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): January 11, 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, 27106
(Address of Principal Executive Offices) (Zip Code)

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

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 7.01. Regulation FD Disclosure.

Processa Pharmaceuticals, Inc. ("***Processa***") will participate in virtual meetings with analysts and investors beginning January 11, 2021 and through the conclusion of the H.C. Wainwright Bioconnect 2021 Conference January 14, 2021. During these meetings, Processa will use a presentation handout, which is attached as Exhibit 99.2 to this Current Report on Form 8-K. The presentation handout will also be made available in the "Investors" section on Processa's website, located at 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.	Description
99.1	Press Release Issued on January, 11 2021
99.2	January 2021 Corporate Presentation Handout

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: January 11, 2021

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

Exhibit 99.1

Processa Pharmaceuticals to Present at the H.C. Wainwright BIOCONNECT 2021 Virtual Conference

HANOVER, MD., -– Processa Pharmaceuticals, Inc. (NASDAQ: PCSA), ("Processa" or the "Company"), a clinical-stage biopharmaceutical company developing products to improve the survival and/or quality of life for patients who have unmet medical needs, announced today that management will present at the H.C. Wainwright BIOCONNECT 2021 Virtual Conference.

The presentation is now available for on-demand listening by visiting https://hcwevents.com/bioconnect/#. The press release can also be viewed on our website at https://processapharmaceuticals.com/investors-events.php.

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 uses 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 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 registration statement relating to the securities being sold in this offering, which identifies important risk factors which could cause actual results to differ from those contained in the forward-looking statements.

For More Information:
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james@haydenir.com

Processa Pharmaceuticals

CORPORATE PRESENTATION
JANUARY 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.

Processa Pharmaceuticals (NASDAQ: PCSA)

- Differentiated Business Model Applying the Processa Regulatory Science Platform to Drug Development
- Capital Efficient – Very Low Overhead, Disciplined Licensing, Intelligent Development, Potentially High ROI
- Focus on Licensing/Acquiring De-Risked, Under-Appreciated Assets with Demonstrated Efficacy & Higher Probability of Successful Development
- Management and Development Team with Track Record of Obtaining FDA Approvals & Creating Significant Shareholder Value
- Raised $19.2 M in NASDAQ Uplist to Move Forward with Three Clinical Trials for Three Separate $1B Markets - Key Value Added Milestones Over the next 12 - 18 Months

Regulatory Science Platform

- ✓ Processa Team Taught FDA Reviewers
- ✓ Received FDA Contracts to Conduct Scientific Studies to Support FDA Regulatory Guidances
- ✓ 30+ FDA Drugs Approved
- ✓ 100+ FDA Meetings

Successful Exit

QUESTCOR PHARMACEUTICALS, INC.

Processa's Differentiated Development Approach

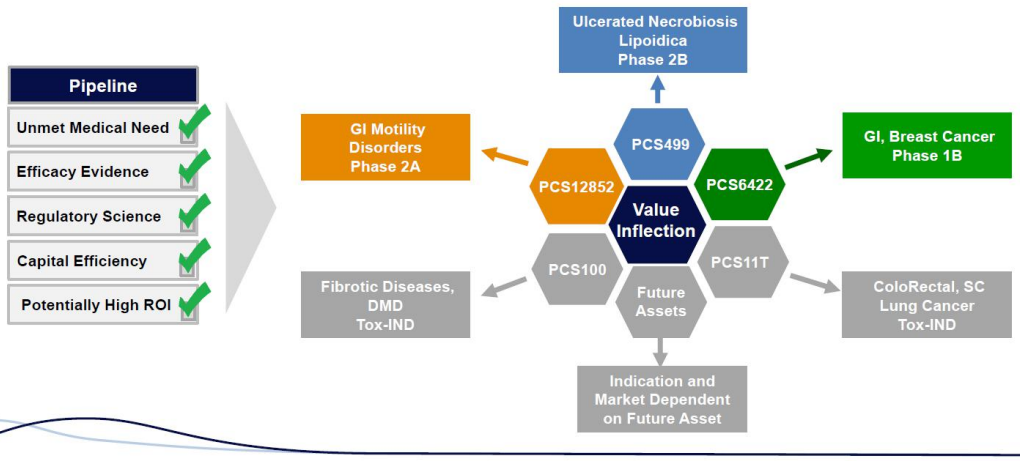
Repeatable, Capital-efficient Blueprint Platform with Potential to Generate Significant ROI

