



Processa Pharmaceuticals

**CORPORATE PRESENTATION
JANUARY 2021**



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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



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**

- Clear and obvious patient need
- Favorable competitive dynamics



**Efficacy
Evidence**

- Direct proof of concept or other proof of principal
- De-risking development, higher probability of successful development



**Regulatory
Science**

- 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



**Capital
Efficiency**

- Leverage considerable investments prior to licensing (tox, CMC etc.)
- Efficient clinical trials and development program



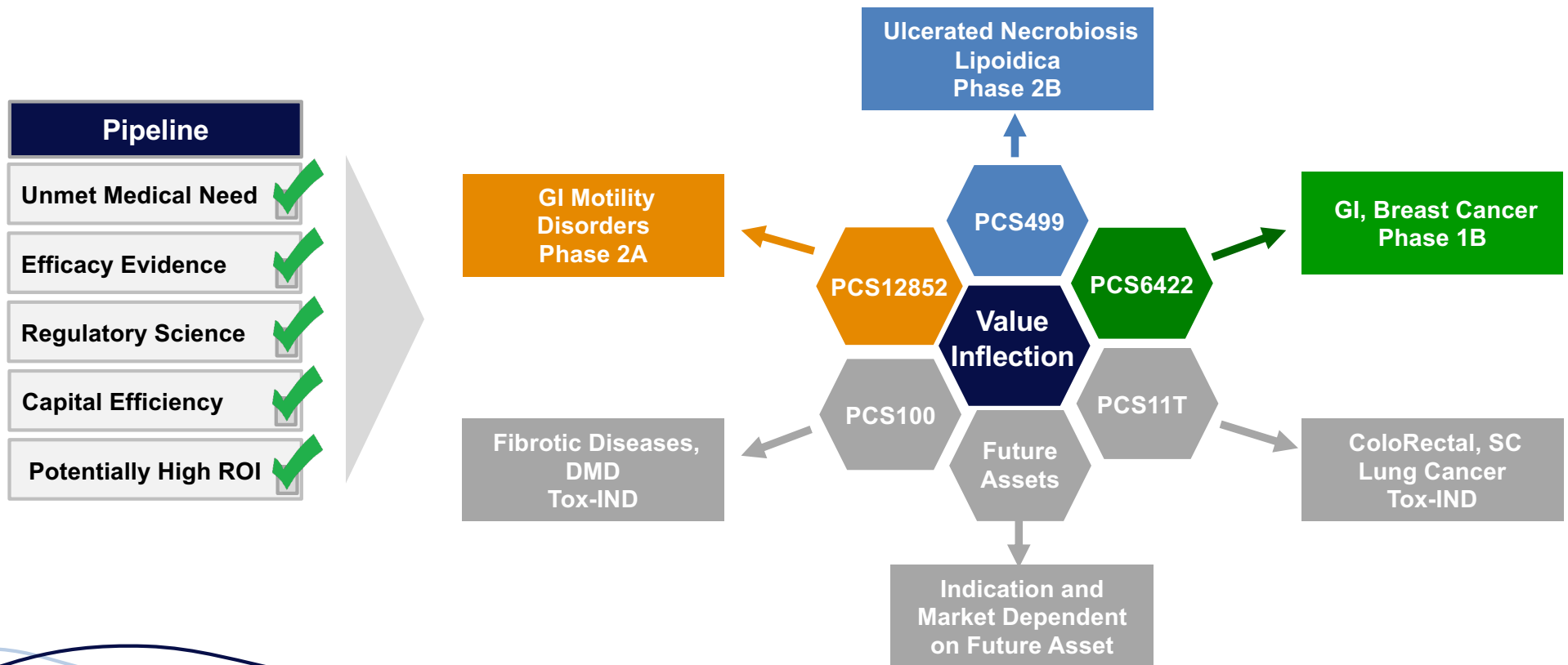
**Potentially
High ROI**



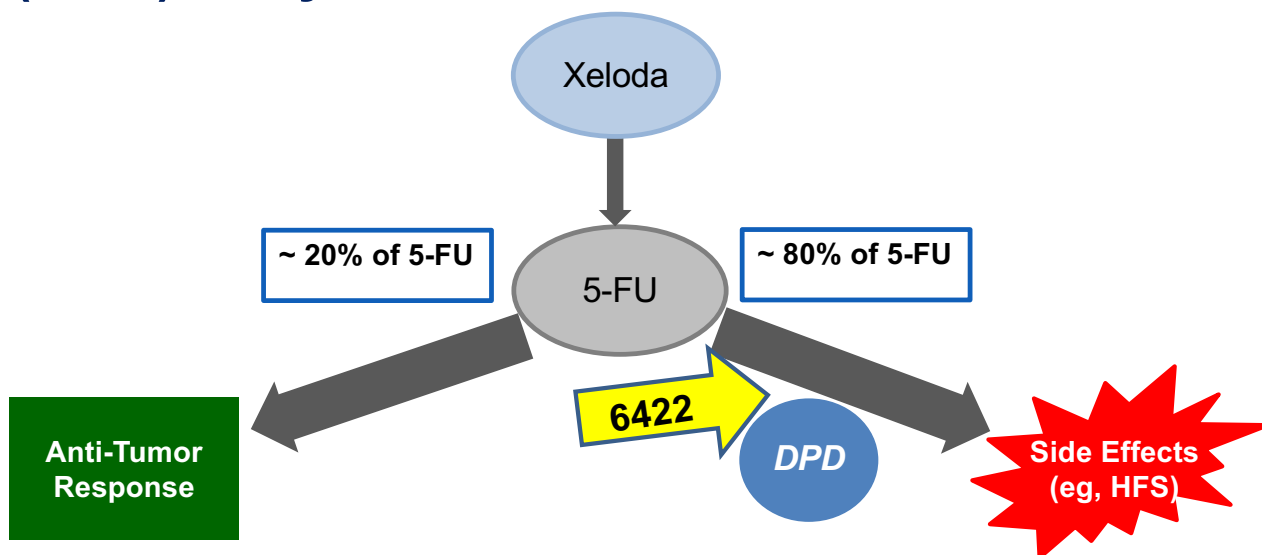
Processa Pharmaceuticals

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

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



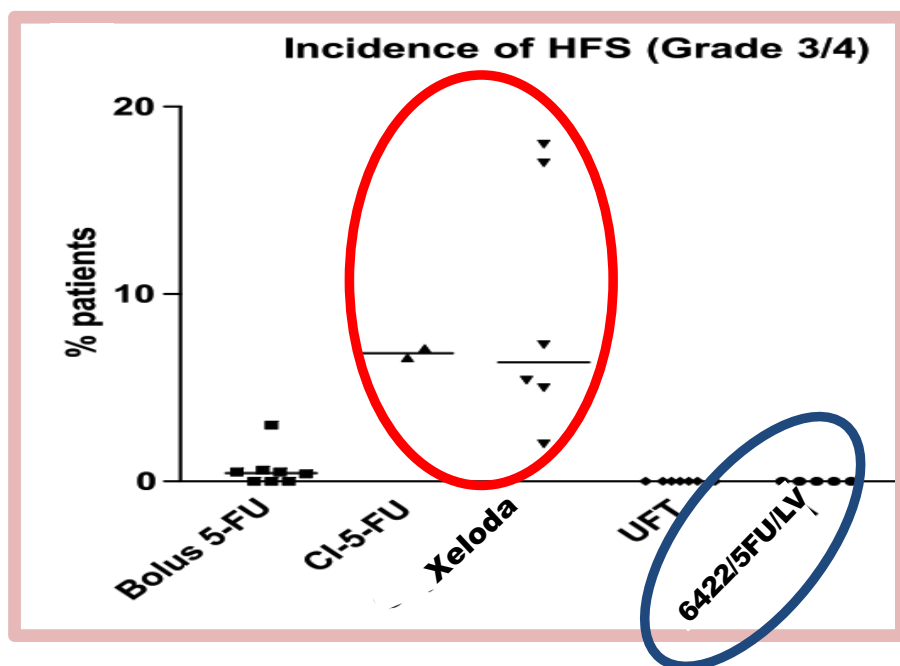
✓ Response Rate
✓ Survival Time



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

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)

