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 25, 2021

PROCESSA PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-39531**	**45-1539785**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
	7380 Coca Cola Drive, Suite 106, Hanover, Maryland (**Address of Principal Executive Offices**)	**21076** (**Zip Code**)

Registrant's telephone number, including area code: (443) 776-3133

Not Applicable
(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, $0.0001 par value per share	PCSA	The Nasdaq Stock Market LLC

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 25, 2021, we issued a press release announcing earnings and other financial results for our fiscal quarter ended December 31, 2020, and that management would present these results in a conference call at 5:30 PM Eastern time on March 25, 2021. Incorporated by reference is a press release and the presentation issued by the Registrant on March 25, 2021 attached as Exhibit 99.1 and 99.2.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release issued on March 25, 2021
99.2	Presentation dated March 25, 2021

SIGNATURES

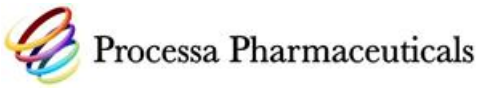
Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PROCESSA PHARMACEUTICALS, INC.

Date: March 25, 2021

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

Exhibit 99.1



Processa Pharmaceuticals Announces Year end 2020 Results and Provides Corporate Update

Clinical drug pipeline is funded and targeting major milestones in 2021

HANOVER, (GLOBE NEWSWIRE) — Processa Pharmaceuticals, Inc. (Nasdaq: PCSA) ("Processa" or the "Company"), a clinical stage company developing drugs for patients who have unmet medical conditions that require better treatment options to improve a patient's survival and/or quality of life, today announces financial results for the year ended December 31, 2020, and provides corporate update.

Dr. David Young, CEO and chairman of Processa, commented, "2020 was a transformational year for our company; we in-licensed three exciting programs with potential markets exceeding $1 billion for each drug, improved our balance sheet, strengthened our management team and Board, up-listed to Nasdaq, and prepared the foundation for successful execution for our three clinical stage programs. I am delighted to report that we anticipate the first patients to be dosed with PCS6422 and PCS499 in the second quarter of 2021 with interim data for PCS6422 near the end of Q3 and for PCS499 in the first quarter of 2022."

Recent Highlights and New Developments

- Selected 5 U.S. clinical sites to enroll patients with ulcerative necrobiosis lipoidica for our Phase 2B trial "A Randomized, Double-blind, Placebo-Controlled Clinical Trial to Evaluate the Efficacy and Safety of PCS499 in Treating Ulcerations in Patients who Have Necrobiosis Lipoidica." Two to three additional clinical sites will be selected in the future including sites outside the U.S.

- Entered into an exclusive licensing agreement with Elion Oncology, Inc. to develop, manufacture and commercialize PCS6422 (eniluracil) globally. PCS6422 is an oral drug to be administered with fluoropyrimidine cancer drugs (e.g., capecitabine, 5-FU). PCS6422 is designed to decrease the breakdown of the cancer drugs, which, without such intervention, reduce to inactive metabolites or metabolites that are known to cause unwanted side effects and to interfere with the anticancer activity.

- Entered into a licensing agreement with Yuhan Corporation, a publicly traded South Korean company, to license PCS12852, a small molecule drug in development for the treatment of gastroparesis and functional gastrointestinal motility disorders.

- Entered into a licensing agreement with Aposense LTD to license PCS11T, a pro-drug of SN38, the active metabolite of the widely used cancer drug irinotecan, that deposits SN38 in the membranes of cancer cells preferentially over normal cells.

- Appointed Dr. Khalid Islam to the Company's board of directors.

- Appointed Michael Floyd as the Company's chief operating officer.

- Uplisted to Nasdaq.

- Closed an underwritten public offering of 4,800,000 shares of common stock for a price to the public of $4.00 per share with net proceeds of $17.1 million.

- In February 2021 we closed a private placement with institutional and accredited investors for $10.2 million. We sold 1,321,132 shares of the common stock at a purchase price of $7.75 per share for $10.2 million in the private placement and received net proceeds of $9.9 million.

Upcoming Clinical Drug Development Milestones

First half of 2021

- Phase 1B First Patient Dosed: PCS6422 (Cancer)

- Phase 2 First Patient Dosed: PCS499 (Ulcerative NL)

Second half of 2021

- FDA IND Submission: PCS12852 (GI/Gastroparesis)

- Interim Cohort Results Begin: PCS6422

First half of 2022

- Interim Results: PCS499

- Phase 2A First Patient Dosed: PCS12852

Financial Results for the Year Ended December 31, 2020

General and administrative expenses were $3.3 million compared to $1.6 million for the year ended December 31, 2019. The increase in our general and administrative expenses was primarily due to stock-based compensation.

