



Processa Pharmaceuticals

**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.

CEO

June 2018

LD**ICRO**

8TH INVITATIONAL

JUNE 4TH - 6TH, 2018 | BEL AIR, CA

Disclaimer: Forward Looking Statements

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Processa Pharmaceuticals (OTC:PCSA) Background

- **Clinical Stage Drug Development** Private Company (Promet Therapeutics, LLC) Formed in Dec 2015; Reverse Merger with a Dormant Non-Biotech OTC Company in Oct 2017
- Mission is to Develop Drugs to Treat Patients with High **Unmet Medical Need Conditions**
- **Decrease the Risk of Failure** by Selecting Drugs in the Portfolio that must
 - Have Some Evidence of Clinical Benefit prior to Being Acquired
 - Be able to Achieve a Major Milestone in 2-4 years
- Presently Negotiating to Acquire Drugs to **Expand the Processa Portfolio** in 2018 – 2019
- **Experienced Team** of Drug Developers, Pharma Executives, Biotech Investors that Collaborate and Negotiate with FDA Using a **Regulatory Science Approach**



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Key Milestones and Achievements

- ✓ Reverse Merged into Dormant Public OTC Company in Oct 2017 followed by 1:7 Reverse Split
- ✓ Raised \$4.27M as Promet in 2015 & \$6.88M in Private Placements, Including an Ongoing PIPE
- ✓ Met with the FDA on the Development of PCS499 for Necrobiosis Lipoidica (Billion Dollar Market) to Ensure Development ROI and Risk was Acceptable
- ✓ Licensed in PCS499 from Concert Pharmaceuticals (Discontinued in 2016 Even Though FDA Green Light for Phase 3 - Lower ROI and More Risky Indication), in Exchange for PCSA Equity
- ✓ Transferred Final Product Manufacturing to New Site (Old site Closed); Confirmed PK Profile & Higher Dose than Concert Used Clinically is Safe in Healthy Volunteers (FDA Agreed Dose)
- ✓ Additional Staff Being Hired to Meet our Drug Development and Corporate Needs



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Processa Pharmaceuticals Financial Overview

Symbol-Share Price (5/30/18)	PCSA - \$3.25
Market Cap (5/30/18)	\$115M
Shares Outstanding	35.3M Prior to Private Placements & ~38.8M Post Private Placements
Private Placements	\$6.88M (Last Closing on June 29, 2018)
Cash (5/30/18)	\$5.4M (Includes \$6.88M from Private Placements)
Insider Ownership %	> 70%
Headquarters	Hanover, MD



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Successful Drug Development



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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 Market Cap in 2007 to \$5.6B in 2014 when acquired by Mallinckrodt
- **Development Team has Worked Together in other Companies and has a Proven Record of Success**
 - 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



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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

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

Chief Financial Officer

- Responsibilities Divided Amongst a Number of Part-Time Individuals who are Former CFOs in Private and Public Companies



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Necrobiosis Lipoidica (NL)

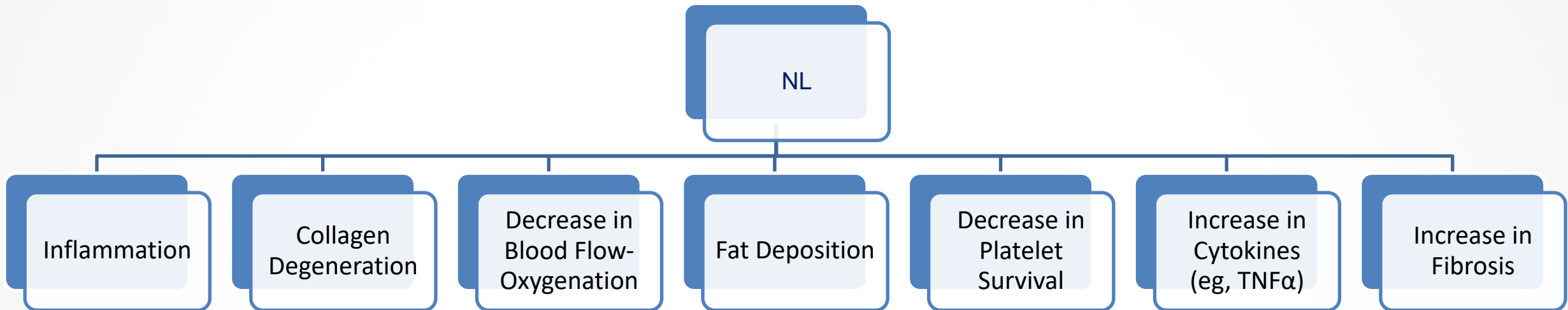
74,000-185,000 in US & 200,000 – 500,000 Worldwide
(Includes Non-Diabetic Patients & 0.3% of All Diabetic Patients)



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Necrobiosis Lipoidica (NL)