DEVELOP NOT DISCOVER — **REGULATORY SCIENCE PLATFORM**

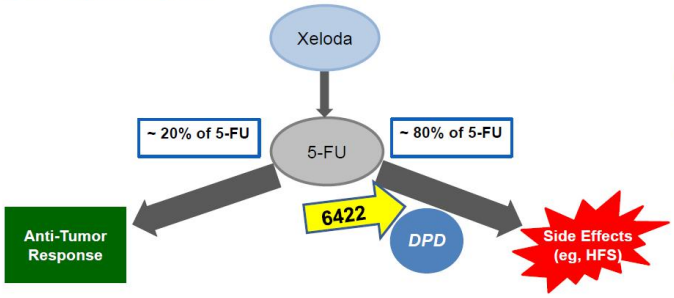
High Unmet Medical Need	+ Efficacy Evidence	+ Regulatory Science	+ Capital Efficiency	= Potentially High ROI
▪ Clear and obvious patient need ▪ Favorable competitive dynamics	▪ Direct proof of concept or other proof of principal ▪ De-risking development, higher probability of successful development	▪ 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 Pipeline – Multiple Opportunities For Success

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



PCS6422 Irreversibly Inhibits Dihydropyrimidine Dehydrogenase (DPD) Enzyme



Xeloda® (Capecitabine) Converts to 5-FU in the body:

- **~ 20% of 5-FU Metabolizes to Molecules with Anti-Tumor Activity**
- **~80% of 5-FU Metabolizes to Molecules that Cause Dose Limiting Side Effects**

6422 Inhibits DPD Allowing Two Ways to Win

1. **Lower Side Effects With Lower 5-FU Metabolite FBAL– Potentially Improve QOL & Reduce Treatment Discontinuations**
2. **Improve Capecitabine Efficacy – Potentially Increase Response Rate and/or Lower Capecitabine Dose**

Processa Pharmaceuticals

PCS6422 – Xeloda Combination Target Population: Cancer Patients Who Need a Better & Safer Cancer Treatment Option - Multiple $1B

Xeloda® (Capecitabine) and 5-FU

- Xeloda and 5-FU are the cornerstones of cancer chemotherapy with millions of patients treated annually
- Widely used as 1st line therapy in
  - Colorectal cancer; > 145,000 new patients/yr U.S., > 1.8 M total patients with colorectal cancer worldwide
  - Breast cancer; > 275,000 new patients/yr U.S., > 2.0 M total patients with breast cancer worldwide
- Xeloda, 5-FU resistant: ~ 25-35% of patients treated
- Side Effects: ~50% - 70% of patients develop Hand-Foot syndrome (HFS) which often requires dose interruptions, adjustments, discontinuation

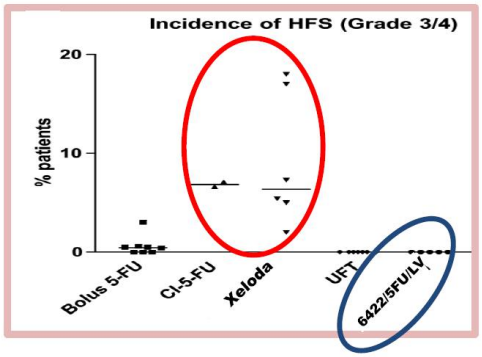
✓ Response Rate
✓ Survival Time

✓ HFS Rate &/or Severity
✓ % Treatment Resist. Pts

Processa Pharmaceuticals

PCS6422 Significantly Reduces HFS

Patients Receiving 6422 and Oral 5-FU Had Lower Incidence of HFS (Particularly Grade 3/4) Compared to Xeloda or i.v. 5-FU Because of Significantly Less Toxic 5-FU Metabolites (F-BAL)



