Processa Pharmaceuticals

Corporate Presentation
May 2020

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Processa Pharmaceuticals

Processa Pharmaceuticals Overview

Corporate Facts (OTCQB: PCSA)

- 2017 reverse merger to form Processa
- $11.8 M total cash raised as private & public company
- > $40M invested in drugs prior to Processa in-licensing
- 2019 overhead (including salaries) < $2.5 M
- 5.5 million shares outstanding
- Nasdaq up-list and raise scheduled for June-July 2020

Competitive Advantage

- Processa staff have previously trained FDA reviewers and conducted FDA funded clinical research
- Our development team has a track record of more than 30 FDA approvals and more than 100 FDA meetings
- Our development team has worked together in other successful companies (e.g., Questcor Pharmaceuticals)

Pipeline Focus

- Acquiring & developing drugs for patients needing treatments to extend survival or improve quality of life
- Each drug must already have some clinical evidence of efficacy, thus increasing the probability of approval
- Each drug must have the potential for a high ROI

Value-Added Catalysts Over the Next 24 Months

- PCS499: Based on our FDA meeting, initiate and complete Phase 2B study in Ulcerative Necrobiosis Lipoidica (uNL)
- PCS11T: Complete non-clinical studies, obtain IND, and, if other clinical ready drugs are not in-licensed (see below), initiate Phase 1B cancer study
- PCS100: Conduct tox studies to better define therapeutic window
- Potential In-Licensing: Conduct Phase 1B study for cancer drug or Phase 2A for GI drug

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Our People Are a Competitive Advantage

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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
  - 30+ years of experience developing drugs
  - Trained FDA reviewers, conducted FDA sponsored research to support 4 FDA Guidances, helped in the writing of 3 FDA Guidances
  - FDA Advisory Committee involvement as Committee Member & Sponsor
  - Involved with more than 30 FDA approvals and more than 100 FDA meetings, the most recent approval was for Acthar which was a key value creation event for Questcor Pharmaceuticals
  - Agnostic to therapeutic area having worked with every FDA Drug Review Division

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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

Sian Bigora, Pharm.D., Chief Development Officer

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

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Our Leadership

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, Small Cap Focus, Numerous $3B+ Mkt Cap Winners
- Former E*Offering Co-Founding Partner Growing Company to 200 Employees and $80M Rev. During 1st Year; Former Principal at Robertson Stephens & Co.

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
- Board of Directors, Chairman of the Audit Committee of GSE Systems, Inc. (NASDAQ: 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 Strategy and Competitive Advantage

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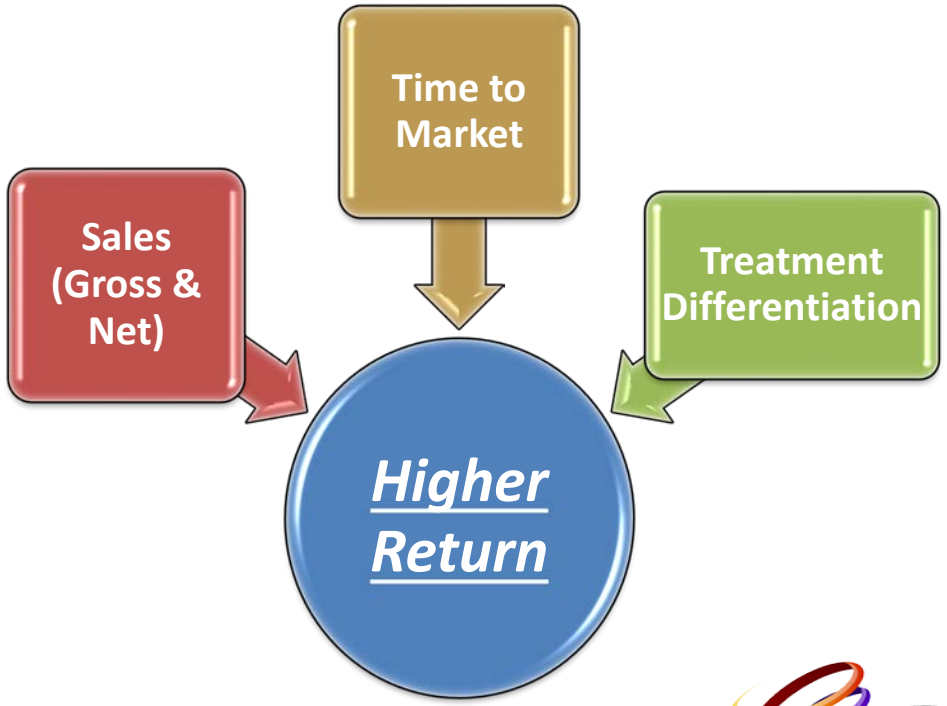
Our Strategy: Obtain Drugs with High Potential Value, Lower Risk of Failure during Development

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



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Our Strategy: Obtain Drugs with High Potential Value, Lower Risk of Failure during Development

Decrease risk of failure by selecting drugs with some clinical evidence of efficacy/safety, pharmacology-tox understood, & value-added catalysts in 1-4 years

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Competitive Advantage: Processa Approach to Obtaining Drug Approval