Research and development expenses totaled $3.2 million compared to $2.3 million for the year ended December 31, 2019.

We also recorded $8.7 million dollars of costs as the acquisition of in-process research and development related to licensing agreements we executed for PCS6422, PCS12852 and PCS11T. A total of $8.6 million of this amount was non-cash consideration.

Our net loss was $14.4 million, compared to a net loss of $3.4 million for the year ended December 31, 2019. During 2020 we recorded non-cash expenses of $8.6 million for acquired in-process research and development and $2.7 million of stock-based compensation costs.

As of December 31, 2020, the Company had cash and cash equivalents of $15.4. In February 2021, we closed a $10.2 million private placement receiving net proceeds of $9.9 million.

Following the close of the offering and related transactions the Company will have 15.5 million common shares outstanding.

Conference Call Information

To participate in this event, dial approximately 5 to 10 minutes before the beginning of the call.

Date: March 25, 2021
Time: 5:30 p.m. ET
Toll Free: 877-545-0320; Entry Code: 805295
International: 973-528-0016; Entry Code: 805295

Live Webcast: https://www.webcaster4.com/Webcast/Page/2572/40452

Conference Call Replay Information

Toll-free: 877-481-4010
International: 919-882-2331
Replay Passcode: 40452

About Processa Pharmaceuticals, Inc.

The mission of Processa is to develop products with existing clinical evidence of efficacy for patients with unmet or underserved medical conditions who need treatment options that improve survival and/or quality of life. The Company used these criteria for selection to further develop its pipeline programs to achieve high-value milestones effectively and efficiently. Active pipeline programs include: PCS6422 (metastatic colorectal cancer and breast cancer), PCS499 (ulcerative necrobiosis lipoidica) and PCS12852 (GI motility/gastroparesis). The members of the Processa development team have been involved with more than 30 drug approvals by the FDA (including drug products targeted to orphan disease conditions) and more than 100 FDA meetings throughout their careers. 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 that 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 that could cause actual results to differ from those contained in the forward-looking statements.

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Processa Pharmaceuticals

CLINICAL PIPELINE UPDATE
MARCH 2021

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.

Highlights of 2020

Expanded Drug Portfolio to 4 Drugs with Each Having Potential Max Sales of $1 B or More

- ✓Completed PCS499 Phase 2A trial in patients with necrobiosis lipoidica, demonstrating 499 was safe and efficacious in patients with ulcers
- ✓Added 2 Drugs to Clinical Pipeline
  - PCS6422: Oral cancer chemotherapy modifier which is designed to decrease side effects of one of the cornerstones of chemotherapy and potentially increase efficacy
  - PCS12852: Drug that increases GI motility in such conditions as gastroparesis and has a better safety profile than drugs used on-label and off-label
  - Developed protocol and began site identification for the PCS6422 Phase 1B & PCS499 Phase 2B trials
- ✓Added PCS11T to Oncology Pipeline: Pro-drug of SN38 that deposits SN38 in cancer cell membranes preferentially over normal cell membranes; SN38 is the active metabolite of FDA approved irinotecan

Expanded Financial and Human Capital

- ✓Up-listed to Nasdaq
- ✓Closed an underwritten public offering, raising $19.2 M in 2020 on NASDAQ up-list
- ✓Appointed Dr. Khalid Islam, former CEO of Gentium and co-founder of Elion Oncology, to the Company's board of directors
- ✓Appointed Michael Floyd, former co-founder and CEO of Elion Oncology, as the Company's Chief Operation Officer

Processa Pharmaceuticals

Processa's Differentiated Development Approach

Repeatable, Capital-efficient Blueprint Platform with Potential to Generate Significant ROI

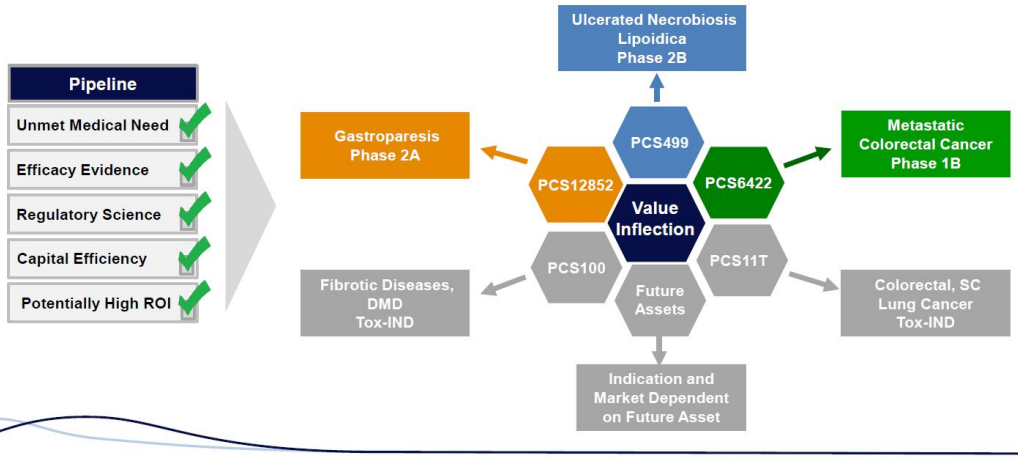
DEVELOP NOT DISCOVER — **REGULATORY SCIENCE PLATFORM**