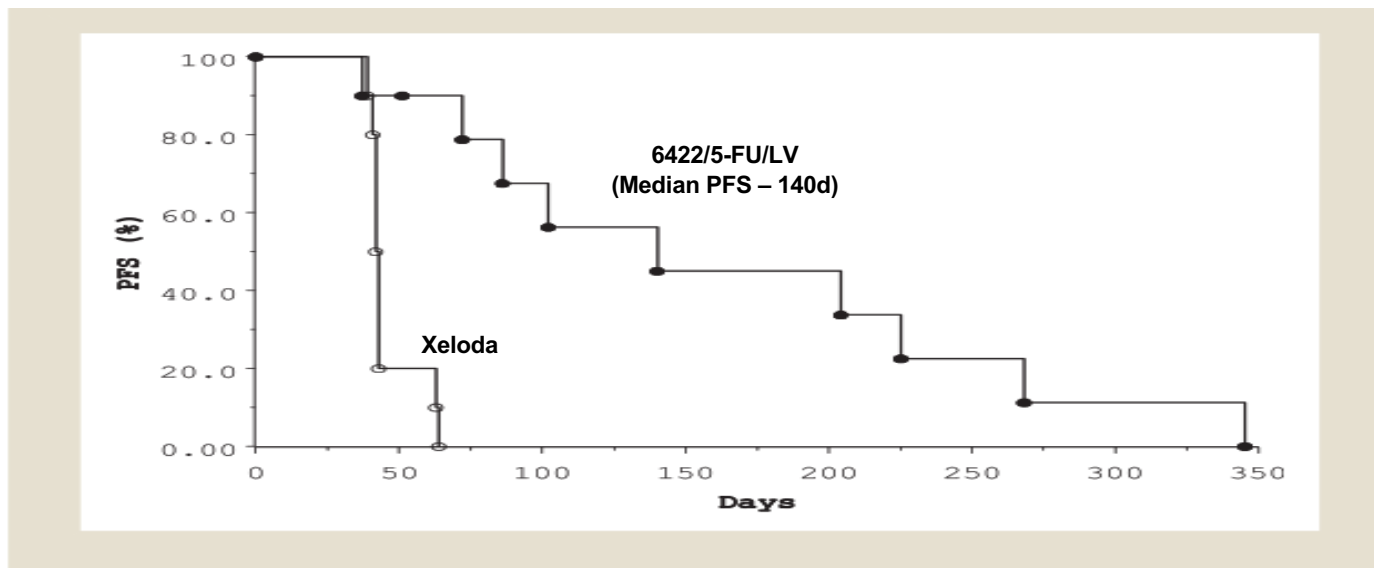


Hand-foot syndrome (HFS) is the most common adverse effect of Xeloda and 5-FU, with an incidence of 50–70%, and its occurrence can lead to dose interruptions, adjustments, discontinuation