We Know The Way To The FDA

Over the Last 30+ Years, Our Team Has Refined a Regulatory Science Platform or Approach for the Development of Drugs for FDA Approval

- The Regulatory Science Platform is based on our experience teaching FDA reviewers, conducting research funded by FDA for FDA Guidances, writing FDA Guidances, developing drugs for FDA approval, and meeting with FDA as a colleague and as a sponsor
- R&D studies are conducted to provide the scientific foundation upon which FDA will make regulatory decisions, not for scientific knowledge
- Processa does not focus on one therapeutic area but has the knowledge and expertise to obtain drug approvals across therapeutic areas having successfully interacted with almost every FDA division

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Processa Unmet Medical Need Pipeline

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Processa Pipeline May 2020

	Pre-IND	Phase 1	Phase 2	Phase 3
PCS499: Ulcerative Necrobiosis Lipoidica			Phase 2B/3	
PCS11T: Small Cell Lung, Metastatic Colorectal, Pancreatic, or Ovarian Cancer	GLP Tox			
PCS100: Fibrotic Disease	GLP Tox			
Potential In-Licensed Drug Cancer or GI		Phase 1B or Phase 2A		

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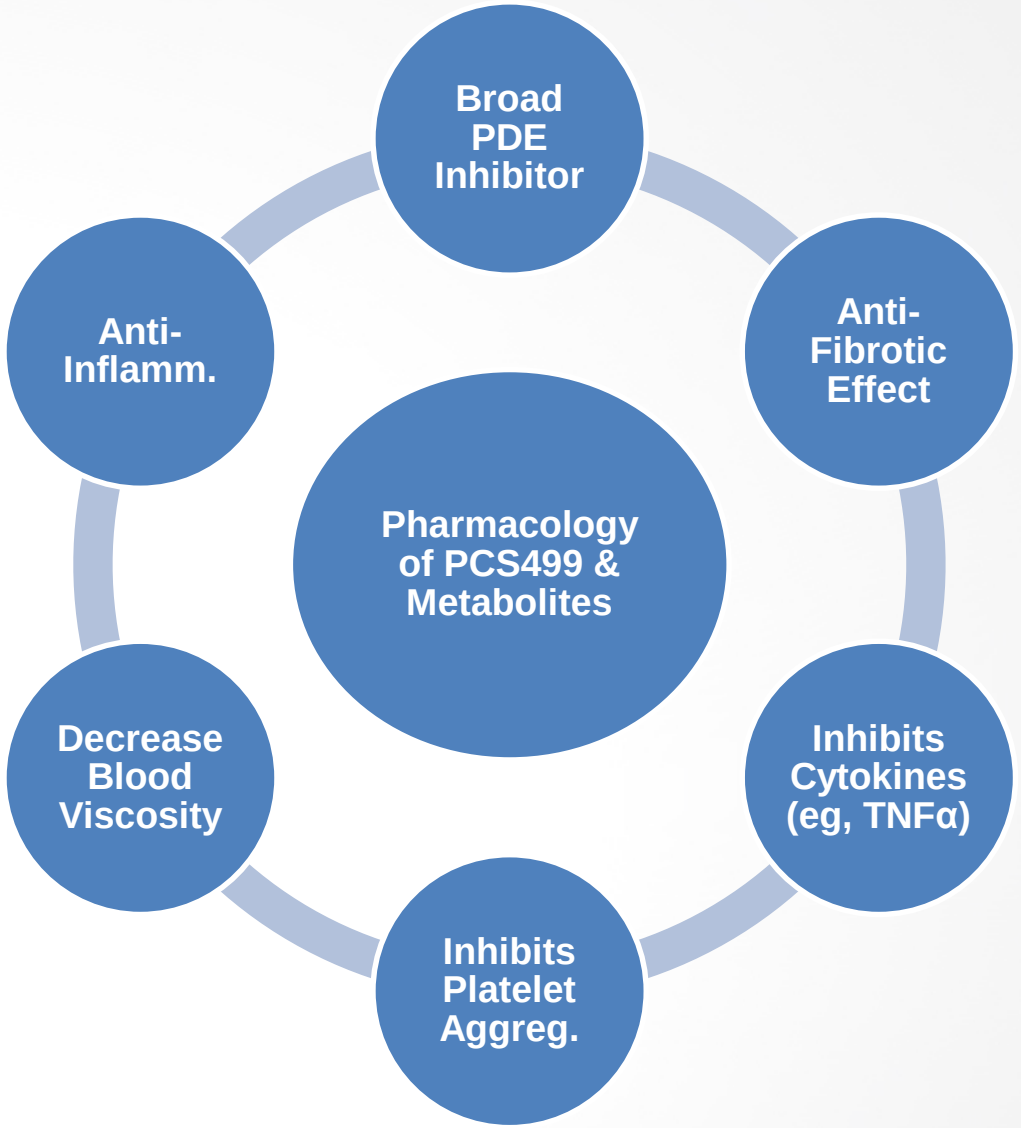
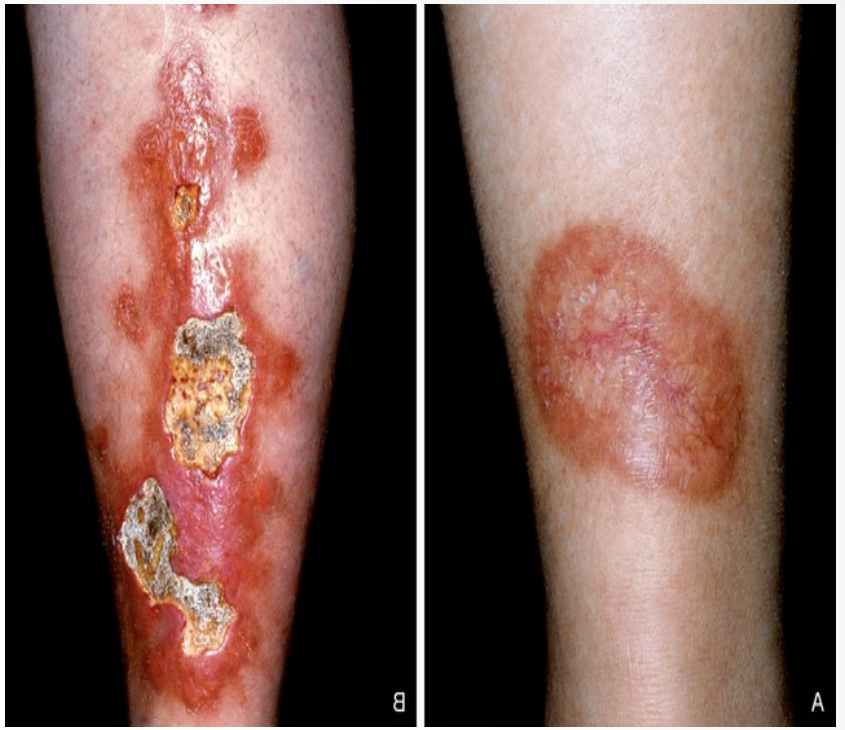
PCS499: Deuterated Analog of a Major Active Metabolite of FDA Approved Pentoxifylline (PTX)

