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): June 7, 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 June 7, 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 June 7, 2019.

PROCESSA PHARMACEUTICALS, INC.
Registrant

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

Processa Pharmaceuticals

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

Jefferies Healthcare Conference
June 4 - 7, 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

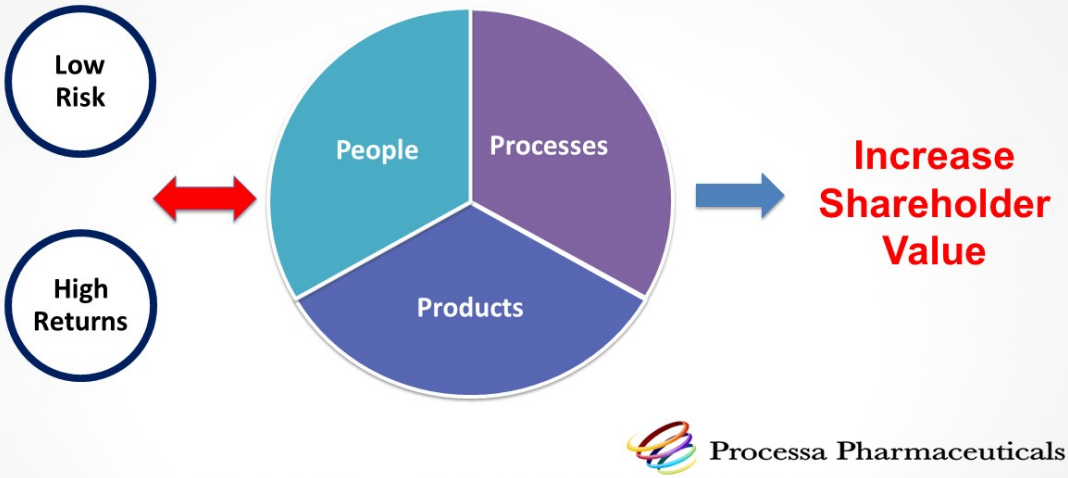
Biotech Approach vs Processa Approach

Biotech Industry:
New Molecular Entity (NME) Drug Development is
Very Risky with a High Likelihood of Failure

Processa Business Model:
Develop Drugs with
Lower Risk of Failure and Potentially High ROI

Processa Pharmaceuticals

Decrease Drug Development Risk & Increase Potential Return



Processa Pharmaceuticals

Return and Risk Depend on People, Processes, Products

People: Requires a drug development & corporate team with the expertise and experience to obtain FDA approval with an acceptable ROI

- ✓ ***Over the last 25+ years Processa team has > 30 FDA approvals, > 100 FDA meetings, trained FDA reviewers, & worked on 3 FDA Guidances --- Last Drug Approved Led to a $5.6B Exit --***

Processes: Requires processes to obtain FDA approvals efficiently and management processes to meet corporate and growth development needs

- ✓ ***Processa has refined their Regulatory Science approach to drug development & has successfully managed companies to exists with > 500x return***

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

- ✓ ***Processa is developing drugs to treat patients with high unmet medical need conditions which have existing clinical evidence of efficacy - safety and a 2-4 year value inflection point***

Processa Pharmaceuticals

Processa Pharmaceuticals

Our People

Our People Lead to Success

- *Established and Proven Executive Team with 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 Committee Member & Sponsor
  - Over 30+ FDA approvals & 100+ FDA meetings
  - *Agnostic to therapeutic area, worked with every FDA Drug Review Division*

Processa Pharmaceuticals

Our Leadership

David Young, Pharm.D., Ph.D., CEO, Chairman of the Board

- 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 and Director, Board of Directors

- 20 Years Financing and Investing Experience in Biopharma Sector;
- 25 years on Wall Street involved with over 500 IPOs and Follow on Offerings
- Principal/Founder Primarius Capital, Focused on Small Cap with Numerous $3B+ Mkt Cap Winners
- Former E*Offering Co-Founding Partner Growing Company to 200 Employees & $80M Rev. During 1st Year; Former Principal at Robertson Stephens & Co.

