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 13, 2019

Commission file number 333-184948

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))

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 [X]

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.

A copy of a slide presentation (Presentation Materials") that Processa Pharmaceuticals, Inc. ("Processa Pharmaceuticals") intends to use during presentations before groups and in hosting one-on-one meetings with individual investors, is attached to this Current Report on Form 8-K and Exhibit 99.1. The Presentation Materials speak as of the date of this Current Report on Form 8-K. While Processa Pharmaceuticals may elect to update the Presentation Materials in the future or reflect events and circumstances occurring or existing after the date of this Current Report on Form 8-K, Processa Pharmaceuticals specifically disclaims any obligation to do so. The information contained in this Item 7.01 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 incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by reference in such a filing.

Exhibit No.	Exhibit Description
99.1	Processa Pharmaceuticals Investor Presentation dated March 13, 2019

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 13, 2019.

PROCESSA PHARMACEUTICALS, INC.
Registrant

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

Processa Pharmaceuticals

Developing Products to Improve Survival and/or Quality of Life for Patients Who Have a High Unmet Medical Need

David Young, Pharm.D., Ph.D.
CEO

Cowen & Co. 39th Annual Health Care Conference 2019
March 13, 2019

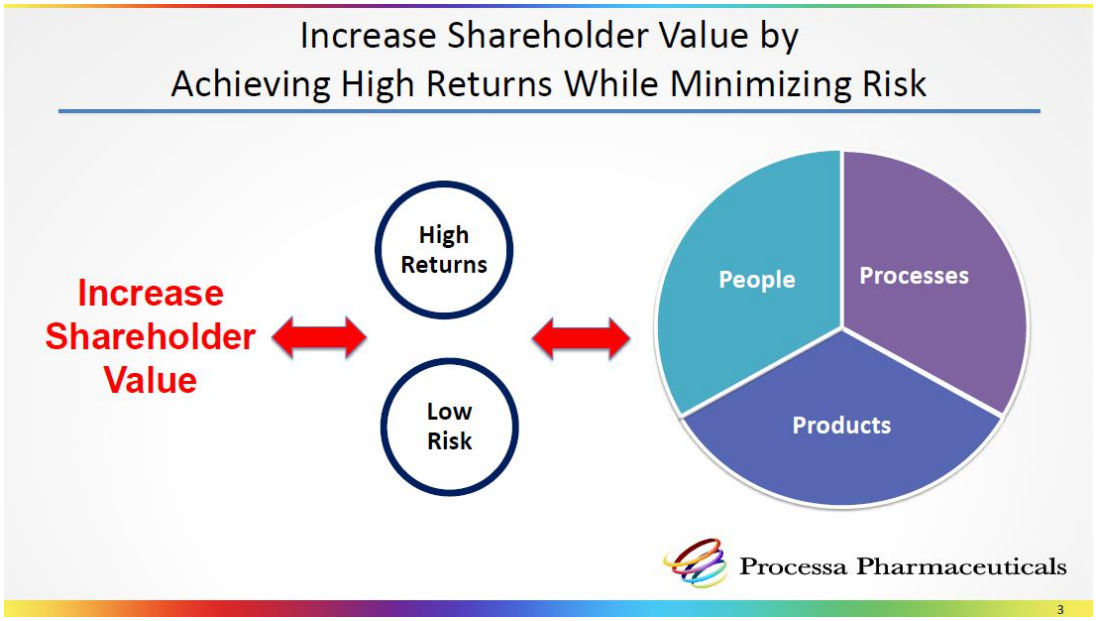
Disclaimer: Forward Looking Statements

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, their members, directors, officers, employees and consultants 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. The Company does not assume any obligation to release updates or revisions to forward-looking statements contained herein.