- PCS499 metabolizes to same active moieties as PTX (including reversibly metabolized to PTX itself) but the metabolite profile is different after PCS499 administration than PTX (i.e., the % exposure to various active metabolites and administered drug is different)
- PCS499 and active metabolites have a diverse pharmacology profile
- Originally developed by Concert Pharmaceuticals in Diabetic Nephropathy, taken to an end of Phase 2 meeting



Patient Need: No Approved Treatment for Necrobiosis Lipoidica (NL)

- Occurs in women/men 20 – 60 y/o and NL can last for months to years
- Skin becomes necrotic with complications such as infections, amputation, squamous cell cancer
- **30% of NL patients have painful ulcers with ulcer closure occurring in < 13% of these patient 1-2 years after onset**
- No standard of care or FDA approved treatment; no other company developing a drug for NL
- Dermatologists mainly use topical steroids and other drugs with poor response
- Pentoxifylline (PTX) is not approved for NL but has been used off-label to close ulcers in a small percentage of patients who can tolerate the highest labelled dose of PTX



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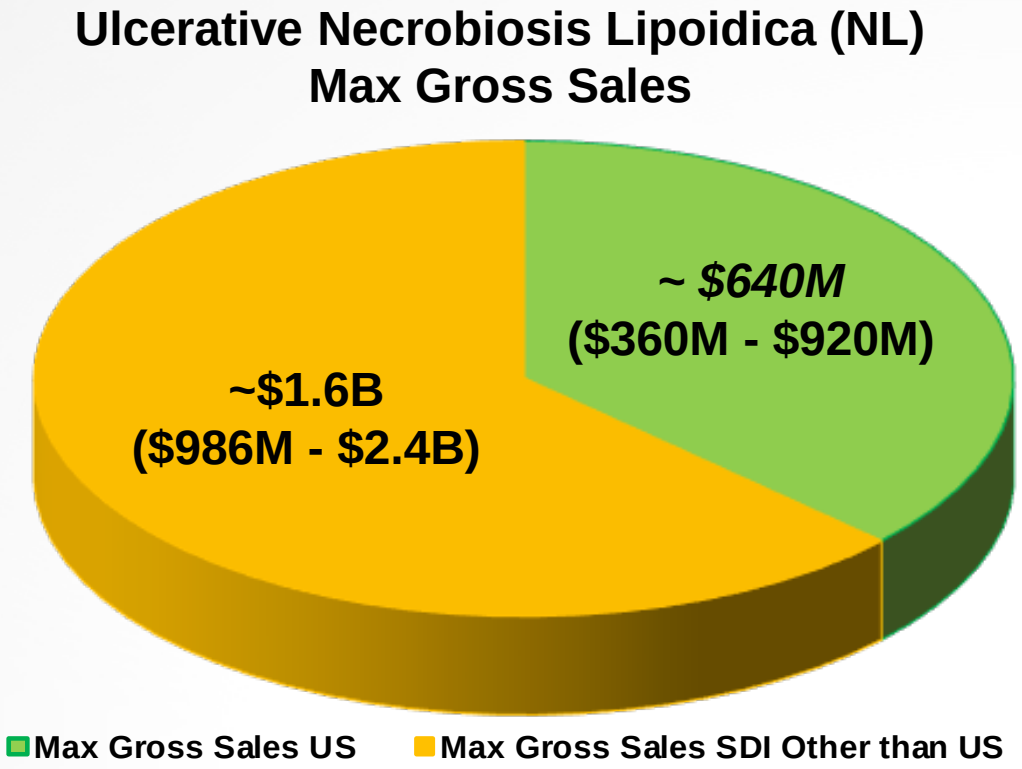
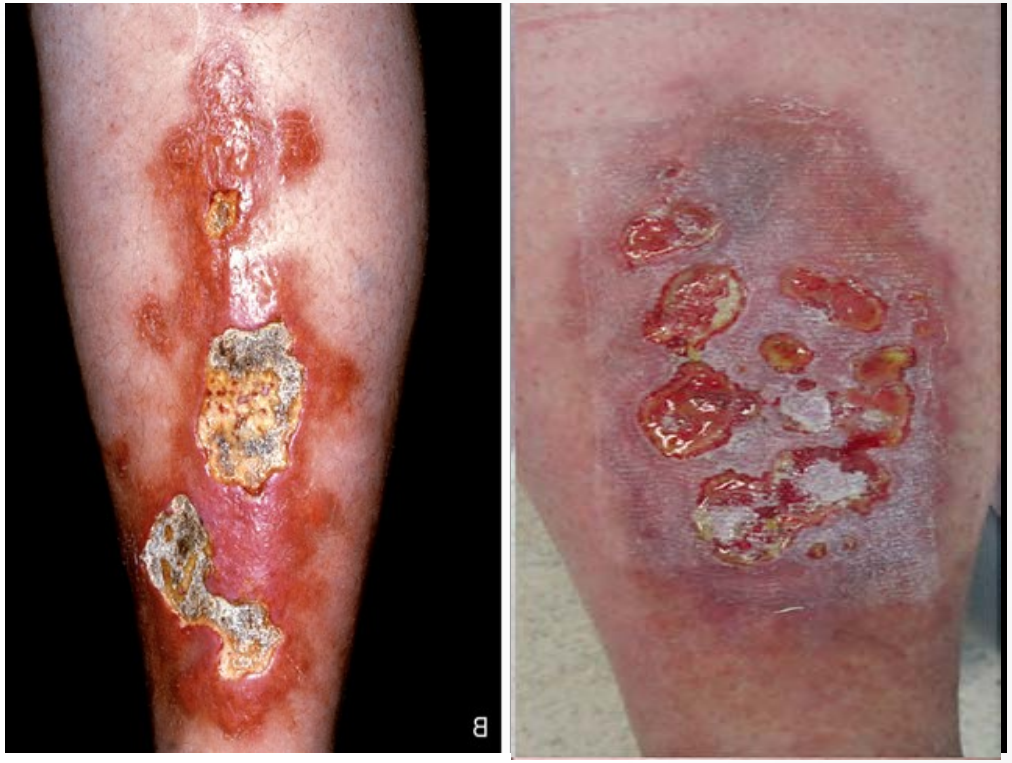
High Value: Ulcerative NL Market Opportunity
Max Annual Gross Sales > *$1.0 B (@$30,000/Patient/Year)*





- 22,200 – 55,500 Patients in US
- 60,000 – 150,000 Patients in High Sociodemographic Index (SDI) Countries
- 60,000 – 150,000 Patients in People's Republic of China

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