Processa Pharmaceuticals

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

- 30 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

Processa Pharmaceuticals

Board of Directors

David Young, Chairman of the Board and Patrick Lin, Director

Virgil Thompson, JD, Independent Director

- Chairman of the Board of Spinnaker Biosciences, Inc.; Former CEO & Director Spinnaker
- Chairman of the Board of Aradigm Corporation; Director of Genz Corporation
- Former Chairman of the Board and Director of Questcor Pharmaceuticals
- President, CEO, Director of Angstrom Pharmaceuticals, Chimeric Therapies, Bio-Technology General Corporation (subsequently Savient Pharmaceuticals, Inc)

Justin Yorke, Independent Director

- Over 25 years of experience as an institutional equity fund manager and senior financial analyst for investment funds and investment banks
- Manager of the San Gabriel Fund, JMW Fund and the Richland Fund
- Former non-executive Chairman of Jed Oil, Director/CEO at JMG Exploration
- Former Fund Manager and Senior Financial Analyst for Darier Henstch, S.A., a private Swiss bank; Assistant Director and Senior Financial Analyst with Peregrine Asset Management; Vice President and Senior Financial Analyst with Unifund Global Ltd.

Processa Pharmaceuticals

Processa Pharmaceuticals

Our Drug Development Process

Processa Regulatory Science Approach to Approval

We Know The Way To The FDA

Over the Last 25+ Years, Our Team Has Formulated 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 *ANTICPATE the science required to make FDA regulatory decisions* - based on training FDA reviewers, assisting in FDA Guidances, membership on FDA Advisory Committees, > 100 FDA interactions, interactions with every drug review division of FDA, and involvement with > 30 FDA approvals

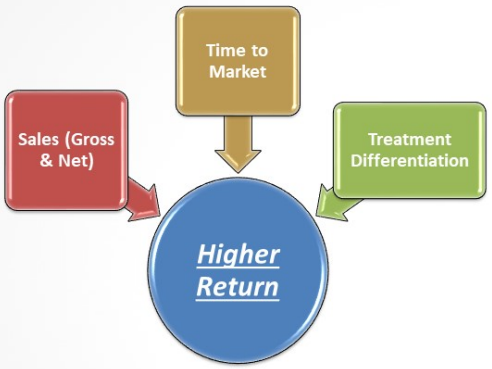
Processa Pharmaceuticals

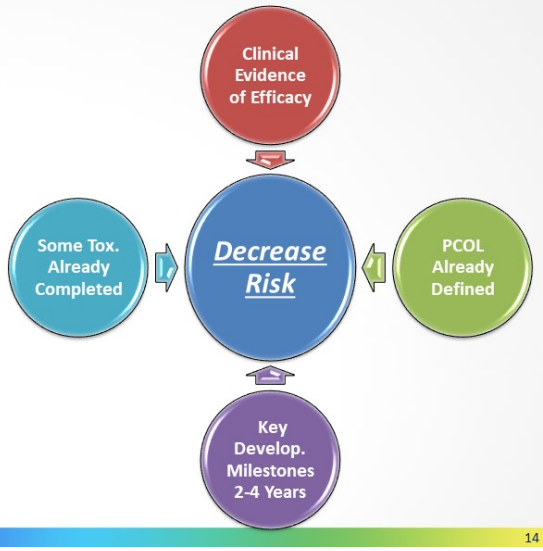
Processa Pharmaceuticals

Our Product

Higher return on investment (ROI) by selecting drugs and indications with higher potential gross sales, faster time to market, & differentiated from existing treatments

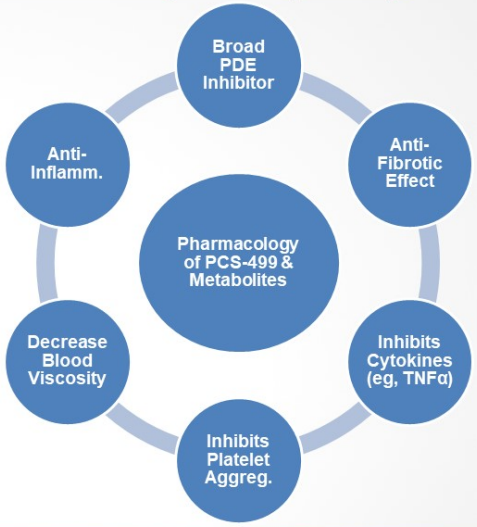
Decrease risk of failure by selecting drugs with some clinical evidence of efficacy/safety, pharmacology-tox understood, & value added milestones in 2-4 years