Hand–foot syndrome (HFS) is the most common adverse effect of Xeloda and 5-FU, with an incidence of 50–70%, and its occurrence can lead to dose interruptions, adjustments, discontinuation

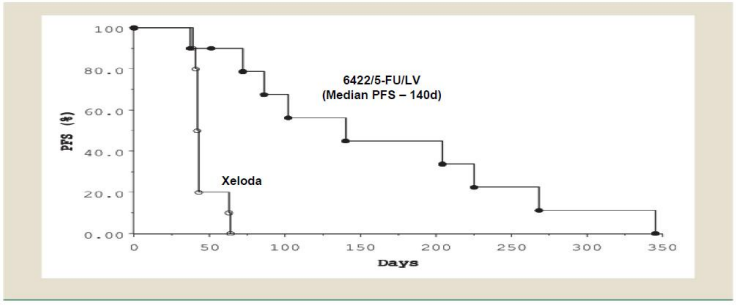
Revollo et al. 2008 Clin Cancer Res; Masuda et al. 2017. NEJM

Processa Pharmaceuticals

PCS6422 Effect on 5-FU Efficacy Depends on Dose Amount and Time of Dosing Relative to 5-FU Administration

Improve Efficacy with 6422:

Lower Dose of 6422 Administered Hours Before 5-FU/LV in Xeloda Resistant Patients



5-FU = 5-Fluoruracil; LV = Leucovorin;
PFS = Progression Free Survival, SD = Stable Disease; PR = Partial Response; PD = Progressive Disease

Adherex files & Rivera E et al, 2014. Clin. Breast Cancer

Processa Pharmaceuticals

Positive 6422-Xeloda Phase 1B Trial Increases Probability of FDA Approval by Providing Information to Help Design Pivotal Trial

PCS6422

- Unmet Medical Need ✓
- Efficacy Evidence ✓
- Regulatory Science ✓
- Capital Efficiency ✓
- Potentially High ROI ✓
- 5-FU Experience ✓

History

- ✓ Completed Pharmacology, Toxicology, CMC
- ✓ 6422 + 5-FU Phase 3 Clinical Trials – Efficacy of 6422 + 5-FU not Demonstrated Due to Sub-Optimal Scheduling and Dosing
- ✓ Phase 2 POC Trial with a More Rational 6422 + 5FU Dosing Regimen-Scheduling Provided Preliminary Evidence of Efficacy

Phase 1B Trial

- ✓ IND Cleared by FDA for Phase 1B 6422 + Xeloda Maximum Tolerated Dose Finding Trial with New Dosing Regimen-Schedule
- ❑ **Increase Exclusivity with Possible New Patents**

Timeline

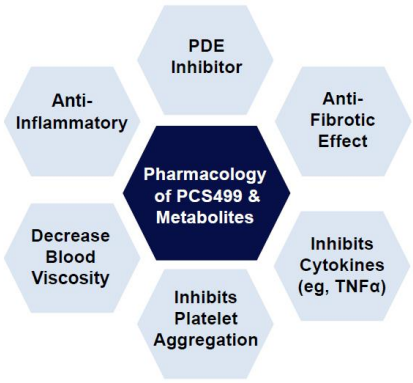
- ❑ **Phase 1B Initiate Sites, Begin Patient Dosing 1H'21**
- ❑ **Phase 1B Interim Cohort Results Begin 3Q'21**
- ❑ **Phase 1B Final Report 2H'22**
- ❑ **Phase 2/3 Trial 1H'23**

Processa Pharmaceuticals

PCS499: Diverse Pharmacological Properties

Deuterated Analog of Major Active Metabolite of Pentoxifylline (PTX), FDA Approved for Claudication

