

(Formerly Promet Therapeutics, LLC)

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



Patrick Lin
Chief Business and Strategy Officer
&
David Young, Pharm.D., Ph.D.

December 2017

**CEO** and Interim CFO

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### **Processa Pharmaceuticals Highlights**

- Clinical Stage Drug Development Company Our focus is Phase 2 on
- <u>Treat High Unmet Medical</u> Need <u>Existing POC Clinical Data</u> for Structural Analog
- Experienced Team of Drug Developers, Pharma Executives, Biotech Investors
- Collaborate and Negotiate with FDA Using a FDA Regulatory Science Approach
- 2 4 Year Outcome for Each Pipeline Product (Out-Licensing or Pivotal Study Completed)
- Portfolio to be Expanded in 2018



#### **Processa Pharmaceuticals Financial Overview**

Symbol-Share Price:	PCSA - \$3.64*	
Headquarters	Hanover, MD	
Market Cap as of 11/27/17	\$128.4M	
Shares Outstanding	35.3M*	
Cash As of 11/27/17	\$3.0 M (Includes \$2.58 M Convertible Bridge Loan)	
Insider Ownership %	76.1%	

#### **Summary of Salient Points**

- October 4, 2017: Promet Therapeutics, LLC signs Option & License Agreement with CoNCERT Pharmaceuticals (CNCE: \$22.93)
- October 4, 2017: Asset purchase of Promet closed to create Processa Pharmaceuticals, Inc.
- December 2017: Licensing Option to be exercised in exchange for \$8M of equity in Processa at market value, 15% of sublicensing fees, 4% - 10% backend royalties on net sales
- December 2017: PIPE financing currently underway at \$80M valuation
- > 2018: Plan to uplist to NASDAQ CM or NYSE MKT

<sup>\*</sup> Post 1 for 7 Reverse Split Processa Pharmaceuticals

### **Summary of PIPE Offering**

Financing:	PIPE
Exemption:	Reg D, 506c
Security:	Common Stock and Warrants
Amount:	1) \$4M (+\$3.0M Existing Cash) Covers One (1) Max. Tolerated Dose Phase 2 Trial, Some Tox for Second Asset 2) \$8M (+\$3.0M Existing Cash) Covers Two (2) Max Tolerated Dose Phase 2 Trials, Some Tox for Second Asset
Price Per Share:	\$2.26 (Total Shares of 35.3M after 1 for 7 Reverse Split)
Pre-Money Valuation:	\$80M Pre-Money Valuation Discounted from Total rNPV Valuation of \$120M - \$400M*^
Target Closing Date:	1Q2018

\*\$80M Pre-Money Valuation ≈ High rNPV for NL in US ≈ Low rNPV for NL in SDI ≈ 70% Discount on the Average Total rNPV ^Source: Company



### We Know How to Succeed in Drug Development



### **Our People Lead to Success**



We Know The Way
To The FDA

- Established and Proven Executive Team with Over 20+ Years of Biotech Management Experience
  - Most Recently Helped Transform Questcor Pharmaceuticals from \$15M in 2007 to \$5.6B Market Cap in 2014 in Mallinckrodt acquisition (370x increase in 7 years)
- Development Team Knows the Process to Obtain Drug Approvals with Proven Track Record
  - Over 25 Years of Experience Developing Drugs
  - Over 30+ FDA Approvals
  - 100+ FDA Meetings
  - Trained FDA Reviewers
  - Worked on 3 FDA Guidance's with FDA
  - FDA Advisory Committee Involvement as a Committee Member and Sponsor



