



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

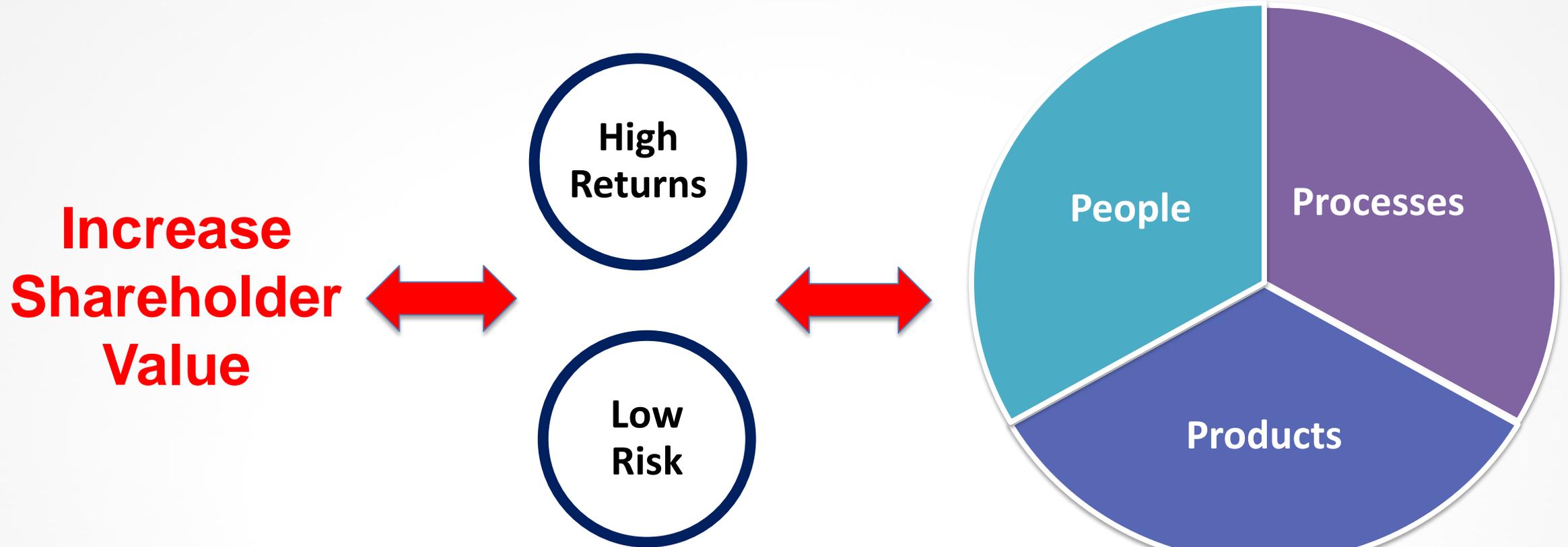
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Increase Shareholder Value by Achieving High Returns While Minimizing Risk



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



Processa Pharmaceuticals

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 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