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 →



High Return: PCS-499 Different than PTX

- In pre-clinical toxicology studies, the maximum tolerated dose *(MTD) 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*
- After *PCS-499* administration, the *same active moieties exist systemically* as in PTX but the *amounts of some active moieties are more than 2 times greater after PCS-499 administration after the same dose is administered*
- *PCS-499 dose of 1.8 gm per day* (900 mg b.i.d. or 600 mg t.i.d.) *is tolerated as well as 1.2 gm per day of PTX* (400 mg t.i.d.), the maximum PTX dose recommended by FDA

Processa Pharmaceuticals

Key Active Moieties after 1.8 gm of PCS-499 > 3x the Amount after 1.2 gm of PTX

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

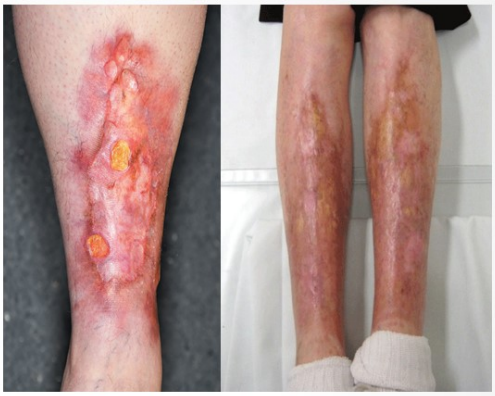
2.2x higher

- 1.8 gm daily dose of PCS-499 tablets (administered as 900 mg BID or 600 mg TID) was *well tolerated despite > 2 x active moieties of PTX exposures on a per mg* administered basis
- PCS-499 active moieties after *1.8 gm daily dose is > 3x active moieties after 1.2 gm daily dose* of PTX

Processa Pharmaceuticals

Higher Return: Indication Dependent Necrobiosis Lipoidica (NL)

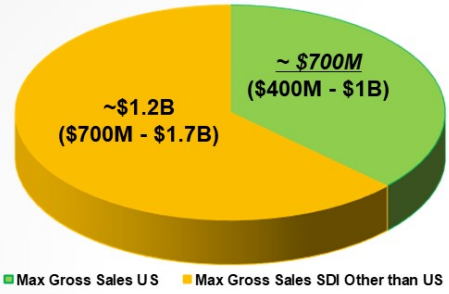
- PTX used off-label
- Occurs in women/men 20 – 60 y/o
- Skin becomes necrotic; 30% of patients have painful ulcerations; complications - infections, amputation, squamous cell cancer
- No standard of care or FDA approved treatment; Dermatologists mainly use topical steroids and other drugs with poor response; no known biotech or pharma company developing a drug for NL
- *Orphan indication and high unmet medical need condition with no approved drugs may provide a faster route to approval*

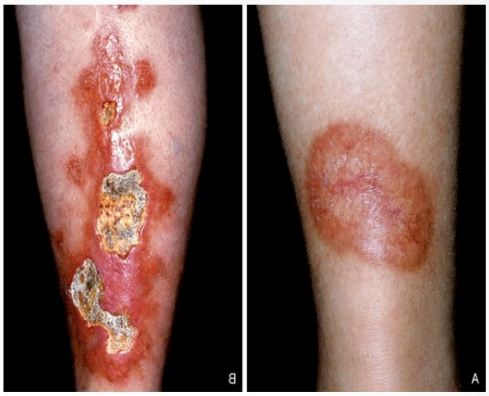


Processa Pharmaceuticals

Potential High Return: NL Market Opportunity
Max Annual Gross Sales Worldwide *$1.2B - $2.7B*

Necrobiosis Lipoidica (NL)
Max Gross Sales



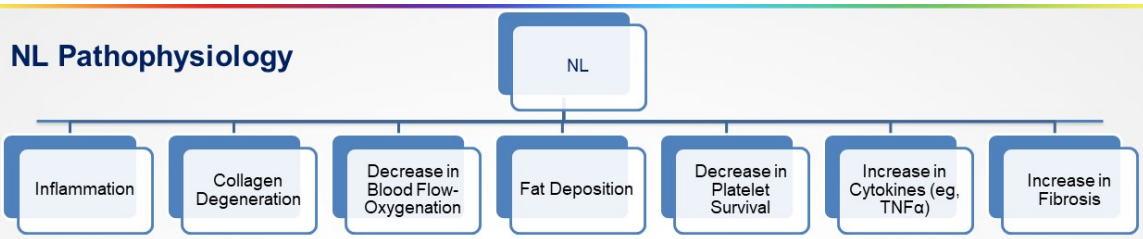


- *74,000 – 185,000 Patients in US*
- *200,000 – 500,000 Patients in High Sociodemographic Index (SDI) Countries*