Processa Pharmaceuticals


Increase Shareholder Value by
Achieving High Returns While Minimizing Risk
Increase Shareholder Value
High Returns
Low Risk
People
Processes
Products
Processa Pharmaceuticals
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Return and Risk Depend on People, Processes, Products

People

Requires a Drug Development and Corporate Team with the *expertise and experience* to obtain FDA approval with an acceptable ROI

Processes

Requires processes to *obtain FDA approvals* and management processes to meet *corporate and growth development* needs

Products

Requires drugs with high gross sales potential, with *acceptable ROI* given FDA development requirements, and with a benefit : risk clinical profile acceptable to FDA

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Processa Pharmaceuticals (OTCQB:PCSA)
Built on High Return – Low Risk Model

- Clinical stage biotech company developing drugs with a higher potential return and lower risk of failure
- **Products**: Developing drugs to treat patients with *high unmet medical need* conditions
- **People**: Team of staff with a *proven track record* for obtaining drug approvals and interacting with the FDA
- **Processes**: Implemented *processes developed over last 25+ years* of success in obtaining FDA approvals and interacting with the FDA

Processa Pharmaceuticals

Processa Pharmaceuticals Financial Overview

OTCQB (3/8/19)	PCSA - $2.36/share
Market Cap (3/8/19)	$91.3M
Shares Outstanding	~38.8M Shares
Cash or Cash Equivalent (3/8/19)	~$1.45M (+ $1.8M Investment Paid Directly to CRO for 100% of Phase 2a Trial)
Total 2019 Expenses Other than Phase 2a Trial	~ $2.5M
Insider Ownership %	> 70%
Headquarters	Hanover, MD

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Processa Pharmaceuticals

Our People

Our People Lead to Success

- **Established and Proven Executive Team with Over 20+ Years of Biotech Management Experience**
  - Most Recently Helped Transform Questcor Pharmaceuticals from $15M Market Cap in 2007 to $5.6B in 2014 when acquired by Mallinckrodt
- ***Development Team Has a Proven Record of Success*** **and Has Worked Together in Other Companies**
  - Over 25 Years of Experience Developing Drugs
  - Trained FDA Reviewers
  - Worked on 3 FDA Guidances with FDA
  - FDA Advisory Committee Involvement as a Committee Member and Sponsor
  - Over 30+ FDA Approvals
  - 100+ FDA Meetings
  - Agnostic to Therapeutic Area Having Worked with Every Drug Review Division at the FDA

Processa Pharmaceuticals

Our Leadership

David Young, Pharm.D., Ph.D., CEO

- Former Board Member, CSO of Questcor Pharmaceuticals ~$15M Market Cap to $5.6B in 7 years
- Former President, AGI Therapeutics; Founder & CEO, GloboMax
- Former Instructor of FDA Reviewers; Former FDA Advisory Committee Member

Patrick Lin, Chief Business and Strategy Officer

- 20 Years Financing and Investing Experience in Biopharma Sector; Principal/Founder Primarius Capital, Focused on Small Cap with Numerous $3B+ Mkt Cap Winners
- Former E*Offering Co-Founder Growing Company to 200 Employees & $80M Rev. During 1st Year
- Former Robertson Stephens & Co. Principal with >500 Successful IPO & Follow-On Offerings

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Our Leadership

Sian Bigora, Pharm.D., Chief Development Officer

- Former VP, Regulatory Affairs at Mallinckrodt, Questcor Pharmaceuticals, AGI Therapeutics, GloboMax
- Former Instructor of FDA Reviewers

James Stanker, CPA, Chief Financial Officer

- 25 years of Financial and Executive Leadership Experience
- Former Audit Partner at Grant Thornton and Global Head of Audit Quality for Grant Thornton International; Former CFO at NASDAQ Listed Company and a Privately Held Company
- Currently on the Board of Directors and Chairman of the Audit Committee of GSE Systems, Inc. (NYSE MKT: GVP)

Wendy Guy, Chief Administrative Officer

- Former Senior Manager in Business Operations at Questcor, AGI Therapeutics, GloboMax with 20 Years Experience in Corporate Management, HR and Finance

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Our Drug Development Process

Processa Technology Platform or Processes

We Know The Way To The FDA

Over the Last 25+ Years Our Team Has Developed a Regulatory Science Approach to Developing Drugs for FDA Approval

- R&D studies performed to provide the scientific foundation upon which FDA will make regulatory decisions
- Processa has the experience to anticipate the science required to make FDA regulatory decisions - based on training FDA reviewers, assisting in 3 FDA Guidances, membership on FDA Advisory Committees, > 100 FDA interactions involving almost every review division of FDA and involvement with > 30 FDA approvals
- Members of this team most recently obtained FDA approval of Acthar for Infantile Spasms and helped transform Questcor Pharmaceuticals from $15M market cap in 2007 to $5.6B in 2014