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High Value: Faster Time to Market

- Development of PCS499 can be expedited given many of the NDA required chemistry, manufacturing, toxicology and Phase 1 studies have already been conducted by Concert Pharmaceuticals prior to Processa acquiring the drug.
- In a March 2020 meeting, FDA stated that, given NL is a serious orphan condition with no approved treatment, PCS499 approval would be possible with one pivotal trial if the statistical significance of the one trial has a $p << 0.05$.
  - Received Orphan Designation (7 years of Market Exclusivity upon approval)

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High Value: Differentiation from other Treatments

- Since there is no standard of care for NL because appears to work, a new efficacious-safe drug would easily differentiate itself from the unsuccessful treatments used today
- After PCS499 administration, the same active moieties exist systemically as in PTX but the amounts of key active moieties after the same dose of PCS499 and PTX are approximately 2 times greater after PCS499 administration
- Although PCS499 has greater plasma levels of some of the key active moieties, PCS499 is better tolerated than PTX
  - In pre-clinical toxicology studies, the maximum tolerated dose for PCS499 >> PTX
  - In Phase 1 and Phase 2 studies, PCS499 is tolerated better than PTX
  - In NL patients 1.8 gm/day of PCS499 administered orally was well tolerated while PTX is not well tolerated at 1.2 gm/day, the max FDA recommended dose

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Lower Risk: Clinical Evidence Exists Supporting the Use of PTX and PCS499 in NL

