

**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): November 16, 2023

Commission file number 001-39531

PROCESSA PHARMACEUTICALS, INC.

(Exact name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

45-1539785
(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.

Dr. David Young, President of Research and Development of Processa Pharmaceuticals, Inc. ("*Processa*") will present at the 20th Orphan Drugs and Rare Diseases Global Congress 2023 Americas. The conference is on November 16-17, at the Revere Hotel Boston Common. Dr. Young's presentation titled "Benefit-Risk Analysis for FDA Approval Requires More Than a Pivotal Trial" will be held on November 16, 2023 at 2:40 PM ET.

During the session, 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 "Presentation" 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
99.1 104	Processa Pharmaceuticals Presentation dated November 16, 2023. Cover Page Interactive Data File (embedded within the iXBRL (Inline eXtensible Business Reporting Language) 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 November 16, 2023.

PROCESSA PHARMACEUTICALS, INC.
Registrant

By: /s/ George Ng
George Ng
Chief Executive Officer



Processa Pharmaceuticals

Benefit-Risk Analysis for FDA Approval Requires More Than a Pivotal Trial

20th ORPHAN DRUGS & RARE DISEASES 2023 AMERICAS
November 16, 2023

David Young, PharmD, PhD
President of R&D
Processa Pharmaceuticals, Inc (NASDAQ: PCSA)

Disclaimer: Forward Looking Statements

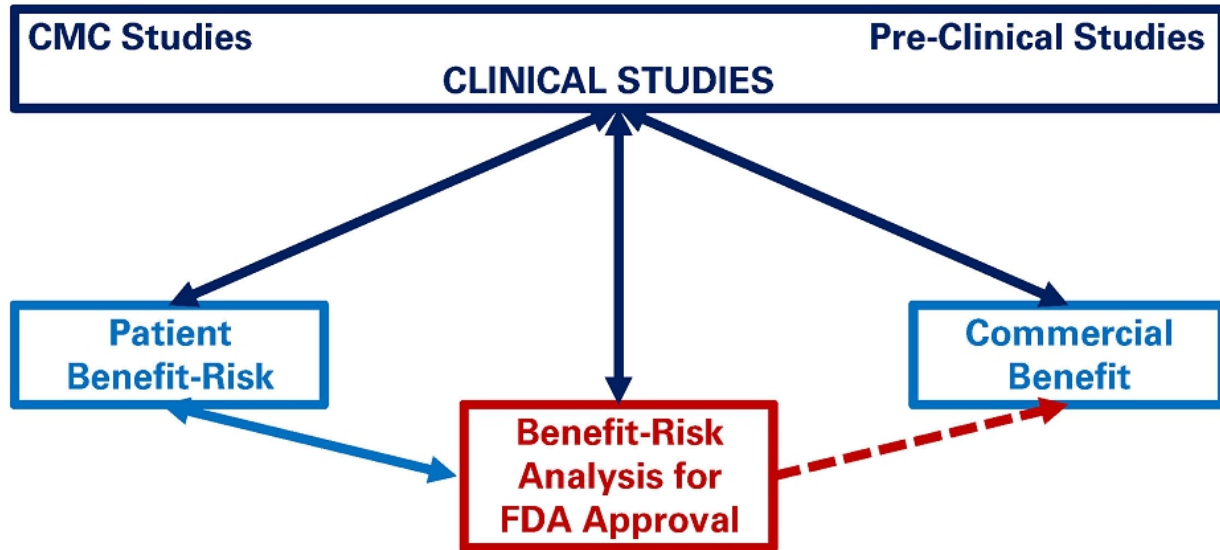
The following summary is provided for informational purposes only and does not constitute an offer or solicitation to acquire interests in the investment or any related or associated company.

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.

How Do You Approach Drug Development?



Benefit-Risk Assessment: Foundation for FDA's Regulatory Review/Approval

FDA States

"For a drug to be approved for marketing, FDA must determine that the drug is effective and that its expected benefits outweigh its potential risks to patients. This assessment is informed by an extensive body of evidence about the drug's safety and efficacy submitted by an applicant."