- 499 metabolizes qualitatively to **same** active moieties as PTX but **quantitatively has different amounts of these metabolites**
- PTX has dose limiting side effects which can limit its use; preclinical and clinical evidence shows that **499 has less side effects than PTX allowing higher doses to be administered**
- PTX has been shown to **successfully treat some patients with a rare disease called Necrobiosis Lipoidica (NL)** and might be able to successfully treat more if a higher dose could be administered without dose limiting side effects
- Identified 499 **diverse pharmacology** could be ideal to treat NL with its **diverse pathophysiology**



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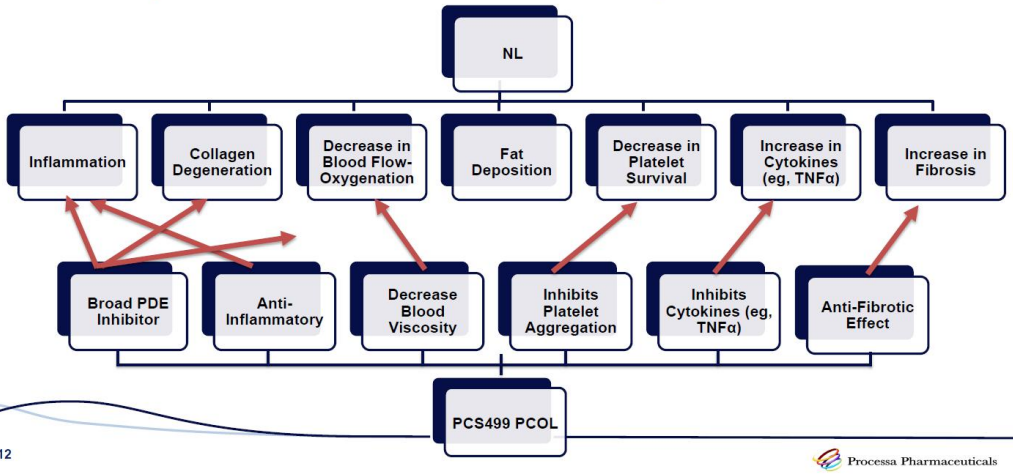
PCS499: Necrobiosis Lipoidica (NL) Diverse Pathophysiology Requires Diverse Pharmacology

PTX Successfully Treats Some NL Patients who can Tolerate the Drug



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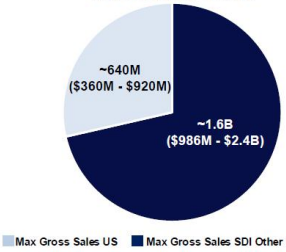
PCS499 Target Population: Ulcerative Necrobiosis Lipoidica (uNL) Patients Have No Treatment Options - $1B Market

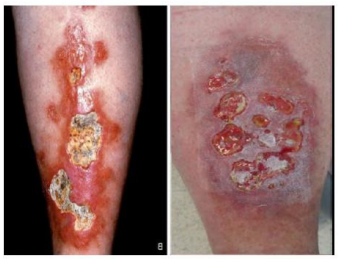
PCS499 has 7-year exclusivity with Orphan Designation for NL

Ulcerative Necrobiosis Lipoidica (uNL)
Max Gross Sales



- 22,000 – 55,000 uNL Patients in US
- 150,000 – 400,000 uNL Patients Worldwide

Ulcerative NL



- **Clinical Presentation**: Skin, tissue below skin becomes necrotic with complications, rare disease, no approved FDA Drugs, no drugs in development
- **Target Patient Population**: 60% of NL patients are diabetic but NL is not dependent on glucose control and not the same as diabetic foot ulcers
- **Natural Healing of Ulcers**: Ulcer closure rate is significantly less than 10% of the patients over the first 1-2 years after onset