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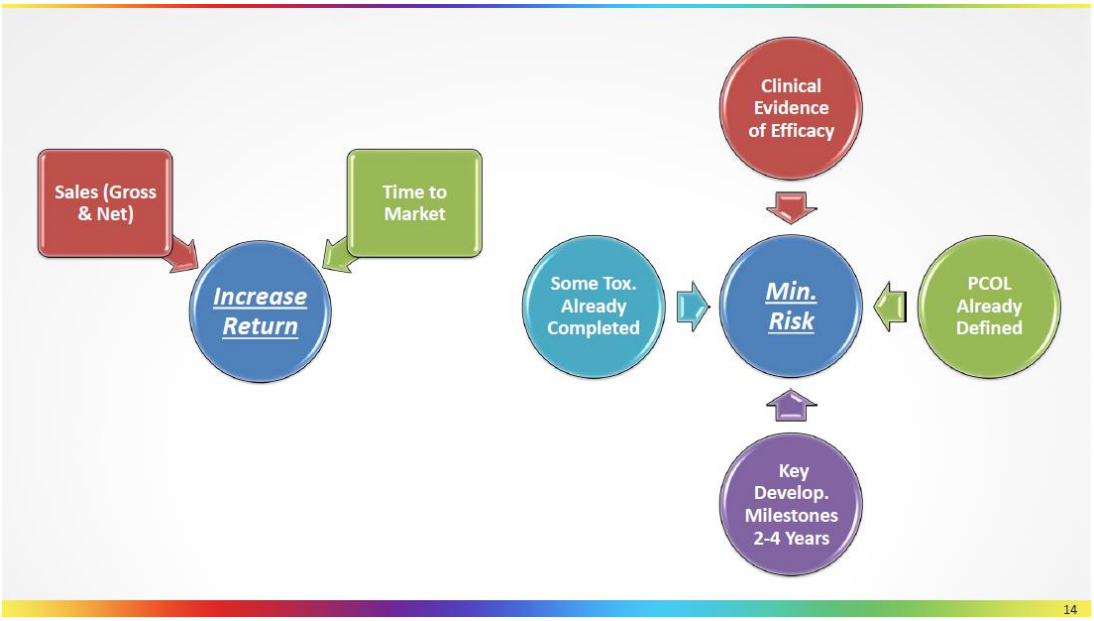
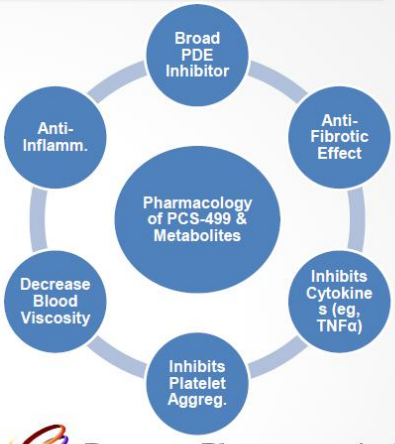
Our Product


Sales (Gross & Net)
Time to Market
Increase Return
Clinical Evidence of Efficacy
Some Tox. Already Completed
Min. Risk
PCOL Already Defined
Key Develop. Milestones 2-4 Years

PCS-499: Deuterated Analog of a Major Active Metabolite of FDA Approved Pentoxifylline (PTX)

- PCS-499 metabolizes to same active moieties as PTX (including reversibly metabolized to PTX itself) but the ***metabolite profile is different after PCS-499 administration than PTX*** (i.e., the % exposure to various active metabolites and administered drug is different)
- PCS-499 and active metabolites have a diverse pharmacology profile



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Evidence PCS-499 Different than PTX

- PCS-499 pharmacology, key GLP tox, key Phase 1 trials completed
- In pre-clinical toxicology studies the maximum tolerated dose for PCS-499 was greater than for PTX
- In Phase 1 studies ***dose limiting side effects*** (e.g., nausea, vomiting, headaches) ***for PCS-499*** administered orally ***occurred at a dose approx. 50% greater than the PTX dose***

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Key Active Moieties from *PCS-499 > 2x PTX* per mg Dose Administered

PK Parameters (Geometric Mean) for Active Moieties (Day 4)

	PCS-499 900 mg BID (n=5)	PCS-499 600 mg TID (n=5)	PTX 400 mg TID (n=6)
Cmax/Dose (ng/mL/mg)	2.11	2.48	1.02
AUC(0-24)/Dose (ng.h/mL/mg)	19.3	16.2	7.32

