Citius Pharmaceuticals, Inc.

Corporate Presentation

Winter 2020-21

NASDAQ: CTXR

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Company Overview

Four Active Programs with a Late Stage Lead Asset	Mino-Lok in late Phase 3; favorable review received for Futility Analysis by Data Monitoring Committee (12/2019); favorable review for safety and efficacy analysis in September (2020).
Large Market Needs	CRBSI market estimated to be **>$1.8 B** worldwide; ARDS market large with no approved therapies; TE infection prevention estimated at **>$0.4 B** worldwide; Rx hemorrhoid market estimated at **>$2.0 B** in US.
Expert Team to Execute	Management has history of >$1B in pharma M&A; Scientific Advisors are key KOL's in infectious disease, breast surgery, pulmonology (ARDS)
Management Commitment	Management / Founders have invested $26.5 million into the company Have persevered with clinical research in the Covid-19 pandemic

Olympic Motto: **"Citius, Altius, Fortius"** ***(Faster**, Higher, Stronger)*

Management

Leonard Mazur, Director and Executive Chairman

- Founder/co-founder of: Genesis, Triax, Akrimax, and others

Myron Holubiak, Director, CEO and President

- Former President of Roche Laboratories, Inc.

Jaime Bartushak, EVP, Chief Financial Officer

- Over 20 years experience in corporate finance, M&A, and strategic planning

Myron Czuczman, M.D., EVP, Chief Medical Officer

- Recent Therapeutic Area Head and Vice President of the Clinical Research and Development Global Lymphoma/CLL Program at Celgene
- Former Chief, Lymphoma/Myeloma service at Roswell Park Comprehensive Cancer Center in Buffalo
- Has published more than 180 peer-reviewed journal articles

Gary Talarico, EVP, Operations

- Has led commercial activities for many corporate expansions and start-ups, including Reliant Pharma and Ventiv Health

Alan Lader, Ph.D, VP, Clinical Operations

- Over 25 years of experience in medical research, former Instructor in Medicine at Harvard Medical School and Brigham and Women's Hospital

Andrew Scott, VP, Business Development

- 20 years of transactional experience in strategic planning, product identification, asset acquisition, and capital markets communication

Key Scientific/Medical Advisors (ID and CA)

Isaam Raad, M.D

- Chair of MD Anderson Cancer Center's Dept. of Infectious Diseases
- Author of the underlying patents for Mino-Lok®
- Dr. Raad's innovations have been endorsed at the highest level (Category 1A) by the Center for Disease Control (CDC)

Mark Rupp, M.D.

- Professor and Chief of the Division of Infectious Diseases in the Dept. of Internal Medicine at the U. of Nebraska Medical Center
- Past-President of SHEA and Past-President of ASM Division L
- Has served as consultant to FDA, CDC, NIH, and VA

Leonard A. Mermel, D.O.

- Technical Expert Panel Member of Medicare Patient Safety Monitoring System, US Dept. of Health & Human Services
- Has co-authored US guidelines dealing with prevention and management of intravascular catheter infections

Jesse Selber, M.D.

- Director of Clinical Research and an Associate Professor in the Department of Plastic Surgery at the University of Texas MD Anderson Cancer Center
- Dr. Selber is an microvascular reconstructive surgeon, whose research involves head and neck reconstruction, breast reconstruction, microsurgery, abdominal wall reconstruction, microsurgical training, robotic-assisted reconstructive surgery, and other areas

George Viola, M.D.

- Associate Professor of Department of Infectious Diseases, Infection Control and Employee Health, and Division of Internal Medicine at The University of Texas MD Anderson Cancer Center
- Associate Professor, Department of Infectious Diseases, Division of Internal Medicine, Baylor College of Medicine

Key Cellular Therapy Advisors

Michael A. Matthay, MD

- Senior Associate at the Cardiovascular Research Institute, and Associate Director of the Critical Care Medicine & Professor of Medicine and Anesthesia at the University of California at San Francisco (UCSF)
- Research focused on the pathogenesis and resolution of the acute respiratory distress syndrome (ARDS) focused on the biology and potential clinical use of allogeneic bone marrow derived mesenchymal stromal cells (MSCs) for ARDS
- Lead investigator “Mesenchymal Stromal Cells for Acute Respiratory Distress Syndrome (START),” a United States Department of Defense supported study of MSCs for ARDS