High Unmet Medical Need	+ Efficacy Evidence	+ Regulatory Science	+ Capital Efficiency	= Potentially High ROI
▪ Clear and obvious patient need ▪ Favorable competitive dynamics	▪ Direct proof of concept or other proof of principal ▪ De-risking development, higher probability of successful development	▪ Optimize trial design (Trifecta: ↓risk, ↓cost, ↓time to approval) ▪ Anticipate what FDA requires to assist in discussions on IND enabling studies, clinical trials, and approval	▪ Leverage considerable investments prior to licensing (tox, CMC etc.) ▪ Efficient clinical trials and development program	▪ Intelligently monetize and partner assets

Processa Pharmaceuticals

Processa Pipeline – Multiple Opportunities For Success

Use Studies of Prior Companies and Hundreds of Millions of Dollars Invested



Processa Pharmaceuticals

PCS6422 Chemotherapy Modifier of Cancer Drug Capecitabine (Xeloda®)

- **Target Indication:**
  - Treatment of metastatic colorectal cancer when combined with capecitabine
- **Target Claims:**
  - 6422+capecitabine a better benefit-risk profile (less adverse events and/or better efficacy) than capecitabine
- **Target Differentiation of 6422+Capecitabine vs Capecitabine**
  - 6422 decreases metabolism of capecitabine to FBAL (FBAL is the major cause for adverse events in 50-70% of capecitabine patients resulting in patients having to decrease dose or stop capecitabine chemotherapy)
  - 6422 increases metabolism of capecitabine to cancer killing metabolites
  - 6422+capecitabine has better benefit-risk profile with less adverse events and/or better efficacy than capecitabine and possibly other chemotherapeutic agents

PCS6422 Chemotherapy Modifier of Cancer Drug Capecitabine (Xeloda®)

- **Economic Value:**
  - > 145k new patients with colorectal cancer/yr in us and > 1.8 M patients worldwide
  - 45% of the new patients with colorectal cancer presently receive capecitabine
  - Potential for 6422+capecitabine combo to replace capecitabine in treatment of colorectal cancer and other cancers
  - U.S. market potential in colorectal cancer is $700 M - $1.5 B
- **Exclusivity Strategy**
  - Patent exclusivity to 2030
  - New patent to be filed

PCS6422 Chemotherapy Modifier of Cancer Drug Capecitabine (Xeloda®)

- **Next Trial - Phase 1B:**
  - General Design: 3+3 cohort capecitabine MTD trial after a single safe dose of 6422; 1 dose 6422, 7d of capecitabine, 7d of no capecitabine; up to 6 cohorts of capecitabine b.i.d. at 75mg/d to 600 mg/d
  - Objective: To determine safe maximum dose of capecitabine after single safe dose of 6422
  - Inclusion Criteria Examples: Advanced, metastatic or unresectable refractory GI cancer; not received treatment with 5-FU or capecitabine in 4 weeks; life expectancy > 12 wks
  - Exclusion Criteria Examples: Has current brain metastasis, has clinically significant cardiac condition; self-reported to be DPD enzyme deficient
  - Key Additional Information: Evaluation of potential biomarkers
- **Development Plan**
  - Next trial a Phase 2B or adaptive designed Phase 3 depending on results of Phase 1B and biomarker findings
  - Potentially patent the clinical use of biomarker(s)

PCS499 Treatment of Ulcerative Necrobiosis Lipoidica

- **Indication:**
  - Treatment of ulcerative necrobiosis lipoidica ("uNL")
- **Claims:**
  - Completely closes open necrobiosis lipoidica ulcers; improves non-ulcerated NL lesions
- **Differentiation of 499 vs Other Drugs Used in Ulcerative Necrobiosis Lipoidica**
  - Natural healing of small ulcers in the first few years ~ 0-15%, for larger ulcers ~ 0 - 5%
  - Open ulcers can lead to infections and amputation of limb
  - No approved NL or uNL treatment in U.S. or worldwide
  - Off-label drugs are prescribed to treat NL with little success, many have side effects limiting their use
  - 499 - deuterated analog of major metabolite of pentoxifylline (PTX) (prescribed for NL, not approved)
  - 499 – orally administered, tolerated much better than PTX (1.8gm 499 well tolerated, 1.2gm tolerated in some patients), and closed all ulcers in the two patients who had ulcers