- Multi-faceted Disorder Affecting the Skin and the Tissue under the Skin



Necrobiosis Lipoidica (NL) - No Approved Treatment

- Occurs in Women/Men 20 – 60 y/o; Potential to Last for Month or Years;
- Skin Becomes Necrotic; 30% of Patients Have Painful Ulcerations; Complications - Infections, Amputation, Squamous Cell Cancer
- No Current FDA Approved Treatment, No Known Biotech or Pharma Companies Developing a Drug for NL
 - Dermatologists Mainly Use Topical Steroids and Other Drugs with Poor Response and Undesired Toxicity Profiles
 - Pentoxifylline (PTX) is Used Off-Label: Response can Start after 1 Month with Significant Improvement 3-12 Months (Case Studies)
 - PTX Does Not Have Widespread Use: Small Percentage of Patients Respond at the FDA Labelled Dose of PTX and Increasing the Dose Results in PTX Dose Limiting Toxicities



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PCS499 Diverse Pharmacology Useful for Multiple Indications

PCS499 is the Deuterated Form of the Major Metabolite of Pentoxifylline (PTX)

- Pharmacology Slightly Different from PTX
- Greater Exposure to PCS499 after PCS499 Administered than the Non-Deuterated Form of PCS499 after PTX Administered

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

- Safe in Humans and Ready to Be Administered to Patients with Other Conditions
- FDA Approved IND, Phase 1 and 2 Studies Complete, at End of Phase 2 Meeting FDA Would Allow Concert to Move into Phase 3
- FDA Strongly Recommended a Higher Dose and Required Different Endpoints for Phase 3 Study



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PCS499 Diverse Pharmacology Useful for Multiple Indications

Evidence of PCS499 Efficacy in Patients with Necrobiosis Lipoidica (NL)

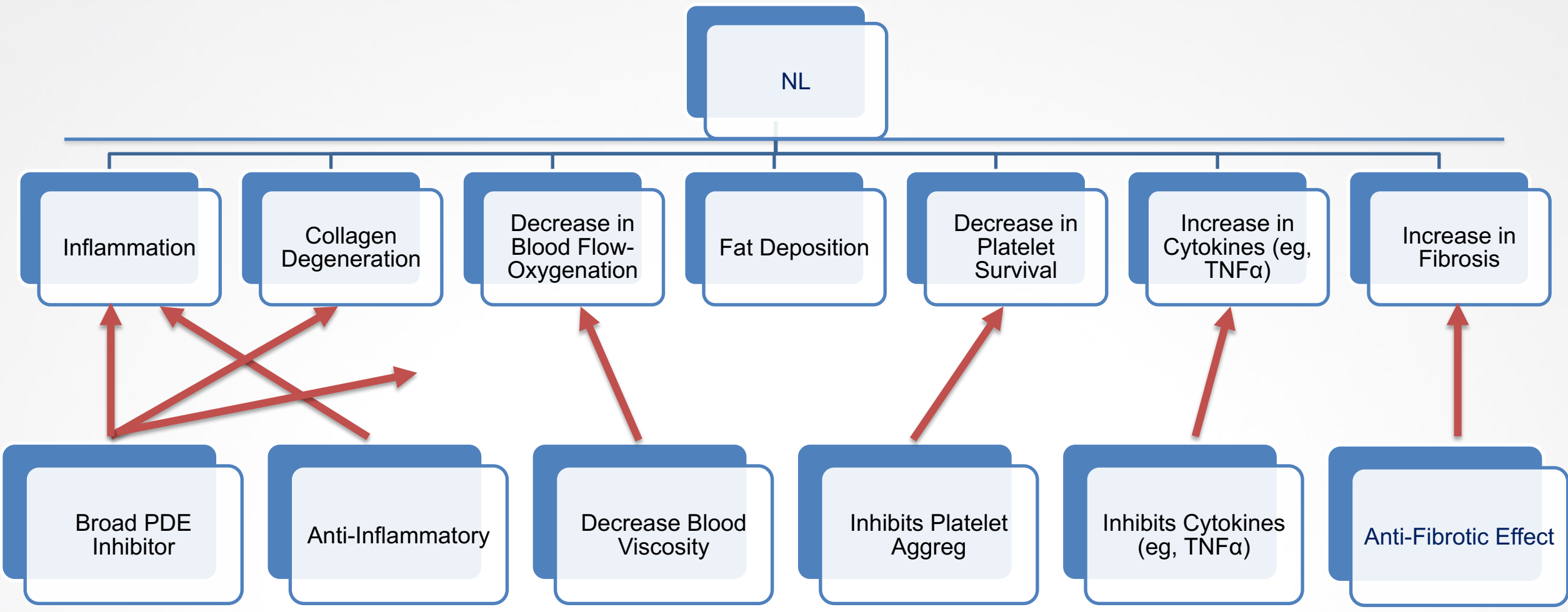
- PTX Case Studies and Experience of NL KOLs
- PCS499 Exposure After PCS499 Administration Significantly Different than Non-Deuterated Metabolite Exposure after PTX Administration
- PCS499 Pharmacology is a Little Different than PTX and Probably More Beneficial
- PCS499 Diverse Pharmacology Matches the Mixed Pathophysiological Changes of NL