2.6x higher

2.2x higher

1800 mg daily dose of PCS-499 tablets (administered as 900 mg BID or 600 mg TID) was ***well tolerated despite > 2 x active moiety of PTX exposures*** on a per mg per day basis

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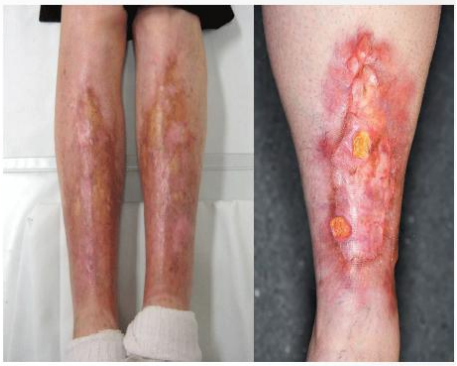
Necrobiosis Lipoidica (NL) - No Approved Treatment

- Occurs in women/men 20 – 60 y/o
- Potential to last for months or years
- Skin becomes necrotic; 30% of patients have painful ulcerations; complications - infections, amputation, squamous cell cancer
- ***No standard of care or FDA approved treatment; no known biotech or pharma company developing a drug for NL***



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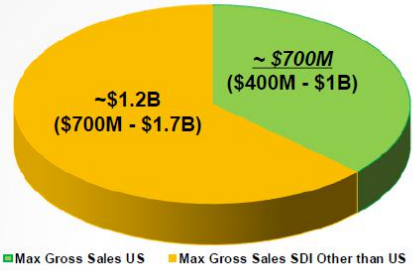
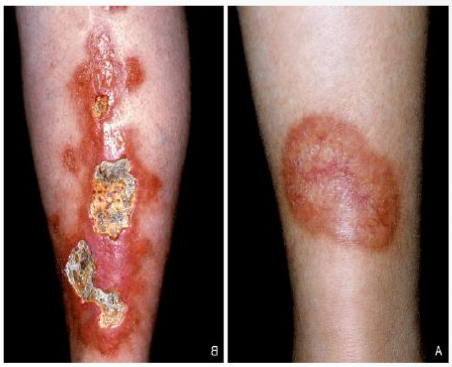
NL Market Opportunity
Max Annual Gross Sales Worldwide *$1.2B - $2.7B*

Necrobiosis Lipoidica (NL)
Max Gross Sales



- *74,000 – 185,000 Patients in US*
- *200,000 – 500,000 Patients in High Sociodemographic Index (SDI) Countries*



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

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Clinical Evidence of NL Efficacy for Pentoxifylline (PTX) and PCS-499

- Dermatologists mainly use topical steroids and other drugs with poor response
- ***PTX*** is used ***OFF-LABEL and response can start after 1 month*** with significant improvement within 3-12 months (published case studies and clinical experience)
- PTX does not have widespread use; ***a small percentage of patients respond at the maximum tolerated dose of PTX***
- ***Increasing PTX dose to achieve higher response rate results in dose limiting side effects***

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Clinical Evidence of NL Efficacy for Pentoxifylline (PTX) and PCS-499

- After ***PCS-499*** administration the ***same active moieties exist systemically*** as in PTX but the ***amounts*** of some active moieties ***are greater after PCS-499 administration***.
- ***PSC-499 tolerated oral dose*** in NL patients (PCSA Phase 2 Trial) and healthy human volunteers ***= 1.5 x PTX*** tolerated oral dose