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

**We Know The Way
To The FDA**

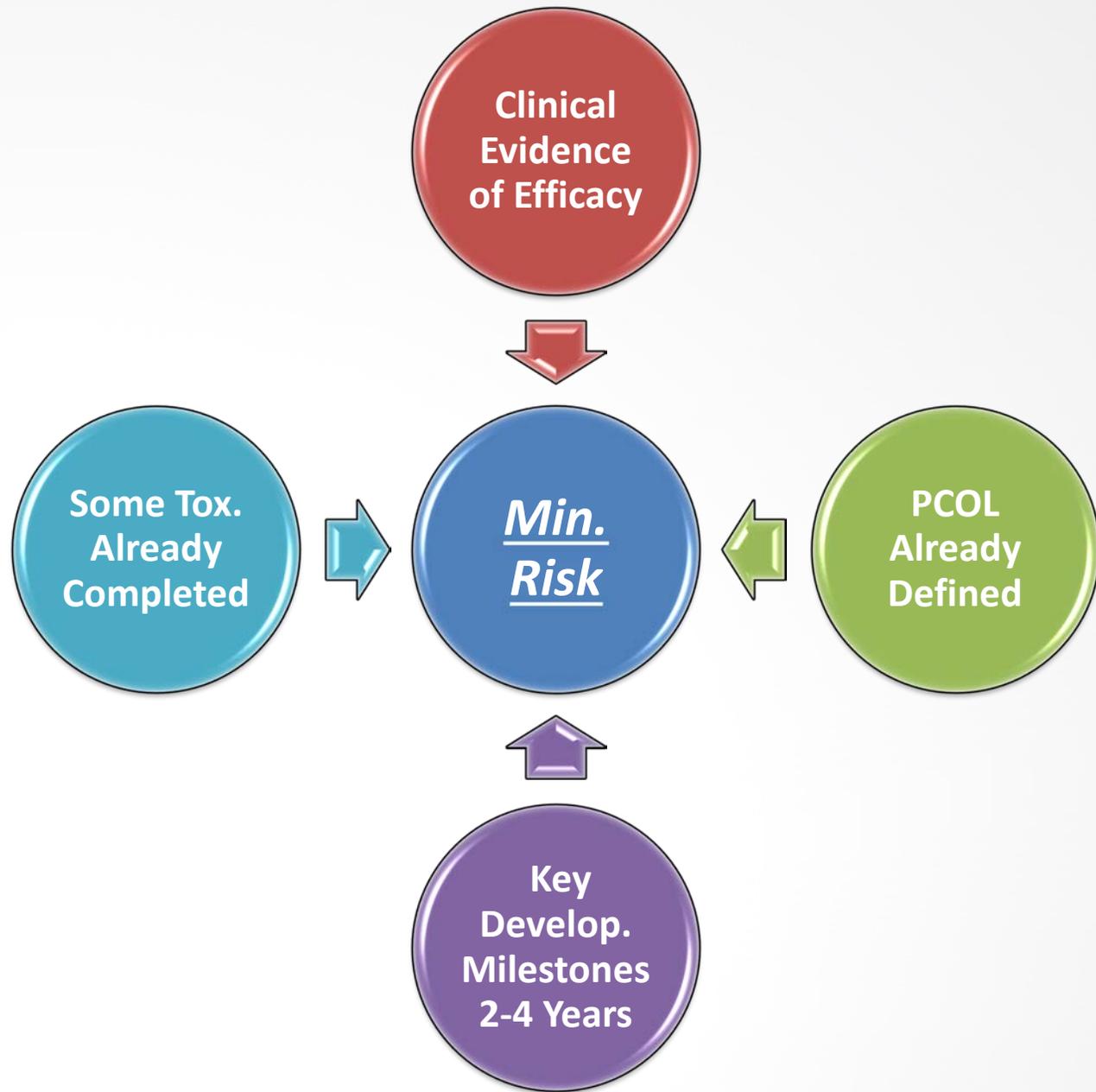


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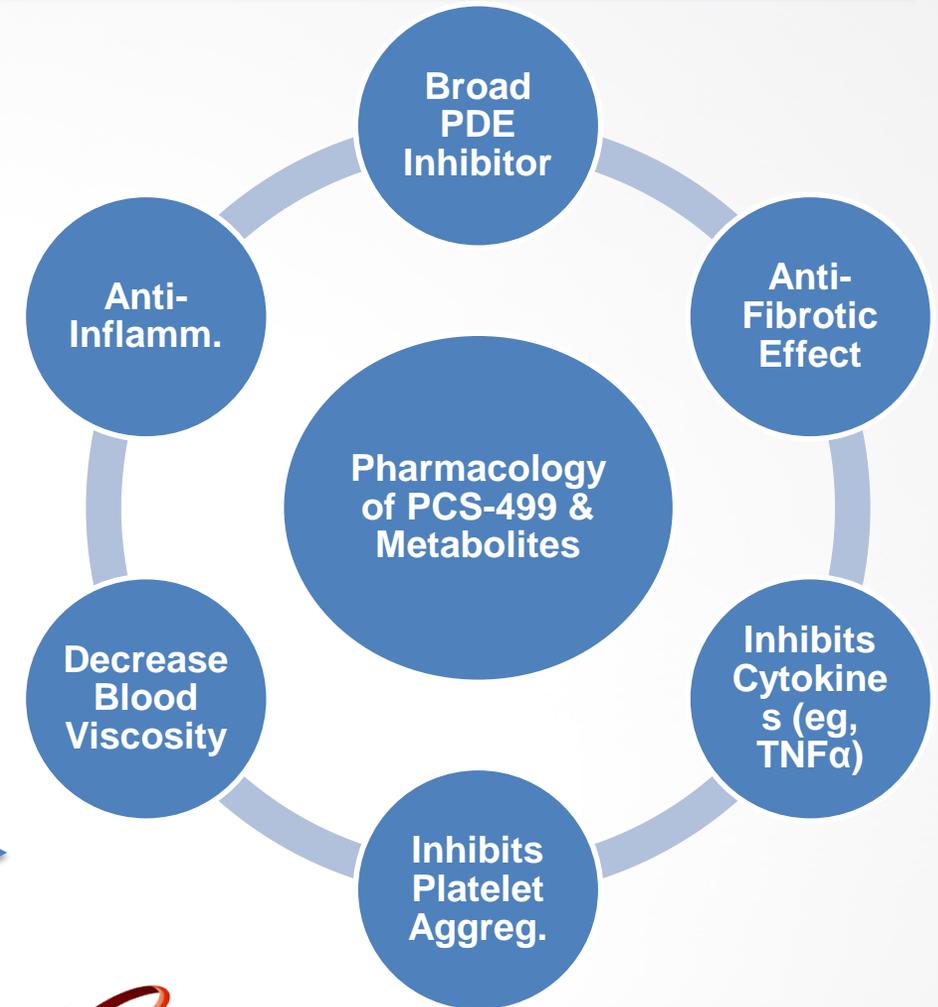
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Our Product



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**



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)
C _{max} /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