13 Source: Muller SA, et al. Arch Dermatol. 1966; Jockenhöfer F, et al, J Dtsch Dermatol Ges. 2016; Company

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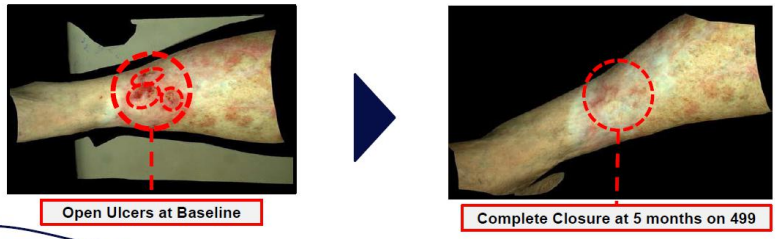
PCS499 Well Tolerated and Completely Closes Ulcers in a Small NL Patient Study

- **Evidence of PTX Efficacy in Ulcerated NL Patients:** Number of case reports that PTX can close ulcers in NL patients if they can tolerate the highest dose of PTX, KOLs would like a more potent PTX
- **Tolerance of PCS499 Better than PTX:** PCS499 is well tolerated at dose greater than PTX in tox studies, and healthy human volunteer studies in NL patients (1.8 gm/d PCS499 vs 1.2 gm/d PTX)
- **PCS499 Treatment Closes All Baseline Ulcers:** In the 2 patients who had ulcers, both patients had complete closing of all their original ulcers
- **PCS499 Treatment Closes New Contact Ulcers:** Closing of contact ulcers also completely healed on PCS499



Open Ulcers at Baseline

Complete Closure at 5 months on 499

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Positive PCS499 Phase 2B Placebo Controlled Increases Probability of FDA Approval by Providing Data to Help Design Phase 3 Trial

PCS499

- Unmet Medical Need ✓
- Efficacy Evidence ✓
- Regulatory Science ✓
- Capital Efficiency ✓
- Potentially High ROI ✓

History

- ✓ Chemistry, Manufacturing, Control (CMC), Pcol, Most Tox
- ✓ Phase 1 Human Volunteer Studies (SD, MD, Food Effect)
- ✓ Phase 2A, 2B Trials in DN
- ✓ Phase 2A Demonstrated Safety, Potential Efficacy in uNL

Phase 2B Trial

- ✓ Phase 2B Randomized Placebo Controlled Trial in uNL Patients to Confirm Placebo and 499 Response Rate for Single Phase 3 Trial
- ✓ Obtained Orphan Designation for PCS499 in NL (7-yr Exclusivity)
- ❑ **Increase Exclusivity with Possible New Patents**

Timeline

- ❑ **Phase 2B Initiate Sites, Begin Patient Dosing 1H'21**
- ❑ **Phase 2B Interim Results 4Q'21**
- ❑ **Phase 2B Final Report 4Q'22**
- ❑ **Adaptive Design Phase 3 Pivotal Trial 1H'23**

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Processa Pharmaceuticals

5HT4 Receptor Agonist, PCS12852, More Potent and Selective to 5HT4 than Other 5HT4 Drugs & Lower Cardiovascular Toxicity Risk

12852 Binds Better to 5HT4 Receptors Than Other Drugs Approved or Being Developed

Compound	5-HT_{4A} receptor		Other 5-HT receptor									
	Binding affinity (IC_{50}, nM)	Agonistic activity (EC_{50}, nM)	Selectivity for 5-HT4 vs. the respective 5-HT subtype (-fold)									
			1A	1B	1D	2A	2B	2C	3A	5A	6	7
YH12852	0.05	0.0048	**1,190**	>10,000	7,300	>10,000	**212**	6,500	>10,000	>10,000	6,150	>10,000
prucalopride	4.2	0.016	**231**	>10,000	NT	>10,000	**106**	NT	NT	NT	NT	>10,000
Tegaserod	15.4	0.25	3	8	16	8	0.5	25	400	20	5	16
Velusetrag (TD-5108)[1-2]	20	5	>500	400	>500	>500	>500	>500	3,000	>500	>500	>500
TAK-954 (TD-8954)[2]	0.4	0.5	>2,500	>2,500	>2,500	>2,500	>2,500	>2,500	>2,500	>2,500	>2,500	>2,500