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

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

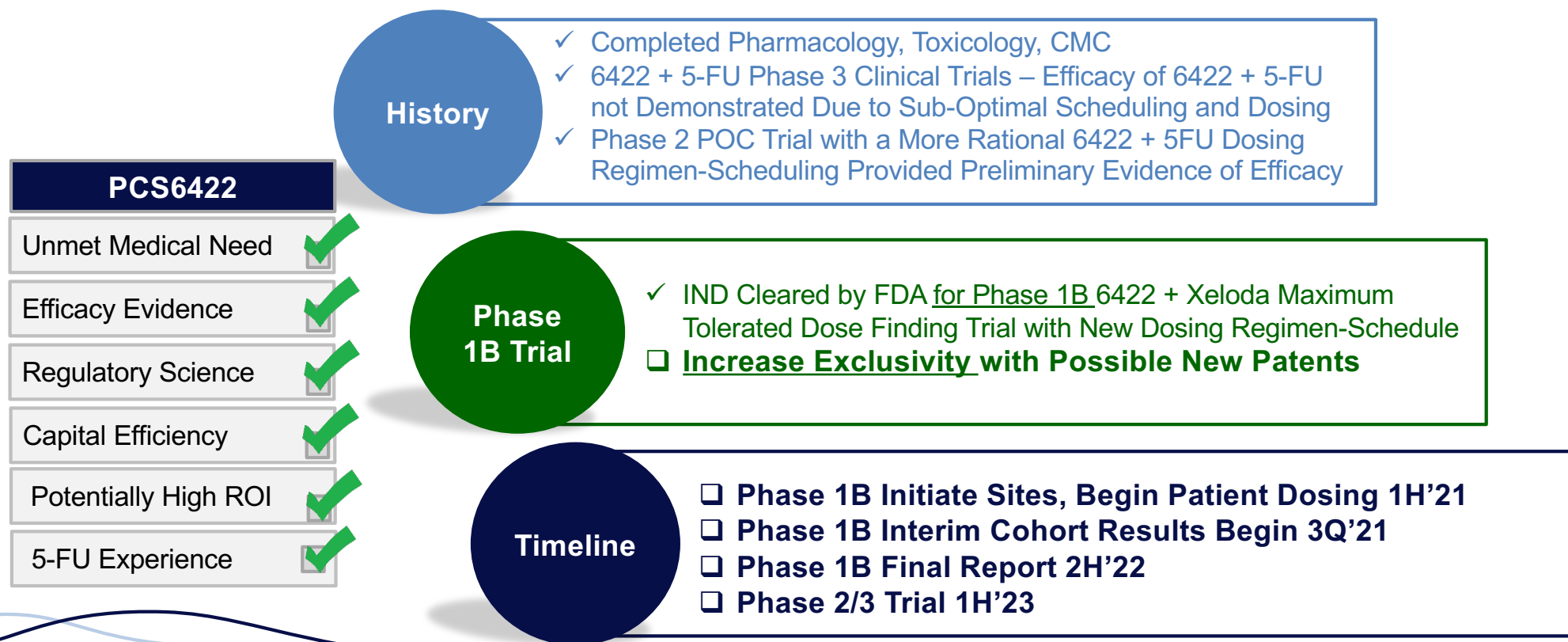
Improve Efficacy with 6422:
Lower Dose of 6422 Administered Hours Before 5-FU/LV in Xeloda Resistant Patients