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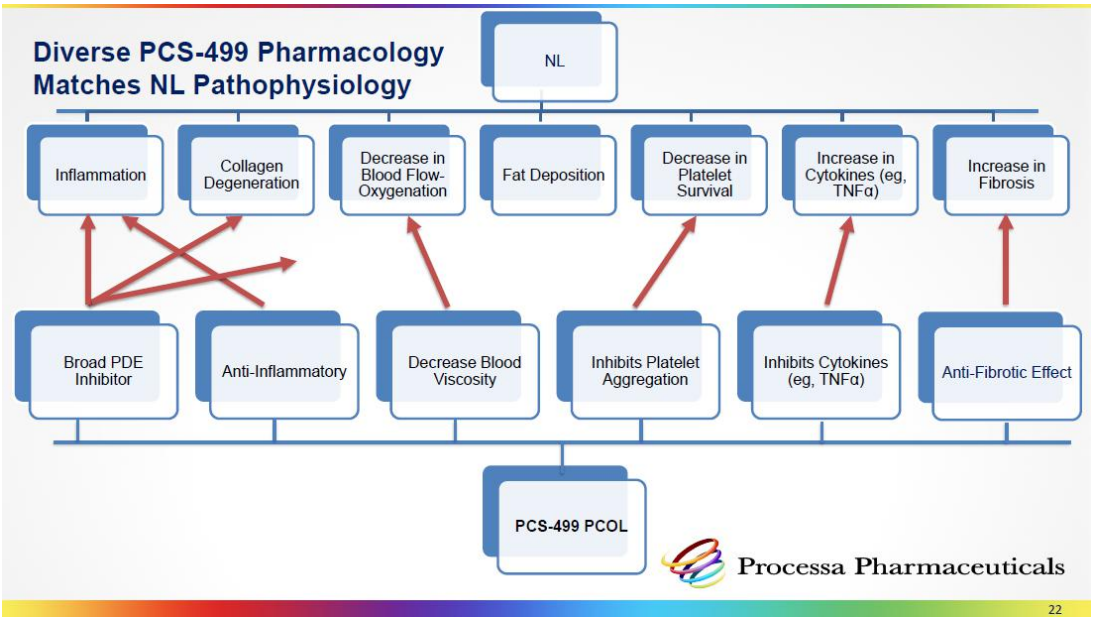
Diverse PCS-499 Pharmacology Matches NL Pathophysiology
NL
Inflammation
Collagen Degeneration
Decrease in Blood Flow-Oxygenation
Fat Deposition
Decrease in Platelet Survival
Increase in Cytokines (eg, TNFα)
Increase in Fibrosis
Broad PDE Inhibitor
Anti-Inflammatory
Decrease Blood Viscosity
Inhibits Platelet Aggregation
Inhibits Cytokines (eg, TNFα)
Anti-Fibrotic Effect
PCS-499 PCOL
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Status of PCS-499 NL Program

- Defined development program in pre-IND collaborative meeting with FDA (Oct 2017); Orphan Designation for PCS-499 in NL (June 2018); PCS-499 NL IND cleared by FDA (Sept 2018) – PCS-499 safety/tolerance trial in NL patients
- First patient dosed January 2019 in Phase 2 trial; ***to date 5 patients dosed with no dose limiting side effects confirming that patients can tolerate PCS-499 at a higher dose***
- In 2019
  - ***Complete enrollment of 12 patients before June 2019 and obtain all tolerance and efficacy data before end of 2019***
  - ***Plan for FDA meeting at end of 2019*** to define larger randomized trial (Phase 2b or Phase 3) and SPA

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Additional Efforts To Increase Shareholder Value

- Evaluating ***PCS-499 in other indications*** where preliminary clinical evidence exists for PTX or PCS-499 efficacy
- ***Evaluating and negotiating acquisition of other drugs*** with existing evidence of clinical efficacy (e.g., CNS, Oncology, Women's Health, orphan diseases)
- Income generating efforts
  - Exploring the ***out-licensing of PCS-499 for ex-US development***
  - ***Negotiating Development Team Collaborations (DTCs)*** where drug ownership remains in existing company, however, development (including FDA interactions) is performed by Processa in exchange for SGA, milestone payments, bio-bucks

Processa Pharmaceuticals

Summary

- *Significant present and future value to be added*
- *Processa offers a higher return and lower risk investment for shareholders as well as a potential future valuation of billions of dollars*
- *Processa has an experienced team to navigate 1) the FDA drug development and approval process using their Regulatory Science approach and 2) SEC/Financial Req. of a public company*
- *Positive news flow expected every 2-4 months throughout 2019*

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Summary

- *Clinical evidence of PCS-499 efficacy in NL patients already exists*
- *Phase 2 trial is confirming that PCS-499 is better tolerated than PTX in NL patients with key results available 2nd and 3rd quarter 2019 (PCS-499 rNPV > $200 M)*
- *2019 end of year meeting with FDA defining next key study (Phase 2b or Phase 3) will add significant value to company (PSC-499 rNPV > $325 M)*
- *Diversification of product portfolio is underway*
- *Processa is working on approaches to obtain income through DTCs and ex-US out-licensing of PCS-499*

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