NT = not tested

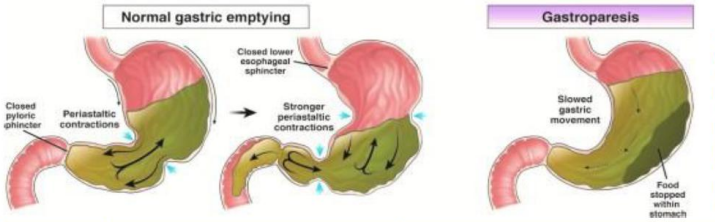
1. *Front Pharmacol. 2011 May 30;2:25*
2. *Gastrointestinal Drugs Advisory Committee Committee-FDA (UCM281534)*

12852 Wider Safety Margin Against Cardiovascular Side Effects than Other 5HT4 Drugs

Measurement	Result	Fold margin at human dose*
hERG inhibition	IC_{50} = 710 nM	**4,300**
Action potential duration in rabbit Purkinje fibers	10% APD90 increase at 220 nM	**1,300**

* Estimated C_{max} multiples based on the free-C_{max} of 3 mg (0.07 ng/mL) in the MAD cohort (healthy males, YH12852-101 study)
APD90 = action potential duration at 90%

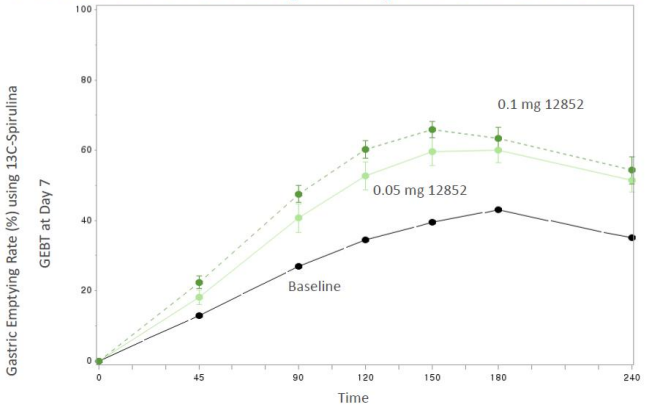
PCS12852 Target Population: Present Therapeutic Options for Patients with Gastroparesis Have Serious Side Effects - $1B Market



Gastroparesis (prevalence > 4M patients in U.S.) is characterized by delayed gastric emptying in the absence of mechanical obstruction of the stomach. The cardinal symptoms include postprandial fullness (early satiety), nausea, vomiting and bloating. The most common causes of gastroparesis are neuropathic disorders which alter gastric motility.

	12852	Other 5HT4 Drug (eg, Cisapride, Prucalopride, Mosapride)	Dopamine D2 Antagonist (eg, Metoclopramide)
Binding	• Very specific 5HT4 receptor binding • Drug very potent to 5HT4	• Less specific binding to 5HT4 than 12852 • Less potent than 12852	• Binds to Dopamine D2 receptors
Side Effects	• **No serious side effects in clinical studies to date**	• **Serious cardiovascular side effects (eg, cisapride removed from market)** • **Suicidal ideation (eg, prucalopride)**	• **Black Box Warning serious neurological side effects**
Efficacy	• Increase gastric emptying rate • Gastroparesis patient study required	• Increase gastric emptying rate • Successful treatment demonstrated	• Only drug FDA approved for treatment of gastroparesis

PCS12852: Enhanced Gastric Emptying Rate in Patients with Decreased GI Motility Compared to Baseline



Change from baseline in gastric emptying rate increased in 0.1 mg and 0.05 mg PCS12852 groups; Gastric Emptying Breath Test (GEBT) showed a statistically significant change from baseline in the 0.1 mg group.