#### **OUR LEADERSHIP**

- David Young, Pharm.D., Ph.D., CEO and Interim CFO
  - Former Board Member, CSO of Questcor Pharmaceuticals ~\$15M Market Cap to \$5.6B in 7 Yearss
  - Former President, AGI Therapeutics; Founder & CEO, GloboMax
  - Former Instructor of FDA Reviewers and 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
- Sian Bigora, Pharm.D., Chief Development Officer
  - Former VP of Regulatory Affairs at Mallinckrodt, Questcor Pharmaceuticals, AGI Therapeutics, ICON, GloboMax
  - Former Instructor of FDA Reviewers
- Helen Pentikis, Ph.D., Interim Chief Scientific Officer
  - Founder of Symbiomix Therapeutics, a venture backed, late stage company acquired by Lupin Pharmaceuticals
  - Former Head of Clinical Pharmacology at AkaRx; Global VP of PK-PD at ICON; VP of PK at GloboMax.
  - Fellow in PK and Clinical Pharmacology at the FDA
- Wendy Guy, Chief Administrative Officer

# Major Criteria for Selecting Pipeline Products for Development

Tens of Thousands of Drugs Evaluated Preclinically by Pharma and Biotech

Thousands of Drugs Evaluated Clinically (6,550 Industry Sponsored Studies in 2014)

Few Drugs FDA Approved (30 NME & 56 505(b)(2) Approvals in 2014) Processa
Pipeline
Selected from
Clinical Stage
Drugs

- ✓ Pharmacology Aligns with Pathophysiology
- ✓ Clinical POC Data Exists for Drug or Analog
- Minimal Risk in FDA Acceptance of IND and Development Program (Often Already Evaluated Clinically in Different Target Population; If CMC/Tox Work Required, Not Extensive)
- ✓ Products Requiring a NDA Program ≥ \$100M & ≥ 7 Yrs, Out-License 2-4 Years After Acquiring (After Dose Ranging, Before Pivotal Study)
- ✓ Products Requiring a NDA Program ≤ \$75M & ≤ 6 Yrs, Pivotal Completed in 3-4 Yrs, Possibly Develop to NDA
- ✓ <u>Attractive ROI</u> (e.g., In-Licensing, Development Cost, Timeline, rNPV)



# PCS499 Diverse Pharmacology Useful for Two Indications

### PCS499 has Multiple Pharmacological Targets and is the Analog of a Major Metabolite of an Approved Drug

- Modulates Immune Cells (e.g., Neutrophils) and Cytokines (e.g., TNFα)
- Effects on Blood Viscosity & Oxygenation, Platelet Aggregation
- Anti-Fibrotic Effect

### Previous Evaluation of PCS499 in Diabetic Nephropathy (Processa Not Pursuing This Indication)

- FDA Approved IND, Phase 1 and 2 Studies Complete, FDA Recommended a Higher Dose
- Safe in Humans and Ready to Be Administered to Patients with Other Conditions

#### **Processa Pipeline for PCS499 Includes Two Unmet Medical Need Conditions**

- Necrobiosis Lipoidica (NL)
- Radiation Therapy Adverse Effects in Oncology (RTAE)



# PCS499 For Treatment of Necrobiosis Lipoidica (NL) - No Approved Treatment

- Inflammatory Site Disorder With Pathophysiology Involving the Immune System and Blood Flow
- Skin Becomes Necrotic; 30% of Patients Have Painful Ulcerations
- Potential to Last for Month or Years
- Complications: Infections, Amputation, Squamous Cell Cancer
- No Current FDA Approved Treatment; Dermatologists Are Mainly Using Topical Steroids with Poor Long Term Response; Some Dermatologists Use Other Products with Mixed Results





# PCS499 For Treatment of Necrobiosis Lipoidica (NL) - No Approved Treatment

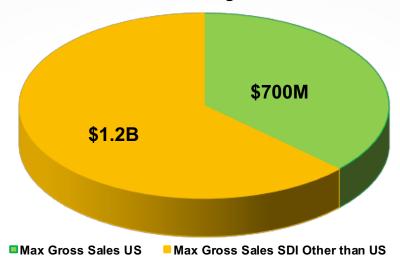
- Evidence of PCS499 Efficacy in Patients with NL
  - Diverse Pharmacology Targets Mixed Pathophysiological Changes Associated with NL
  - Some Dermatologists Use a Drug with Similar Pharmacology but Have Mixed Results (Dose Probably Too Low But Unable to Give Higher Doses Because of Adverse Events)
  - PCS499 and PCS499 Metabolite Profile Likely to Improve Efficacy/Safety over Drugs Presently Used
- <u>Target Population 200,000 500,000</u> Patients in High Sociodemographic Index (SDI) Countries (74,000-185,000 in US)
- Anticipate Orphan Drug Designation