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

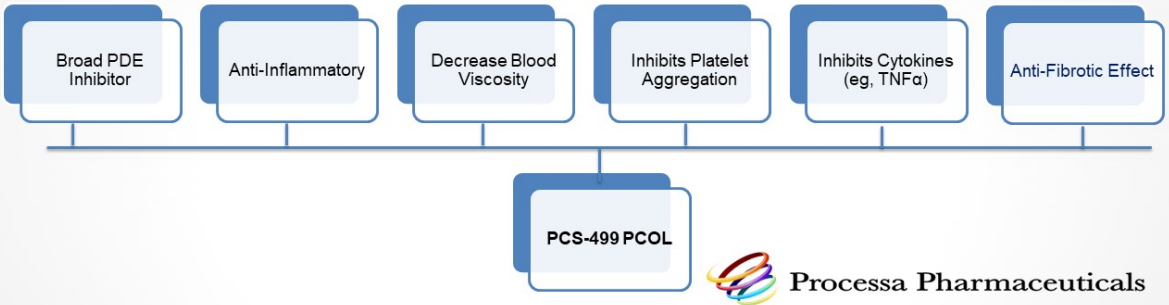
Processa Pharmaceuticals

NL Pathophysiology

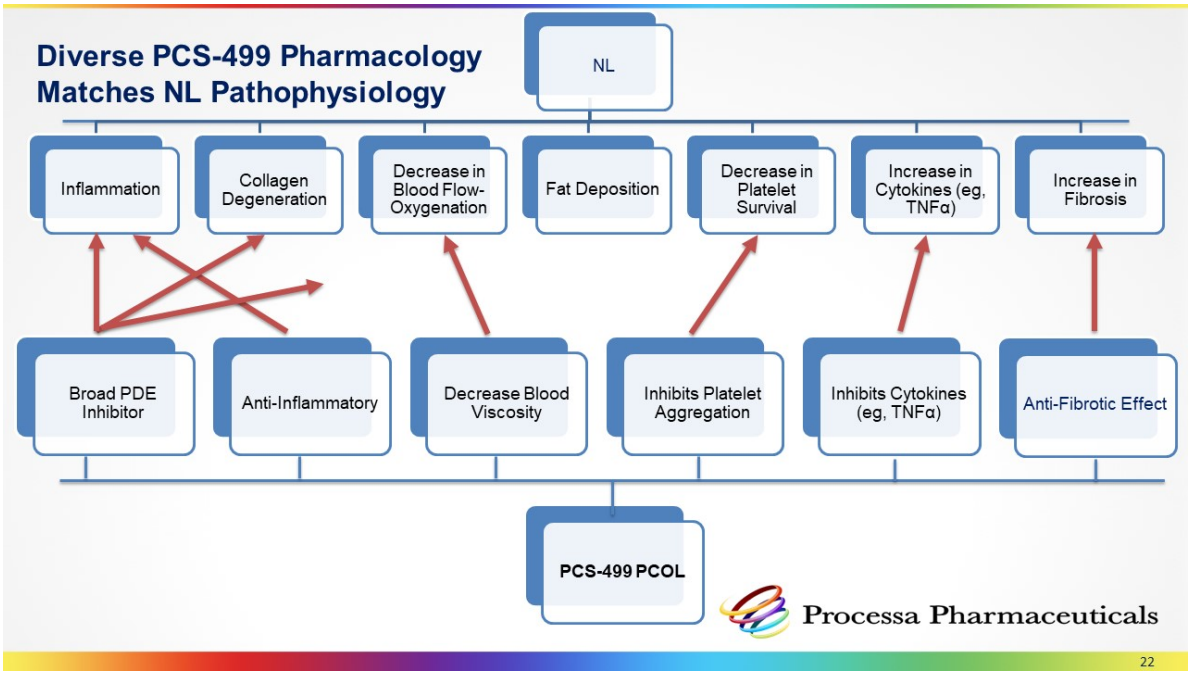


Processa Pharmaceuticals

PCS-499 Diverse Pharmacology Beneficial for The Treatment of a Number of Indications