- PTX is used OFF-LABEL and response can start after 1 month with significant improvement within 1-9 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 while some patients cannot tolerate the highest dose of PTX
- Increasing PTX dose beyond 1.2 gm/day to achieve higher response rate results in dose limiting side effects (nausea, vomiting, headaches)
- The Phase 2 PCS499 NL study demonstrated that 1.8 gm/day is well tolerated and completely closed the ulcers in the only two patients who had severe ulcerative NL
  - Closing of ulcers is also observed clinically in some patients who can tolerate PTX
  - Ulcer closure occurs in < 13% of non-treated ulcerated patients 1-2 years after onset

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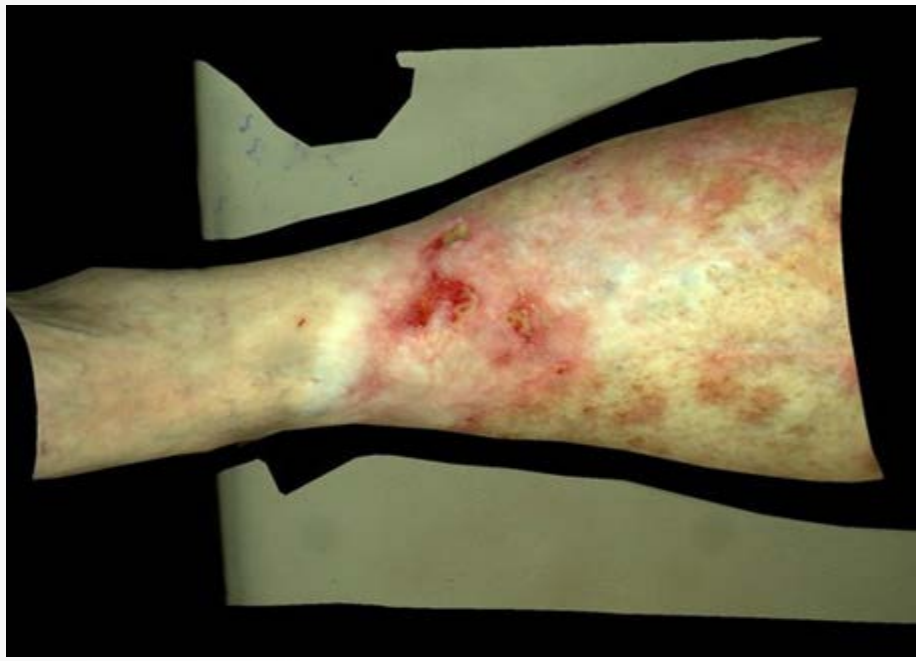
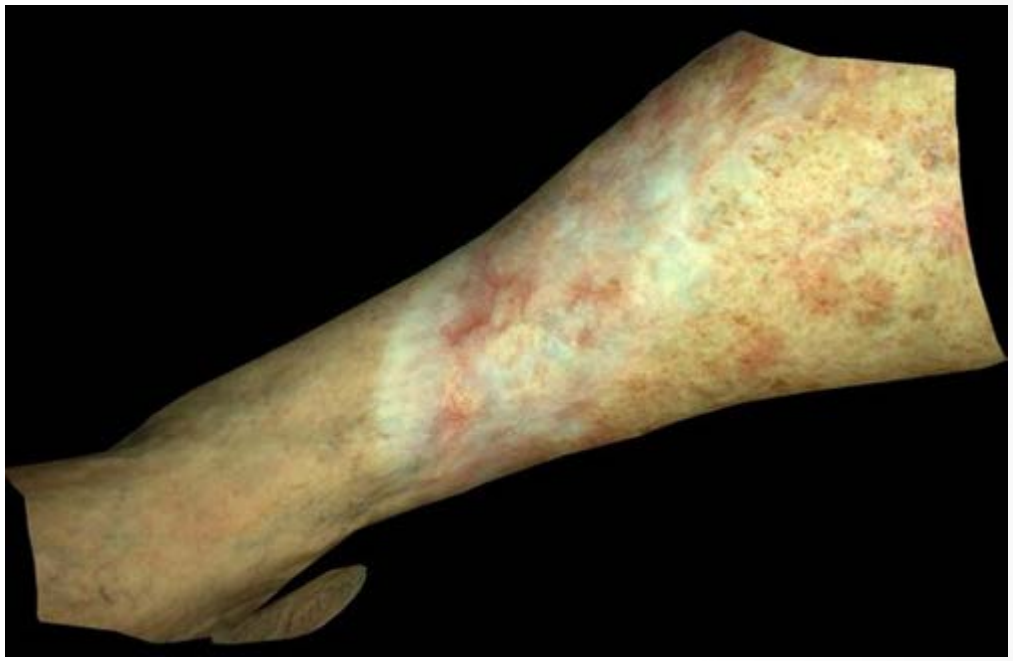
Status of Safety/Tolerability PCS499 NL Study

- PCS499 well tolerated at 1.8 gm/d and efficacy seen in the two NL patients with open ulcers; the ulcers in these severe NL patients completely closed
- Ulcers occurring from physical contact during the study were also completely closed