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

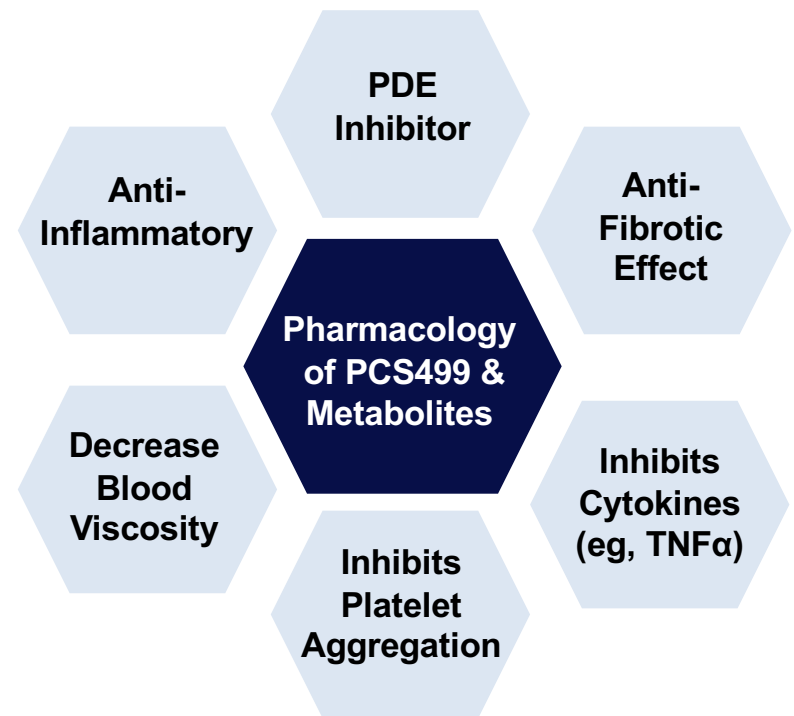
Positive 6422-Xeloda Phase 1B Trial Increases Probability of FDA Approval by Providing Information to Help Design Pivotal Trial



PCS499: Diverse Pharmacological Properties

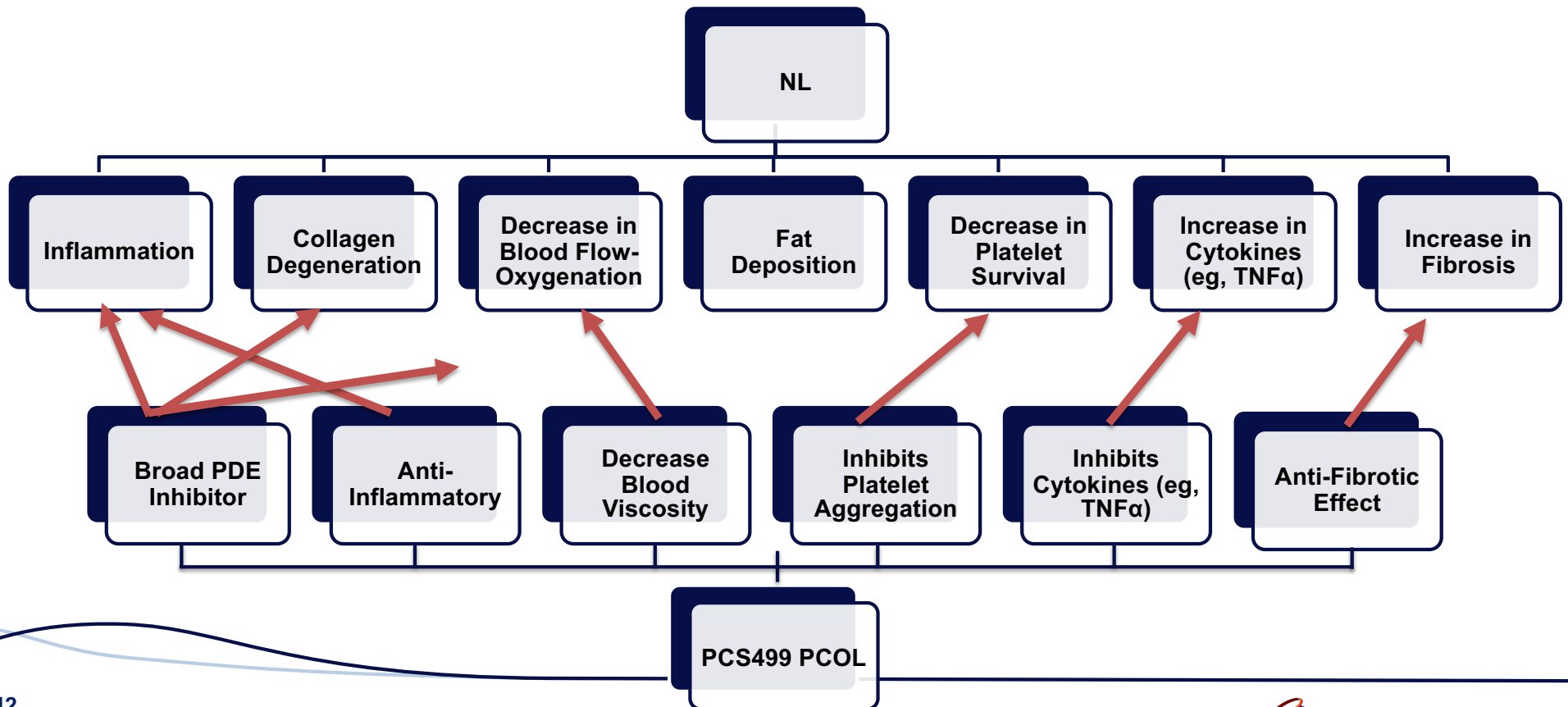
Deuterated Analog of Major Active Metabolite of Pentoxifylline (PTX), FDA Approved for Claudication