Mitchell M. Levy, MD

- Chief of the Division of Pulmonary, Critical Care, and Sleep Medicine, Department of Medicine, and Professor of Medicine at Brown University
- Medical Director of the Medical ICU at Rhode Island Hospital. He has been an investigator on numerous pharmacologic and biologic trials intended to treat sepsis, cardiovascular and pulmonary pathology

Lorraine B. Ware, MD

- Professor of Medicine, Pathology, Microbiology, and Immunology at Vanderbilt University & Director of Vanderbilt’s Medical Scholars Program
- Research centers on the pathogenesis and treatment of sepsis and acute lung injury with a current focus on mechanisms of lung epithelial and endothelial oxidative injury by cell-free hemoglobin.
- Dr. Ware is also a lead investigator for the “Mesenchymal Stromal Cells for Acute Respiratory Distress Syndrome (START)” study

Perenlei Enkhbaatar MD., PhD., FAHA

- Charles Robert Allen Professor of Anesthesiology & Director of Translational Intensive Care Unit, Department of Anesthesiology at University of Texas Medical Branch (UTMB), Galveston, TX
- Research focus on investigate pathophysiologic mechanisms of multi-organ failures with especial emphasis tissue regeneration, stem cell biology, and modified mRNA
- Principal or co-investigator on three NIH RO1 grants and one industry sponsored grant (Citius MSCs). Two of the RO1 grants are in ARDS

Unique Pipeline in Progressive Stages (current as of 12/2020*)

Program	Estimated Market (Worldwide)	Preclinical	Phase I	Phase II	Phase III
Mino-Lok® Treat CVC Infections	> $1.5B	Interim Safety/Efficacy Analysis (Sep); Last Pat. Visit est. Q2'21			
CITI-002 (Halo-Lido) Rx Therapy for Hemorrhoids	> $2B	Next milestone: IND (exp Q1 2021); Ph 2B Initiated (exp Q2)			
CITI-101 (Mino-Wrap) Prevent Infections Associated with Breast Implants	> $400M	IND by Q4'21			
CITI-401 (*i*MSC) Treat ARDS	Multi-billion	IND by Q4'21			

* Best estimate, subject to impact of Covid pandemic on clinical trial conduct.

CITIUS PHARMA

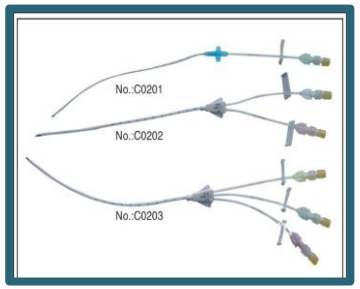
Mino-Lok®

LEAD PRODUCT

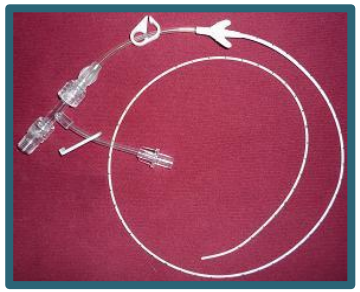
Minocycline/EDTA/Ethanol
Antibiotic Lock Therapy for Salvaging Catheters That Cause Bloodstream Infections

Central Venous Catheters

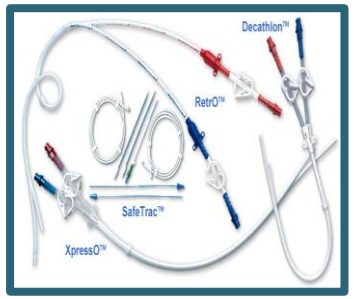
Central Venous Catheters (CVCs), Peripherally Inserted Central Catheter (PICCs), and Hemodialysis