Baseline



Month 5 – Complete Closure

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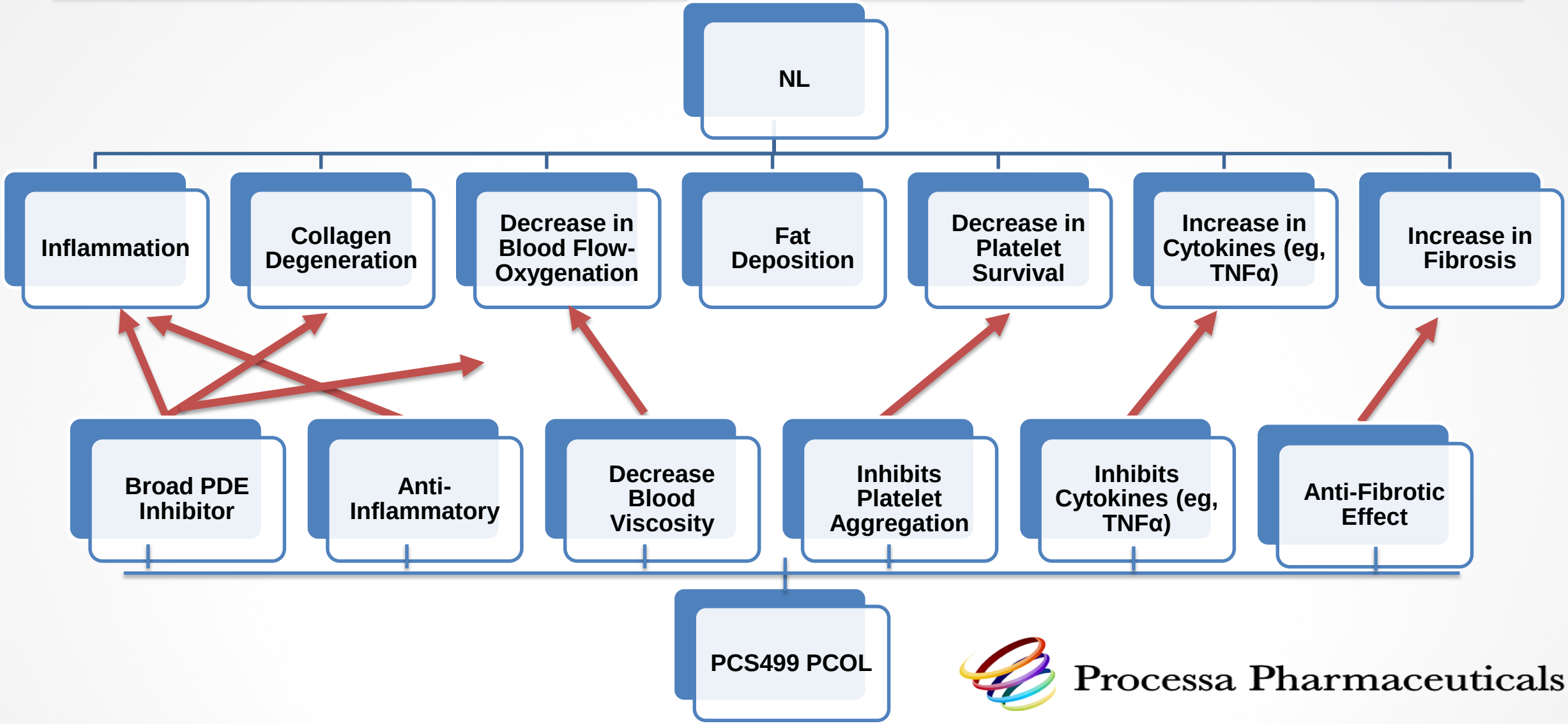
PCS499 Pharmacology Affects the Many Pathophysiological Changes Occurring in NL



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PCS499 Catalysts

	2020	2021	2022	2023 - 2026
Phase 2B/3 Study		**Phase 2B/3**		**2024-2025 NDA**
Complete CMC, Non-Clinical, Phase 1 NDA Requirements			**Other NDA Requirements**	

- FDA agreed next study a Phase 2B or 3 study with only difference being the number of patients
- Preparing Phase 2B/3 protocol for U.S./E.U. and recruiting lead investigators
- Planning to conduct a Phase 2B study if total raise is $20M
- Enroll first patient in 1H2021
  - If Phase 2B, study to be completed in 2022 (~ 18 months after enrolment of first patient)
  - If Phase 3, study to be completed in 2023 (~ 30 months)

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PCS11T: Next Generation Irinotecan Cancer Drug

- A pro-drug of SN-38, the active molecule formed from Irinotecan
  - SN-38 is connected to a molecule that interacts with the cell membrane; SN-38 preferentially accumulates in the membrane of tumor cells and the tumor core more than normal cells
- PCS11T development will target cancers where Irinotecan is widely used (eg, small cell lung, metastatic colorectal, pancreatic)
- Irinotecan sales prior to generics was > $1B
- Pre-clinical studies
  - PCS11T has an efficacy advantage over Irinotecan as demonstrated by tumor eradication at much lower doses than Irinotecan across various tumor xenograft models
  - GMP CMC studies and GLP tox studies need to be completed for IND
- Pre-IND FDA meeting completed with agreement on IND requirements