- 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



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

PTX Successfully Treats Some NL Patients who can Tolerate the Drug

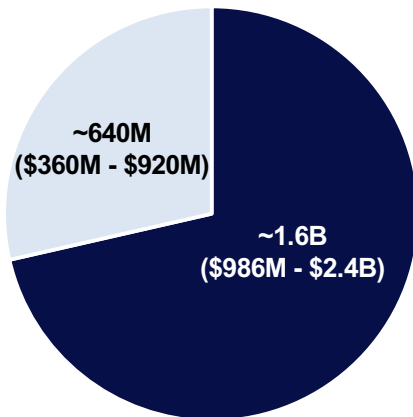


PCS499 Target Population: Ulcerative Necrobiosis Lipoidica (uNL) Patients Have No Treatment Options - \$1B Market

PCS499 has 7-year exclusivity with Orphan Designation for NL

Ulcerative Necrobiosis Lipoidica (uNL)

Max Gross Sales



■ Max Gross Sales US ■ Max Gross Sales SDI Other than US

- 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

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

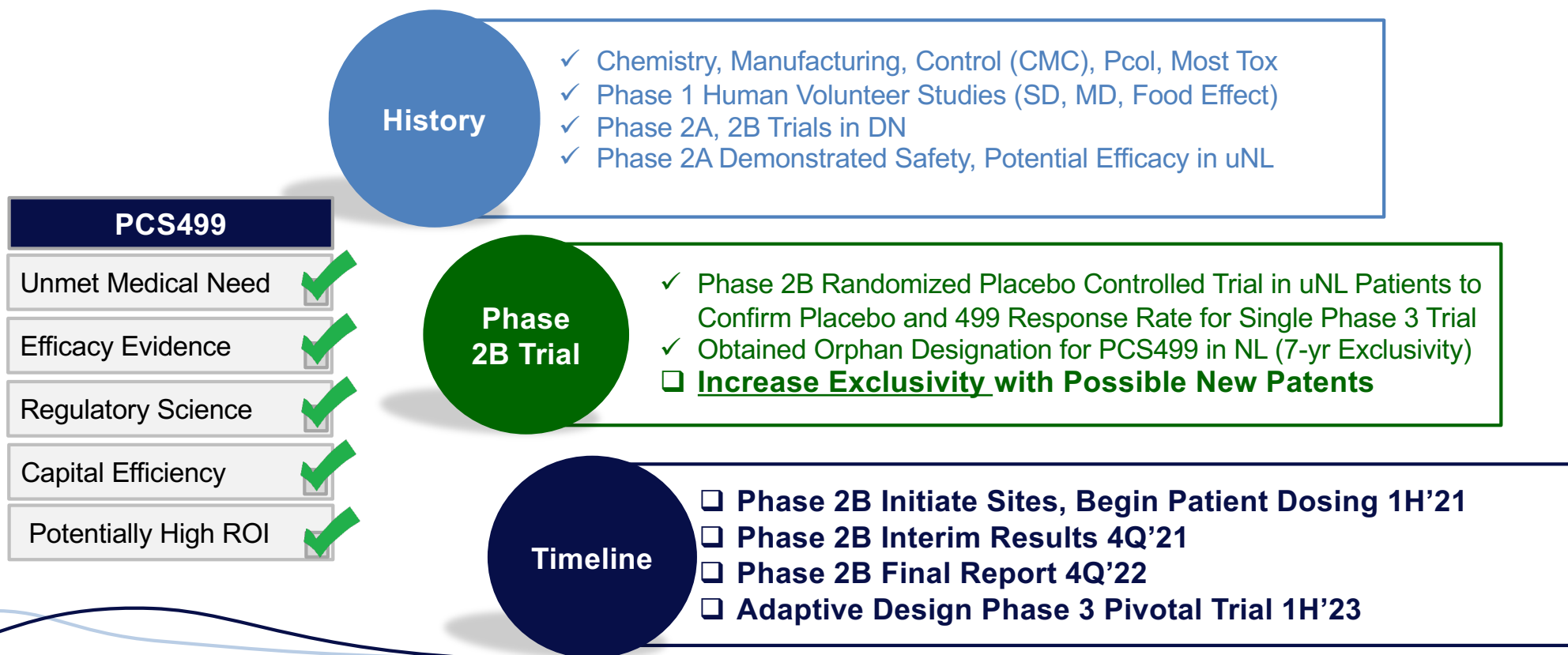


Open Ulcers at Baseline



Complete Closure at 5 months on 499

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



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)*

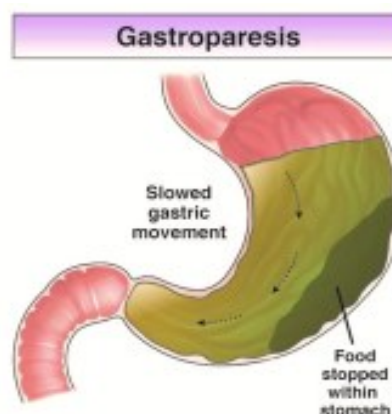
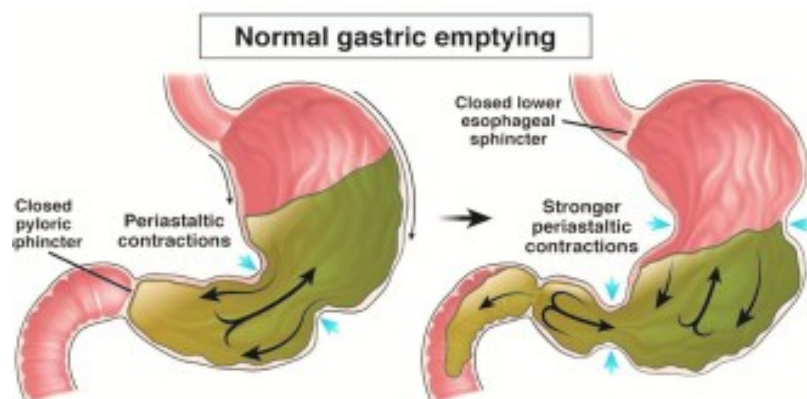
12852 Wider Safety Margin Against Cardiovascular Side Effects than Other 5HT4 Drugs

