phase 2B safety-efficacy trial with interim analysis & next development steps.
  - Complete the Phase 1B trial to refine our understanding of the adverse event-exposure relationship.
  - Hope to initiate Phase 2B in 2H2023 with the goal of interim analysis mid-2024 & complete enrollment in 2024.
- **NGC-Gemcitabine**
  - Meet with FDA in mid-2023 on the Phase 2B safety-efficacy trial and next development steps.
  - Plan to submit Phase 2B protocol to IND in 4Q2023 with the hope of initiating trial in 2024.
- **NGC-Irinotecan:**
  - Hope to initiate IND-enabling studies in 2023 with a goal to complete studies in 2024.
- **License or Partner Drugs**
  - License or partner non-oncology drugs.
  - Consider licensing or partnering one or more of the NGC drugs.
- **Corporate**
  - Expand IR/PR presence including social media and more communication with investors.
  - Expand interaction with Oncology Community including Key Opinion Leaders and patient advocacy groups.

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

Next Generation Chemotherapy Improving Safety and Efficacy