Benefit-Risk Analysis

The **benefit-risk analysis is more than the efficacy-safety evaluation** in a pivotal trial for orphan and non-orphan designated drugs:

- **Risk assessment includes more than drug safety in Orphan Diseases**
- **Benefit assessment includes more than the magnitude of efficacy**
- **FDA must consider the existing standard of care if it exists**
- Other considerations

Benefit-Risk Integrated Assessment

Added Importance for Orphan Disease

Dimension	Disease and Drug
Analysis of Condition	<ul style="list-style-type: none">Identify patients and the seriousness of their condition while recognizing and measuring what matters most to patients
Current Treatment Options	<ul style="list-style-type: none">Define standard of care and therapeutic treatment optionsBenefit-risk of present options
Benefit of New Approved Treatment	<ul style="list-style-type: none">Identify and measure clinically meaningful endpoints for the patient and FDABenefit includes efficacy of the drug as well as having clinical trial-based evidence of efficacy rather than case study off-label evidence
Risk & Risk Management of New Approved Treatment	<ul style="list-style-type: none">Identify and measure the safety risk of new and existing treatmentsRisk includes both safety & potential of not having approved treatment option

Examples from Processa Founders and Processa Pipeline

➤ Evaluate and Minimize Risk

- Acthar FDA approval - Risk is more than the safety of a drug (Questcor sNDA approval in 2010)

➤ Next Generation Cancer Drugs with Proven Cancer-Killing Mechanisms and Superior Benefit-Risk Profile

- Next Generation Chemotherapy – Capecitabine (NGC-Cap)
- Next Generation Chemotherapy – Gemcitabine (NGC-Gem)
- Next Generation Chemotherapy – Irinotecan (NGC-Iri)



Example 1:

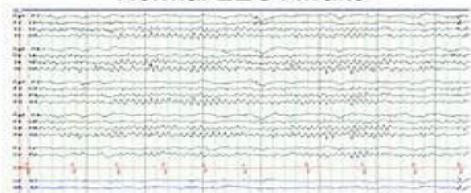
Acthar Approval for Infantile Spasms (Questcor sNDA approval in 2010)

Risk = More Than Drug Safety in a Clinical Trial

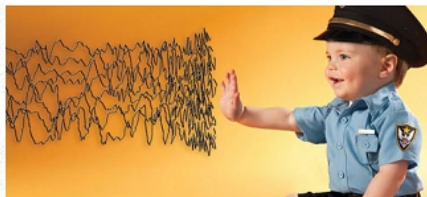
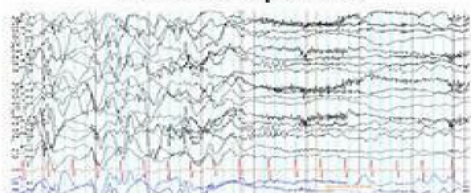
Example 1: Risk is More than Safety of Drug

- Typically occurs in children less than 2 years old; occurs in 2,000 – 2,500 children per year
- Premature death rate of 5-31% and > 60% of untreated/inadequately treated patients have serious mental/physical disabilities with other types of seizures developing over time
- Characterized by seizures (“spasms”) and abnormal EEG called hypsarrhythmia

Normal EEG Awake



Infantile Spasms



- In order to improve cognitive development and mortality rate, therapeutic objective is to rapidly control seizures and normalize EEG.

Example 1: Acthar Gel Used Off-Label for IS

Acthar, a purified preparation of adrenocorticotrophic hormone in a gel, was used off-label for treatment of IS for over 30 years with IS sales in 2006-2007 representing almost 100% of sales

Acthar was approved in 1952 and became a DESI (Drug Efficacy Study Implementation) drug in 1962. Prior to being acquired by Questcor Pharmaceuticals, the Acthar label included over 50 indications including 1978 approval for multiple sclerosis flares



In 2007 Questcor received an FDA Complete Response Letter for the IS sNDA
(Tried to Obtain Approval Based on Need without Efficacy-Safety Clinical Data)



In 2010 FDA approved Acthar for IS
(Approval Based on Benefit of Acthar Treatment Outweighing Acthar Safety Risks and Risks of Patients Having Off-Label Use or Not Treating Patients)

Benefit Outweighed Safety Risk & Risks Associated with Off-Label Use

- Negotiated with FDA what was to be included in the sNDA given conducting a trial when patients are treated off-label for IS was not ethical
- BENEFIT
 - Emphasized that approval would provide consistent guidance on Acthar IS treatment given the different regimens that were used off-label
 - Evaluated Acthar in a previous academic trial of 29 patients (Acthar vs prednisone), not powered to FDA standards; Combined endpoint of spasms and EEG improvement was statistically better in the Acthar treated group than prednisone group; other smaller studies supported the efficacy and regimen
- RISK
 - Safety supported through evaluation of 311 patients on Acthar (134 patients on proposed labelled regimen, 177 on different regimens than proposed)
 - Safety profile was acceptable to FDA, but a Risk Evaluation and Mitigation Strategy (REMS) drug safety program was required