### **Market Opportunity Based on Average Prevalence**

Necrobiosis Lipoidica (NL) \$1.9B Max Gross Sales Based on Average Prevalence in All SDI Countries



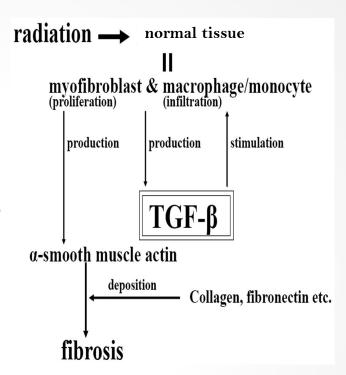
Target Population 200,000 – 500,000 Patients in
High Sociodemographic Index (SDI) Countries (74,000-185,000 in US)
(Range of Max Gross Sales Based on Prevalence Range:
\$1.1B - \$2.7B SDI Countries, \$400M – \$1.0B in US)

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



## PCS499 To Treat Radiation Therapy Adverse Effects (RTAE) in Head/Neck Cancer – No Approved Treatment

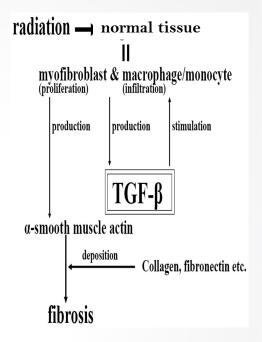
- Patients with Head/Neck Cancer Receiving Radiation Therapy (RT) Often Have Progressive Fibrotic Tissue Sclerosis and/or Xerostomia from Normal Tissue Being Exposed to Radiation
- Normal Tissue Continues to Change from Months Years after RT
- No FDA Approved Treatment; Radiation Oncologists Do Not Have a Standard of Care and Use a Variety of Drug Products to Treat Various Symptoms





## PCS499 To Treat Radiation Therapy Adverse Effects (RTAE) in Head/Neck Cancer – No Approved Treatment

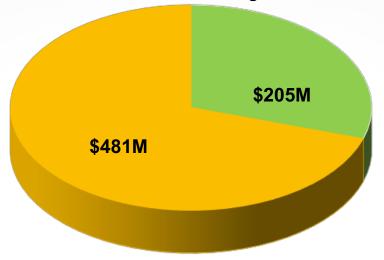
- Evidence of PCS499 Efficacy In Patients with RTAE
  - Diverse Pharmacology Targets Mixed Pathophysiological Changes Associated with RTAE
  - Some Radiation Oncologists Use a Drug with Similar Pharmacology but Have Mixed Results (Dose Probably Too Low But Unable to Give Higher Doses Because of Adverse Events)
  - PCS499 and PCS499 Metabolite Profile Likely to Improve Efficacy/Safety over Drugs Presently Used
- <u>Target Population 76,000 184,000</u> Patients in High Sociodemographic Index (SDI) Countries (26,000 – 52,000 in US)
- PCS499 Efficacy in Treating RTAE in Head/Neck Cancer Opens Up More Opportunities to Treat Other Types of Radiation Treated Cancer
- Anticipate Orphan Drug Designation





### Market Opportunity Based on Average Prevalence

Radiation Related Adverse Effects in Head/Neck Cancer \$686M Max Gross Sales Based on Average Prevalence in All SDI Countries



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

Target Population 76,000 – 184,000 Patients in

High Sociodemographic Index (SDI) Countries (26,000 – 52,000 in US)