Processa Pharmaceuticals

Positive PCS12852 Phase 2A Trial Increases the Probability of FDA Approval by Providing Data to Help Design Phase 2/3 Trial

History

- ✓ Pharmacology
- ✓ Toxicology,
- ✓ Chemistry, Manufacturing, Control (CMC)
- ❑ New Manufacturing Site Change (Final Product)
- ❑ Pre-IND Meeting, IND Submission

PCS12852

- Unmet Medical Need ✓
- Efficacy Evidence ✓
- Regulatory Science ✓
- Capital Efficiency ✓
- Potentially High ROI ✓

Clinical History

- ✓ Phase 1 Human Volunteer Studies (SD, MD, Food Effect)
- ✓ Proof-of-Concept Demonstrating Efficacy/Safety
- ✓ Patent Exclusivity

Phase 2A to NDA

- ❑ **Finalize Phase 2A Trial Design with KOLs**
- ❑ **FDA IND Submission, Begin Site Initiation 3Q'21**
- ❑ **Phase 2A Begin Patient Dosing 2H'21**
- ❑ **Phase 2A Interim Results 2H'22, Completed 2023**
- ❑ **Phase 2B/3 To Initiate in 2H'23**

Processa Pharmaceuticals

Summary: How Do We Increase the Value of Processa?

Increase Probability of FDA Approval with Key Interim Results in 2021, Completion of our 3 Clinical Trials, Obtain Information to Design Larger FDA Registration Trials

	1Q 2021	2Q 2021	3Q 2021	4Q 2021	1H 2022	2H 2022	2023-2026
PCS6422 Phase 1B	Initiate Sites, ***Begin Patient Dosing***		Trial Ongoing, ***Interim Cohort Results 3Q'21-1H'22***, Final Report 2H'22				Phase 2/3 Trial Initiated 1H'23
PCS499 Phase 2B	Initiate Sites, ***Begin Patient Dosing***		Trial Ongoing, ***Interim Results 4Q'21***, Final Report 4Q'22				Phase 3 Trial Initiated 1H'23
PCS12852 Phase 2A		Pre-IND Meeting, IND, Initiate Sites, ***Begin Patient Dosing 2H'21***			***Interim Results 2H'22***, Trial Completed 2023		Phase 2B/3 Trial Initiated 2H'23

Processa Pharmaceuticals

Our People Lead To Success

Management Team

David Young, PharmD. PhD
Chief Executive Officer, Chairman of the Board

Sian Bigora, PharmD.
Chief Development Officer

Michael Floyd
Chief Operating Officer

Patrick Lin
Chief Business – Strategy Officer

James Stanker, CPA
Chief Financial Officer

Wendy Guy
Chief Administrative Officer

Board of Directors

David Young, PharmD. PhD
Chairman of the Board, CEO

Justin Yorke
Independent Director
Manager of the San Gabriel Fund, JMW Fund and the Richland Fund

Geraldine Pannu
Independent Director
Founding and Managing Partner of GLTJ Pioneer Capital

Virgil Thompson
Independent Director
Former Chairman of the Board, Questcor Pharmaceuticals, Inc.

Khalid Islam, PhD
Director
Chairman of the Board of Fennec Pharmaceuticals

Processa Capital Structure and Share Information

- **Stock Listing**: PCSA – NASDAQ
- **52 Week Low-High:** $3.95 - $18.00
- **Price:** January 4, 2021 $6.60
- **Shares Outstanding: 14,187,977**
- **Fully Diluted Shares: 14,874,743**

- **Cash, Cash Equivalents:** $15,400,000
- **2020 Overhead Cash Burn:** $2,100,000
- **Debt:** No Outstanding Debt

- **Research Analysts:**
  Robin Garner – Craig Hallum;
  Aydin Huseynov M.D., CFA – Benchmark

Processa Pharmaceuticals

Thank you for your kind attention

Any questions or to schedule a meeting
mfloyd@processapharma.com