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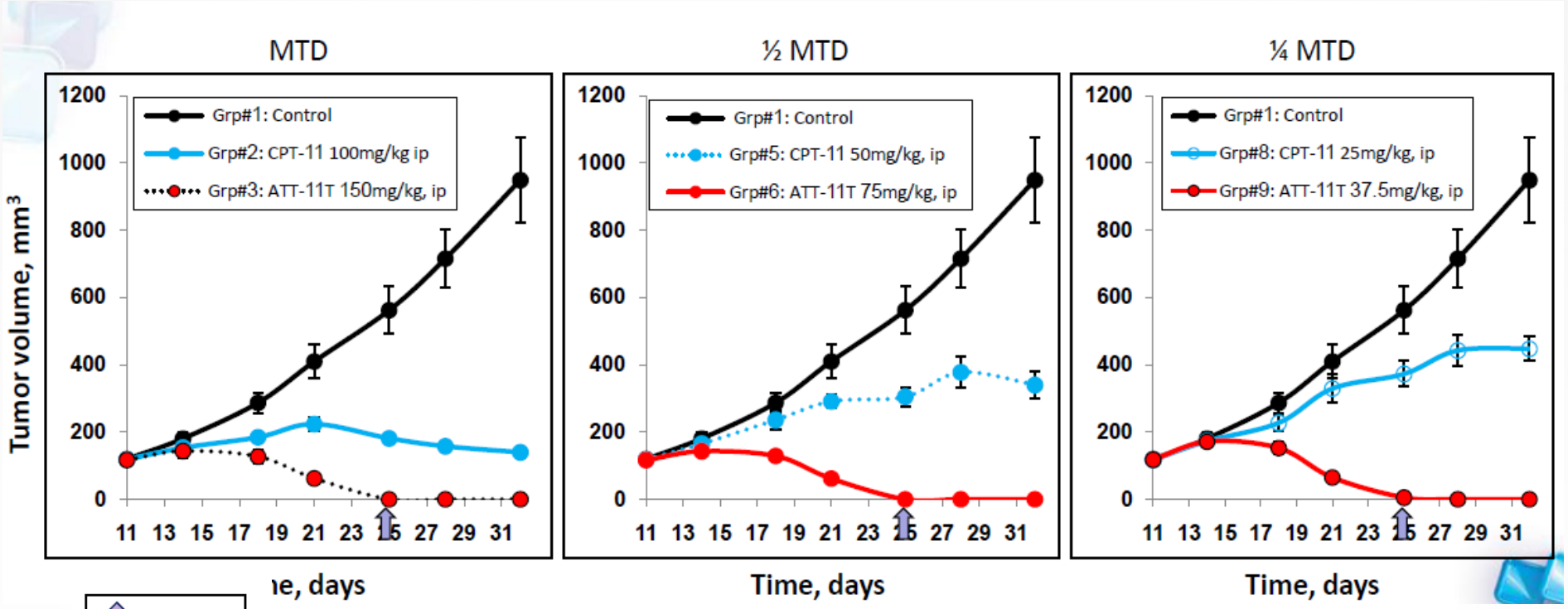
Efficacy Maintained at Lower Doses of PCS11T When Compared to Irinotecan in SW620 Colorectal Cancer Xenograft Model



At MTD
Tumor Growth Inhibition
100% ATT11-T
100% CPT-11

At ½ MTD
Tumor Growth Inhibition
100% ATT11-T
64% CPT-11

At ¼ MTD
Tumor Growth Inhibition
100% ATT11-T
53% CPT-11

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Efficacy Studies in Tumor-Bearing Mice

Tumor	Compound	Treatment	Number of Mice	Anti-tumor Effect (%TGI vs. Control)
H-69: Small Cell Lung Carcinoma	ATT-11T	80mg/kg, q2wx2	9	93
	Irinotecan	72mg/kg, q2wx2	9	67
SW620: Colorectal Carcinoma	ATT-11T	40mg/kg, qwx3	10	100
	Irinotecan	36mg/kg, qwx3	10	44
MiaPaCa: Pancreatic Carcinoma	ATT-11T	40mg/kg, qwx3	8	86
	Irinotecan	36mg/kg, qwx3	8	42
H-82: Small Cell Lung Carcinoma	ATT-11T	20mg/kg, qwx3	9	80
	Irinotecan	18mg/kg, qwx3	8	57
OVCAR-3: Ovarian Carcinoma	ATT-11T	20mg/kg, qwx3	10	98
	Irinotecan	18mg/kg, qwx3	10	77
HCT-116: Colorectal Carcinoma	ATT-11T	10mg/kg, qwx3	8	79
	Irinotecan	9mg/kg, qwx3	8	66
A375: Melanoma	ATT-11T	5mg/kg, q3dx9	10	100
	Irinotecan	75mg/kg, qwx3	9	91

At equimolar doses, PCS11T (formerly ATT-11T) demonstrated superior efficacy across a variety of cancers

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PCS11T Catalysts

	2020	2021	2022	2023 - 2026
IND Enabling Studies (GMP CMC, GLP Tox)		IND Enabling Studies		
IND Submission		IND		
Phase 1B Study			Phase 1B Study	

- FDA Pre-IND meeting completed with agreement on IND requirements
- Phase 1B IND to be submitted December 2021
- If other clinical ready drugs are not in-licensed, initiate Phase 1B study in 1H 2022