| 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%

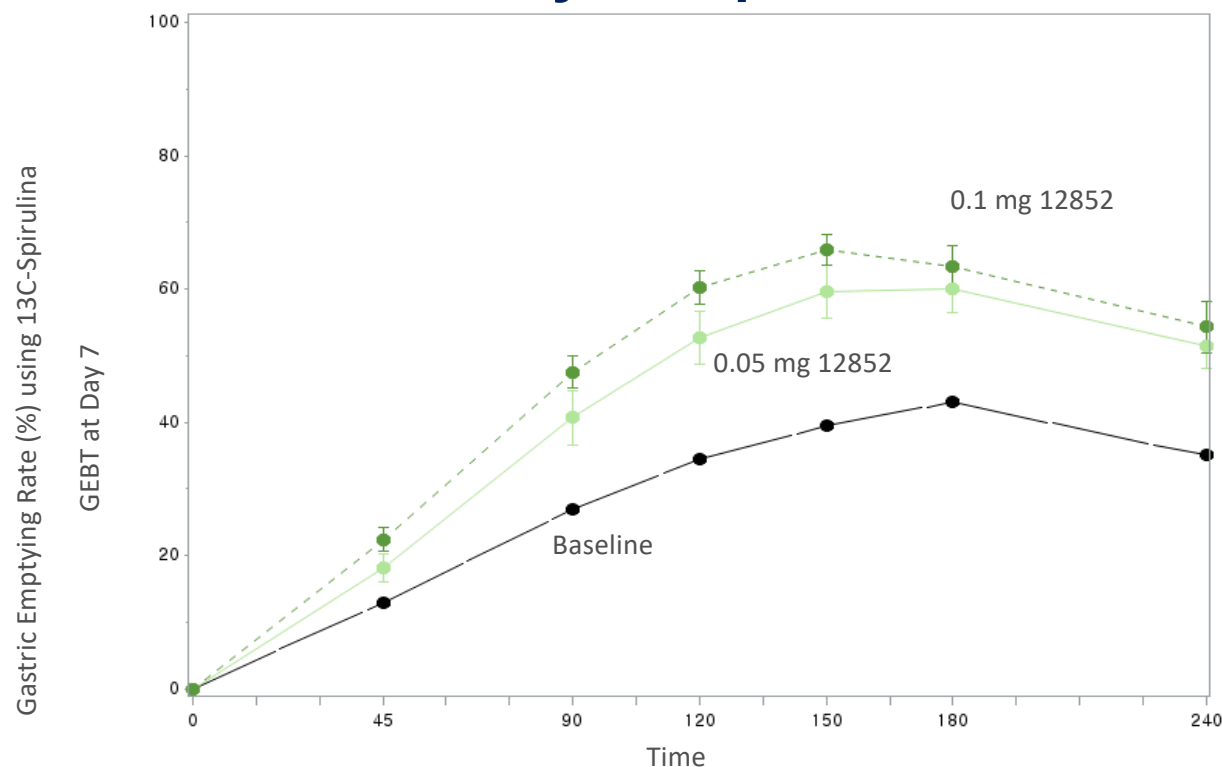
PCS12852 Target Population: Present Therapeutic Options for Patients with Gastroparesis Have Serious Side Effects - \$1B Market



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 | <ul style="list-style-type: none"> Very specific 5HT4 receptor binding Drug very potent to 5HT4 | <ul style="list-style-type: none"> Less specific binding to 5HT4 than 12852 Less potent than 12852 | <ul style="list-style-type: none"> Binds to Dopamine D2 receptors |
| Side Effects | <ul style="list-style-type: none"> <u>No serious side effects</u> in clinical studies to date | <ul style="list-style-type: none"> <u>Serious cardiovascular side effects</u> (eg, cisapride removed from market) <u>Suicidal ideation</u> (eg, prucalopride) | <ul style="list-style-type: none"> <u>Black Box Warning serious neurological side effects</u> |
| Efficacy | <ul style="list-style-type: none"> Increase gastric emptying rate Gastroparesis patient study required | <ul style="list-style-type: none"> Increase gastric emptying rate Successful treatment demonstrated | <ul style="list-style-type: none"> 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.

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

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

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

Virgil Thompson

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

Geraldine Pannu

Independent Director
Founding and Managing Partner of GLTJ
Pioneer Capital

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**