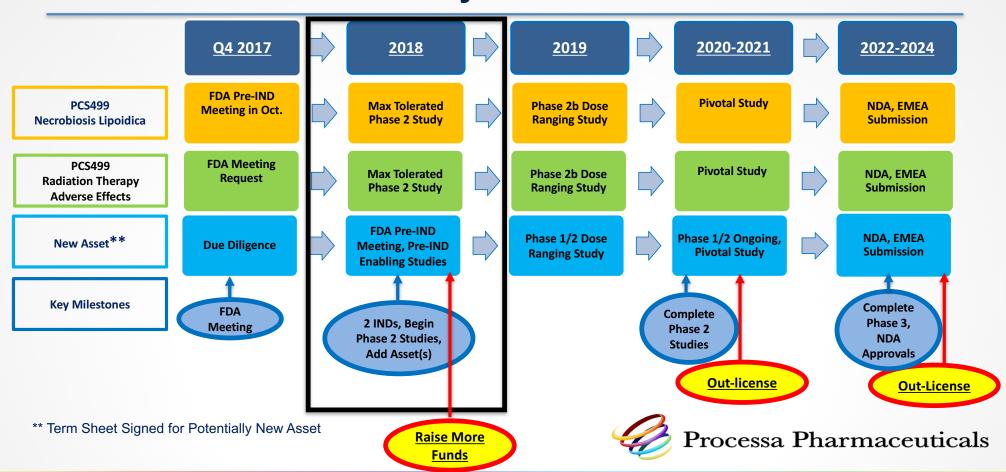
(Range of Max Gross Sales Based on Prevalence Range:

\$400M – \$972M SDI Countries, \$137M – \$274M in US)

Source: Siegel, et al. CA Cancer J Clin. 2017; Global Burden of Disease Cancer Collaboration. JAMA Oncol. 2017; Company



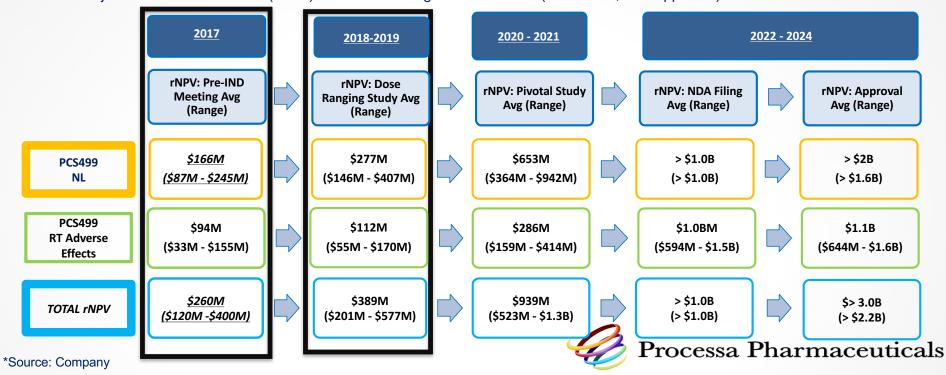
# Portfolio and Anticipated Pipeline Timeline with Key Milestones



### Processa rNPV for Only NL and RTAE by Clinical Milestone

#### Valuation Based on:

- Team Experience and Past Successes
- PCS499 in Clinical Stage of Development for 2 Indications
- Risk Adjusted Net Present Value (rNPV) of PCS499 in High SDI Countries (See Below, See Appendix)\*



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^Source: Company



### **Summary**

#### The Challenge:

To Maximize ROI by Efficiently Developing Drugs in High Unmet Medical Need Conditions

#### The Solution:

- Assemble a Team Experienced in Navigating Through Development and FDA Approval
- Follow Processa Pipeline Selection Criteria (e.g., Clinical or Pre-Clinical POC Data Exists, Minimal Risk in FDA Acceptance of IND and Development Program)
- Define and Achieve Value Added Milestones Including Out-licensing Products at Various Stages of Development to Further Increase Value and Obtain Non-Diluting Cash
- Raise Capital to Support Cost Effective Programs, Not Scientific Knowledge
- Increase Shareholder Value Through Development, Out-Licensing/Selling Assets, Merger and/or Acquisition