PCS499 has Multiple Pharmacological Targets

- Broad Spectrum Phosphodiesterase (PDE) Inhibitor
- Modulates Immune Cells (e.g., Neutrophils) and Cytokines (e.g., TNF α)
- Effects Blood Viscosity & Oxygenation, Platelet Aggregation
- Anti-Fibrotic Effect



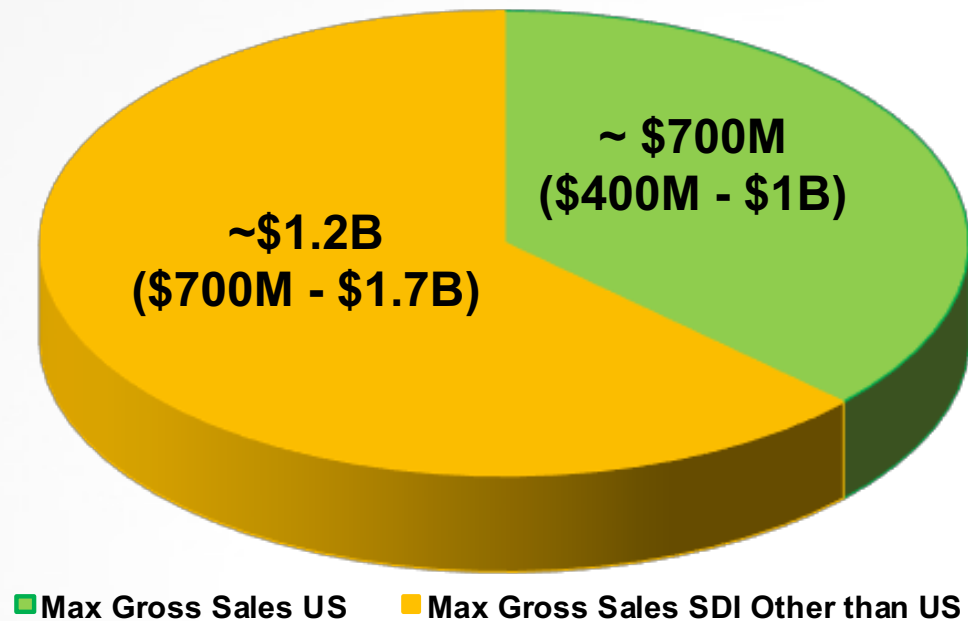
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Market Opportunity

Maximum Gross Annual Sales Worldwide \$1.2B - \$2.7B

Necrobiosis Lipoidica (NL) Max Gross Sales



- 200,000 – 500,000 Patients Worldwide
- 74,000-185,000 in US
- Max Gross Annual Sales Based on Prevalence Range:
 - \$1.1B - \$2.7B Worldwide
 - \$400M – \$1.0B in US

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



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Negotiations Underway for Additional Assets

- **Presently Negotiating with 3 Companies to License/Develop Drugs in the Oncology, Cardiovascular and CNS Space**
- **Two Types of Agreements Being Negotiated**
 - Option to Purchase or In-License Drug
 - Development Team Collaboration (DTC) Partnership where the Drug Ownership Remains in the Present Company but Development Performed by Processa in Exchange for Expenses at Cost, Milestone Payments and Royalties.



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Plan and Timeline

	2H2018	1H2019	2H2019	2020 - 2022
PCS499 NL	<ul style="list-style-type: none"> • Submit IND • Begin Phase 2 Max Dose Safety Study, Prelim Eff 	<ul style="list-style-type: none"> • Readout on Max Dose Acceptable to Patients, FDA 	<ul style="list-style-type: none"> • Begin Phase 2b/3 Pivotal • Begin Last Phase 1 & Tox Studies 	<ul style="list-style-type: none"> • Phase 2b/3 Readout; if FDA Acceptable, Single Pivotal Study • NDA Submission in NL
Portfolio	<ul style="list-style-type: none"> • Finalize Options to Acquire New Assets 	<ul style="list-style-type: none"> • Meet with FDA on New Assets to Evaluate ROI/Timeline 	<ul style="list-style-type: none"> • Exercise Options on New Assets 	<ul style="list-style-type: none"> • Develop All Drugs in Portfolio
Corp.	<ul style="list-style-type: none"> • Complete Requirements for NASDAQ/NYSE Uplist 	<ul style="list-style-type: none"> • Uplist to NASDAQ or NYSE • Raise \$15-40M 	<ul style="list-style-type: none"> • Possible Out-License Drug(s) in Portfolio 	<ul style="list-style-type: none"> • Possible Out-License Drug(s) in Portfolio



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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 Evidence of Efficacy Exists, Minimal Risk in FDA Acceptance of IND and Development Program)
- Raise Capital to Support Cost Effective Regulatory Science, Not Scientific Knowledge
- Develop our New Development Team Collaboration (DTC) Business Model to Increase Value and Obtain Non-Diluting Cash
- Define and Achieve Value Added Milestones to Increase Likelihood of Out-Licensing or Selling Assets
- Increase Shareholder Value Through Development, Out-Licensing/Selling Assets, Merger and/or Acquisition



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