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**

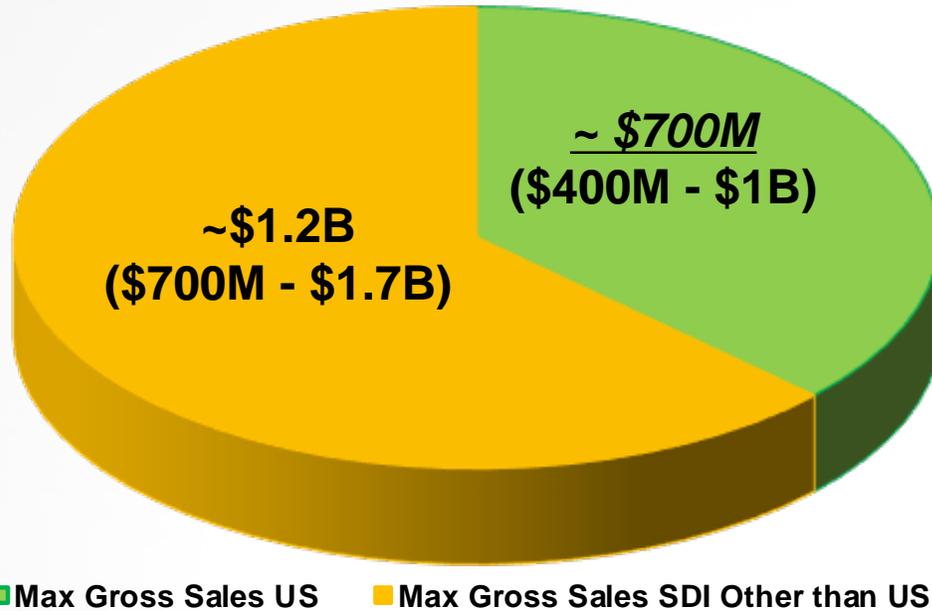


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NL Market Opportunity

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



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**

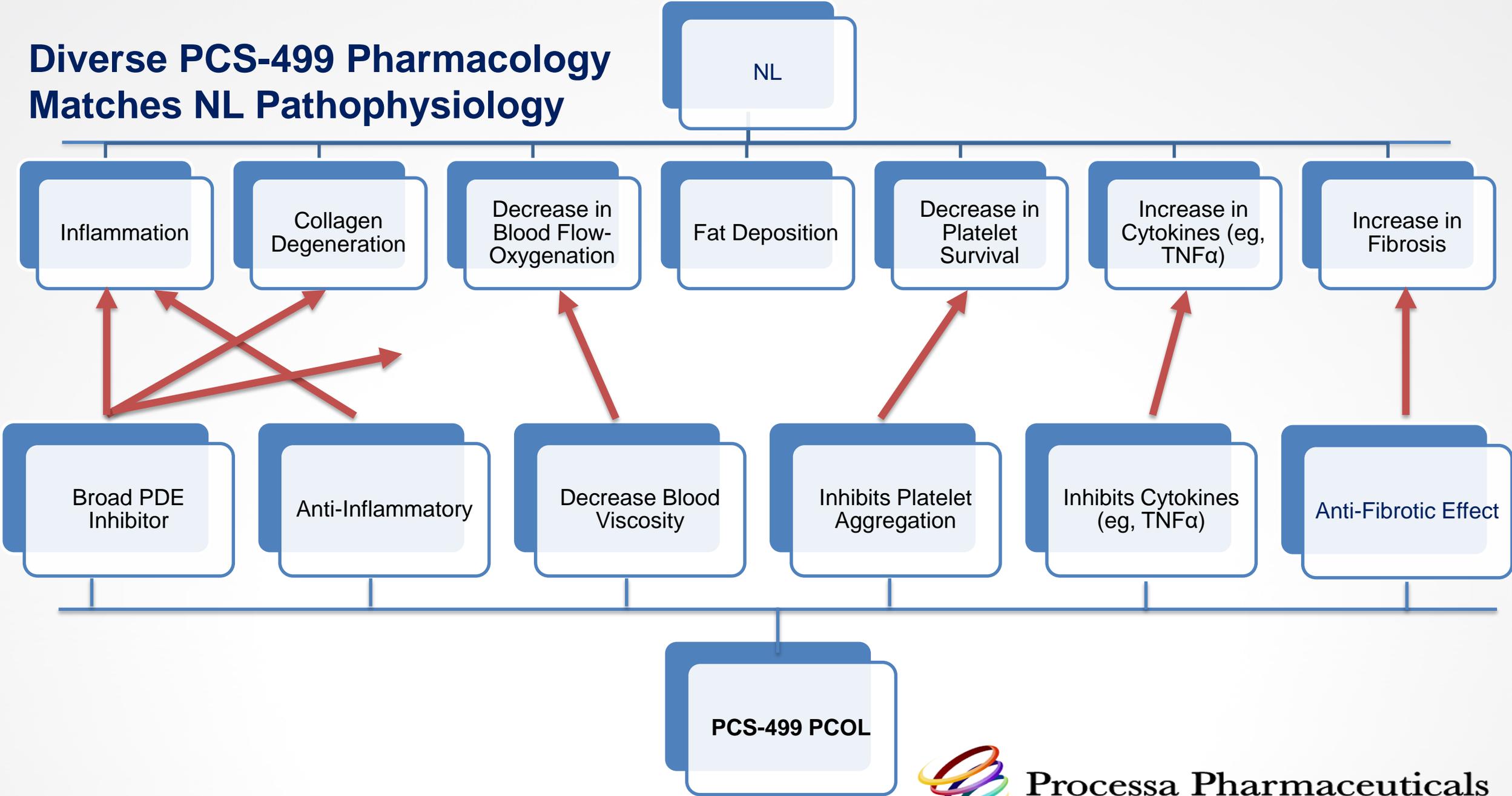


Clinical Evidence of NL Efficacy for Pentoxifylline (PTX) and PCS-499

- 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**.
- **PCS-499 tolerated oral dose** in NL patients (PCSA Phase 2 Trial) and healthy human volunteers **= 1.5 x PTX** tolerated oral dose



Diverse PCS-499 Pharmacology Matches NL Pathophysiology



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



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



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***



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***