PCS499 Treatment of Ulcerative Necrobiosis Lipoidica

- **Economic Value:**
  - 22,000 – 55,000 patients in U.S. have uNL
  - Presently no approved treatment and off-labeled drugs not proven to be significantly effective/safe in patients with NL or uNL
  - 499 would be the first approved drug to treat patients with uNL or any NL
  - U.S. market potential in uNL is $600 M - $1.4 B
- **Exclusivity Strategy**
  - Orphan designation in NL with 7 years of U.S. exclusivity on FDA approval
  - Patent exclusivity to 2030
  - One additional patent may come from Phase 2B trial

PCS499 Treatment of Ulcerative Necrobiosis Lipoidica

- **Next Trial - Phase 2B:**
  - General Design: Randomized, double-blind placebo-controlled trial of 1.8 gm/d of 499 in 20 uNL patients with primary efficacy evaluation at 6 months
  - Objective: To determine complete closure response rate of ulcers in patients on placebo vs 499
  - Inclusion Criteria Examples: Biopsy-confirmed diagnosis of ulcerated NL; at least one (1) ulcer with a minimum surface area of 1 cm^2, total ulcer area of a minimum of 2 cm^2, and no more than 6 ulcers
  - Exclusion Criteria Examples: In the last 6 weeks took other drugs such as oral corticosteroids, topical drugs, systemic pentoxifylline, theophylline, immunosuppressant or immunomodulatory drugs

- **Development Plan**
  - NL clinical thought leaders believe the placebo response rate for ulcer closure to be 0% - 5% for larger ulcers the first 1-2 years after presentation
  - EOP2 meeting planned with FDA to discuss Special Protocol Assessment Submission of an adaptive designed Phase 3 trial with size of study depending on Phase 2B trial

PCS12852 Treatment of Gastroparesis

- **Indication:**
  - Treatment of moderate to severe gastroparesis

- **Claims:**
  - Improves the symptoms associated with moderate to severe gastroparesis

- **Differentiation of 12852 vs Other Drugs Used in Gastroparesis**
  - 12852 - Highly specific, potent 5HT4 agonist (more specific, potent than other 5HT4 drugs developed)
  - All FDA approved drug products for gastroparesis have active ingredient of metoclopramide
  - Side effect profile of metoclopramide and existing 5HT4 agonist limits their use
  - 12852 pre-clinical pharmacology and toxicology studies show less side effects than metoclopramide, approved 5HT4 agonists, and 5HT4 agonists in development

PCS12852 Treatment of Gastroparesis

- **Economic Value:**
  - Prevalence of moderate to severe gastroparesis in U.S. reported to be over 200,000 to > 1,500,000 patients depending on formal diagnosis vs symptom presentation
  - Present use of approved drugs and off-labelled drugs in gastroparesis is limited by side effects
  - U.S. market potential is $500 M to > $1 B
- **Exclusivity Strategy**
  - Composition of matter patents through 2032
- **Next Trial (Phase 2A), Development Plan**
  - Waiting for FDA written response to pre-IND documents and any additional FDA discussion that might be required

Summary: Timeline for Trials

Obtain Key Interim Results in 2021/2022, Complete 3 Clinical Trials,
Obtain Information to Design FDA Registration Trials & Increase Probability of FDA Approval

	1Q 2021	2Q 2021	3Q 2021	4Q 2021	1H 2022	2H 2022	2023-2026
PCS6422 Phase 1B	Initiate Sites, ***Begin Patient Dosing***		***Analysis First 2 Cohorts 2H'21***, Final Analysis 2H'22				Phase 2 or 3 Initiate 2023
PCS499 Phase 2B	Initiate Sites, ***Begin Patient Dosing***		***Interim Analysis 1Q'22***, Final Analysis 2H'22				Phase 3 Initiate 2023
PCS12852 Phase 2A	Pre-IND Meeting, IND, Initiate Sites, ***Begin Patient Dosing Before 2Q'22***				***Interim Results 2H'22***, Final Analysis 1H'23		Phase 2B Initiate 2023

Summary: Key Clinical Catalysts

	1Q 2021	2Q 2021	3Q 2021	4Q 2021	1H 2022	2H 2022	2023-2026
PCS6422 Phase 1B		FPI		Cohort 1, 2 Analyses	Cohort 3 & 4 Analyses	Final Analysis	Phase 2 or 3
PCS499 Phase 2B		FPI			Interim Analysis	Final Analysis	Phase 3
PCS12852 Phase 2A				IND	FPI	Interim Analysis	Final Analysis / Phase 2B

* FPI – First Patient In (or First Patient Dosed)