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PCS100 Anti-fibrotic and Anti-inflammatory Drug

- Affects collagen expression and TGF-β pathway
- History
  - Incomplete tox package but FDA cleared IND for Duchenne Muscular Dystrophy (DMD)
  - Efficacy observed in pediatric DMD patients; previous company mismanaged DMD study resulting in a Serious Adverse Event; placed on clinical hold, later removed off clinical hold
- Potential Indications (Processa plans to first develop PCS100 in an adult indication, then move back to pediatric indications after more is known about therapeutic window)
  - Idiopathic Pulmonary Fibrosis, Scleroderma, other fibrotic related conditions in adults
  - DMD or other fibrotic related conditions in pediatric patients
- Plan to meet with FDA in 2021 to define the development in an adult fibrotic condition where there is existing clinical evidence that a drug with ant-fibrotic properties would be efficacious

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Catalysts for PCS100 and Potential In-Licensed Drug

	2020	2021	2022	2023 - 2026
PCS100 **Fibrotic Conditions,** **GLP Tox Needed for IND**		**GLP Tox, IND, Phase 1**		
Potential In-Licensed Drug **Cancer or GI**		**Phase 1B or Phase 2A Study**		

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Financial Metrics
&
Catalysts Over the Next 24 Months

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Processa Financial Overview

OTCQB (5/22/20)	PCSA - $6.90/share
Market Cap (5/22/20)	$38M
Shares Outstanding	5.5 M Shares
Prior Cash Investment in Processa	$9.8 M as OTCQB Processa ($11.8 M total as Processa + Predecessor Company Promet)
Present Cash Balance (5/22/20)	$369K
Convertible Line-of-Credit	$1.4 M ($1.2 M still available)
PCSA Insider Ownership %	55%
Nasdaq Listing	Presently working on June-July 2020 Nasdaq listing and raising funds to support catalysts over the next 24 months

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Value-Added Catalysts Occurring Over the Next 24 Months By Drug

- Obtain Nasdaq listing, raise funds to support the catalysts (3Q2020)
- PCS499
  - Initiate Phase 2B study (1Q2021); Complete study within 18 months (4Q2022)
  - Out-license PCS499 for development and commercialization outside the U.S.
- PCS11T
  - Complete GMP CMC tasks, GLP tox studies; obtain IND (4Q2021)
  - If other clinical ready drugs not in-licensed (see below), initiate Phase 1B study (1Q2022)
- PCS100
  - Pre-IND meeting with FDA on first IND indication for adults
  - Depending on FDA meeting, complete GLP IND Tox and submit Phase 1 IND (2Q2022)
- Potential in-licensed drugs
  - Complete Phase 1B study for cancer drug or Phase 2A study for GI drug (1Q2021 – 4Q2022)

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Value-Added Catalysts Occurring Over the Next 24 Months by Date

- 2020
  - Obtain Nasdaq listing, raise funds to support the catalysts (3Q2020)
- 2021
  - PCS499: initiate Phase 2B or Phase 3 study (1Q2021)
  - Potential In-Licensed Drugs: Initiate Phase 1B or Phase 2A (1Q2021)
  - PCS11T: Obtain IND (4Q2021)
- 2022
  - PCS11T: If Potential In-Licensed Drugs not acquired, initiate Phase 1B study (1Q2022)
  - PCS100: Obtain IND (2Q2022)
  - PCS499: Complete study within 18 months (4Q2022)
  - Potential In-Licensed Drugs: Complete Phase 1B or Phase 2A (4Q2022)

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2020 – 2022 Use of Proceeds ($20M Net)

- ***No Additional Drugs In-Licensed***
  - $5 M SG&A
  - $5 M PCS499 Phase 2B study (completed n 2022)
  - $3 M PCS11T (IND enabling studies)
  - **$7 M PCS11T (Phase 1B study initiated in 2022, completed in 2023-2024)
  - Shifting $1M of proceeds to PCS100 dependent on FDA pre-IND meeting
- ***Additional Drug In-Licensed***
  - $5 M SG&A
  - $5 M PCS499 Phase 2B study (completed in 2022)
  - $3 M PCS11T (IND enabling studies)
  - **$7 M In-Licensed Drug (Phase 1B or 2A completed in 2022)
  - Shifting $1M of proceeds to PCS100 dependent on FDA pre-IND meeting

** Difference between the two Use of Proceeds scenarios

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Summary

Focused on Acquiring and Developing Drug Products for Patients Needing Treatments to Extend Survival and/or Significantly Improve Quality of Life

- Building a pipeline of high value drugs for patients with unmet medical need conditions
- Experienced management, development team with a track record of successful FDA approvals and value creation
- Present pipeline of drugs with addressable markets of > $1 B each
  - Clinical evidence of efficacy for drugs decreasing the risks associated with development
  - Clinical diversity of each drug allows for other indications to be added in the future
  - One to two additional drug acquisitions for the pipeline are being negotiated
- Overhead burn rate was less than $2.5 M in 2019
- In June-July 2020 up-list to Nasdaq and complete capital raise of ≥ $20 million net
- Several value-added catalysts should be achieved over the next 24 months

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