Processa Pharmaceuticals


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
Processa Pharmaceuticals
22

Lower Risk: Clinical Efficacy Evidence already Exists Supporting the Use of PTX and PCS-499 in NL

- *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 to the maximum tolerated dose of PTX*
- *Increasing PTX dose beyond 400 mg t.i.d. would be needed to achieve a significantly higher response rate but increasing PTX dose results in dose limiting side effects within a week*
- Advantage of a higher dose of PCS-499 (1.8 gm/day) than PTX (1.2 gm/day) is that there is >3x *more active moieties and greater possibility of seeing a statistically significant efficacy response* while not increasing the side effect rate or seriousness of the side effects

Processa Pharmaceuticals

Status of PCS-499 NL Program

- Defined development program in pre-IND collaborative meeting with FDA (Oct 2017); FDA stated that *1 pivotal study may be acceptable* for NL
- Received Orphan Designation providing 7 years of Market Exclusivity (June 2018)
- PCS-499 IND cleared by FDA (Sept 2018) for PCS-499 safety/tolerance trial in NL patients
- First patient dosed January 2019 in Phase 2 trial; *9 patients dosed to date with no dose limiting side effects, confirming that patients can tolerate a higher dose of PCS-499*
- Anticipate *enrollment of Phase 2 NL patients* will be completed in June/July 2019 with *tolerance data obtained for all patients by Sept/Oct and efficacy data obtained by end of 2019*
- *Plan for FDA meeting at end of 2019* to define Special Protocol Assessment (SPA) for larger randomized trial (Phase 2b or Phase 3); *Phase 2b/3 trial anticipated to start 1H2020*

Processa Pharmaceuticals

Additional Efforts To Increase Shareholder Value

- Evaluating *PCS-499 in other indications* where preliminary clinical evidence exists for PTX but where PCS-499 can be differentiated from PTX and other treatments
- *Negotiating acquisitions* of new molecular entities and re-purposed drugs with some evidence of clinical efficacy
- Income generating efforts
  - Exploring the *out-licensing of PCS-499 for development outside the US*

Processa Pharmaceuticals

Processa Financial Overview

OTCQB (6/4/19)	PCSA - $2.50/share
Market Cap (6/4/19)	$96.7M
Shares Outstanding	~38.7M Shares
Cash or Cash Equivalent (6/4/19)	~$1.0M (Plus an Additional $1.3M from Investor who Directly Pays CRO for Phase 2 Trial Costs)
Total 2019 Remaining Expenses Other than Funded Phase 2 Trial Costs	~ $1.4M (2019 Annual Salaries + G&A Burn Rate ~ $2.5M)
Present PIPE Raise	Maximum $10M @ $2.27 per share ($88M pre-money valuation), 1:1 warrants, anti-dilution clause
Up-Listing to NASDAQ	Preparing to up-list to NASDAQ in 4-12 months after additional drugs acquired
Insider Ownership %	> 70%

Processa Pharmaceuticals

Summary

- The potential future valuation of Processa is significantly greater than the present market cap-stock price
- Processa has an experienced team to navigate 1) the FDA drug development and approval process using their Regulatory Science approach and 2) the SEC/Financial requirements of a public company
- Although developing drugs for FDA approval is risky, the Processa Development Team and Regulatory Science approach makes the likelihood of success greater thus decreasing the risk of drug development failure and potentially providing a higher ROI
- Salaries and G&A burn rate are much less than the typical Biotech company with $2.5M in 2019 with 14 employees

Processa Pharmaceuticals

Summary

- Clinical evidence of PCS-499 efficacy in NL patients already exists through PTX off-label use
- Phase 2 trial is confirming that NL patients can tolerate a significantly higher dose of PCS-499 than a PTX dose with key results available 2H2019
- 2019 end of year FDA meeting planned to define NL Phase 2b/3 trial and SPA (begin 2020)
- Diversification of our product portfolio is underway through the acquisition of other drugs or drug portfolios
- Plan is to up-list to NASDAQ 4-12 months after additional drug(s) acquired

Processa Pharmaceuticals