Acthar FDA Approval

- Negotiated new, updated Acthar label with FDA
- Questcor desired to eliminate many of the over 50 indications and obtained a modernized label with 19 indications by providing the data supporting each of the 19 indications
- FDA appropriately evaluated more than the efficacy and safety data from a clinical trial, they evaluated all aspects of the drug, the orphan condition, seriousness of the IS, existing approved treatments, and the off-labelled use of Acthar

Example 1: Benefit-Risk Integrated Assessment of IS

Dimension	Disease and Drug
Analysis of Condition	<ul style="list-style-type: none">Identify patients and the seriousness of their condition while recognizing and measuring what matters most to patients Very serious orphan condition resulting in death or severe mental disabilities
Current Treatment Options	<ul style="list-style-type: none">Define standard of care and therapeutic treatment optionsBenefit-risk of present options No approved drug, Acthar used off-label with various regimens
Benefit of New Approved Treatment	<ul style="list-style-type: none">Identify and measure clinically meaningful endpoints for the patient and FDABenefit includes efficacy of the drug as well as having clinical trial-based evidence of efficacy rather than case study off-label evidence Conducting a new trial not possible, approving Acthar provided guidance,
Risk & Risk Management of New Approved Treatment	<ul style="list-style-type: none">Identify and measure the safety risk of new and existing treatmentsRisk includes both safety & potential of not having approved treatment option Risks associated with both off-label use of drugs & not treating patients



Processa Pharmaceuticals

Example 2:

Next Generation Cancer Drugs with Proven Cancer-Killing Mechanisms and Superior Benefit-Risk Profile

**Benefit = More Than Demonstrating Efficacy,
More Patients Treated**

**Next Generation Chemotherapy – Capecitabine (NGC-Cap)
Next Generation Chemotherapy – Gemcitabine (NGC-Gem)
Next Generation Chemotherapy – Irinotecan (NGC-Iri)**

Example 2: NCE Next Generation Chemotherapy (Not New Formulations)

- NCE Next Generation Chemotherapies (NGCs) are designed to **improve the efficacy and safety profile for more cancer patients than their currently FDA-approved counterparts**
- The cancer-killing metabolites of the NGCs are either the exact same as their counterparts or analogs such that the **MOA of killing cancer cells is the same**
- The major difference is that the **metabolism and/or distribution of the NGCs are different resulting in an improved side effect profile and/or greater efficacy given more exposure to the cancer cells**

Example 2: Oncology Opportunity

- **The FDA-approved counterpart of each NGC is used to treat multiple types of cancers with more than 200,000 new patients diagnosed in the US with these cancers**
 - Orphan-designated cancers presently treated (e.g., pancreatic, ovarian, gastric, biliary, small cell lung)
 - Other types of cancers (egg, colorectal, breast, bladder)
- **35%-85% of the patients receiving the existing FDA-approved counterparts:**
 - **Require a decrease in their dose or discontinuation of the drug because of side effects or**
 - **Are resistant or become resistant to their treatment**
- If NGCs **improve the efficacy-toxicity profile and allow more patients to receive treatment at an optimal dosage regimen**, the NGCs will be different from their existing counterparts
- Processa's **Regulatory Science Approach seeks to find the optimal dosage regimen (ODR)** based on the evaluation of the exposure-response relationship (FDA's Project Optimus Oncology Initiative and draft oncology guidance on finding the optimal dosage regimen)

Benefit-Risk Integrated Assessment

Dimension	Disease and Drug
Analysis of Condition	<ul style="list-style-type: none">Identify patients and the seriousness of their condition while recognizing and measuring what matters most to patients Serious condition with 35%-85% of treated patients not receiving ODR, poor survival
Current Treatment Options	<ul style="list-style-type: none">Define standard of care and therapeutic treatment optionsBenefit-risk of present options Approved drugs but poor survival, high % of patients receive sub-optimal dose, high % of non-responders
Benefit of New Approved Treatment	<ul style="list-style-type: none">Identify and measure clinically meaningful endpoints for the patient and FDABenefit includes efficacy of the drug as well as having clinical trial-based evidence of efficacy rather than case study off-label evidence Treat more patients with ODR, improve benefit-risk profile
Risk & Risk Management of New Approved Treatment	<ul style="list-style-type: none">Identify and measure the safety risk of new and existing treatmentsRisk includes both safety of new treatment but also safety of existing treatment Side effect profile may change requiring further evaluation of the seriousness of side effects as well as the prevalence

FDA States

"For a drug to be approved for marketing, FDA must determine that the drug is effective and that its expected benefits outweigh its potential risks to patients. This assessment is informed by an extensive body of evidence about the drug's safety and efficacy submitted by an applicant."

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