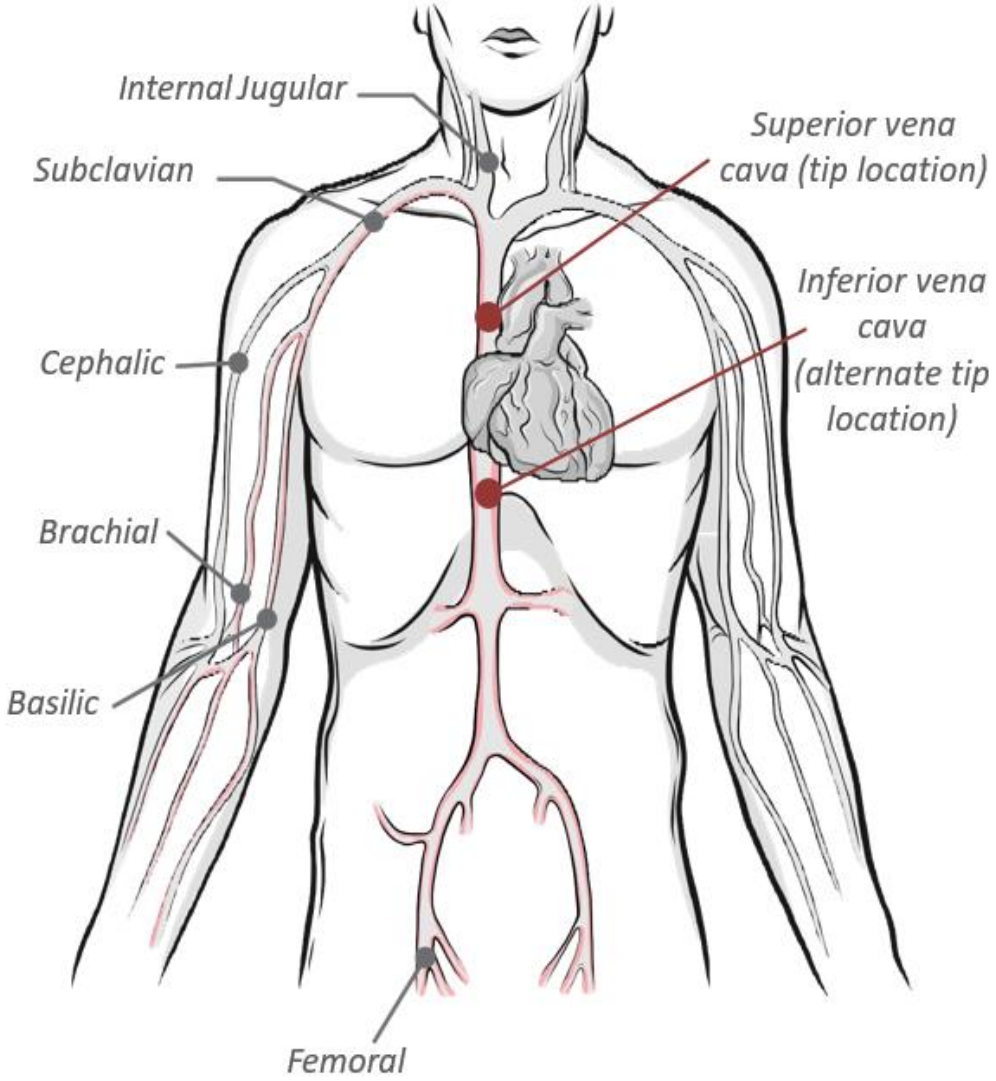
Central Venous Catheter

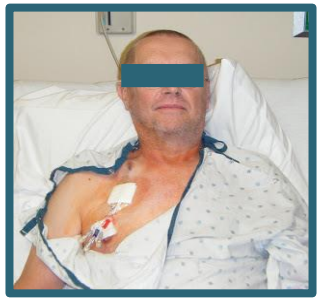


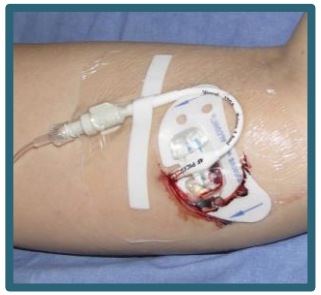
PICC

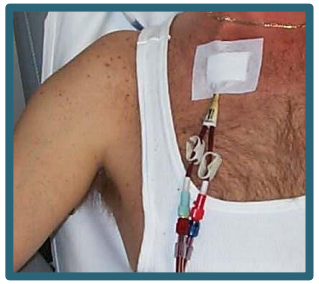


Hemodialysis

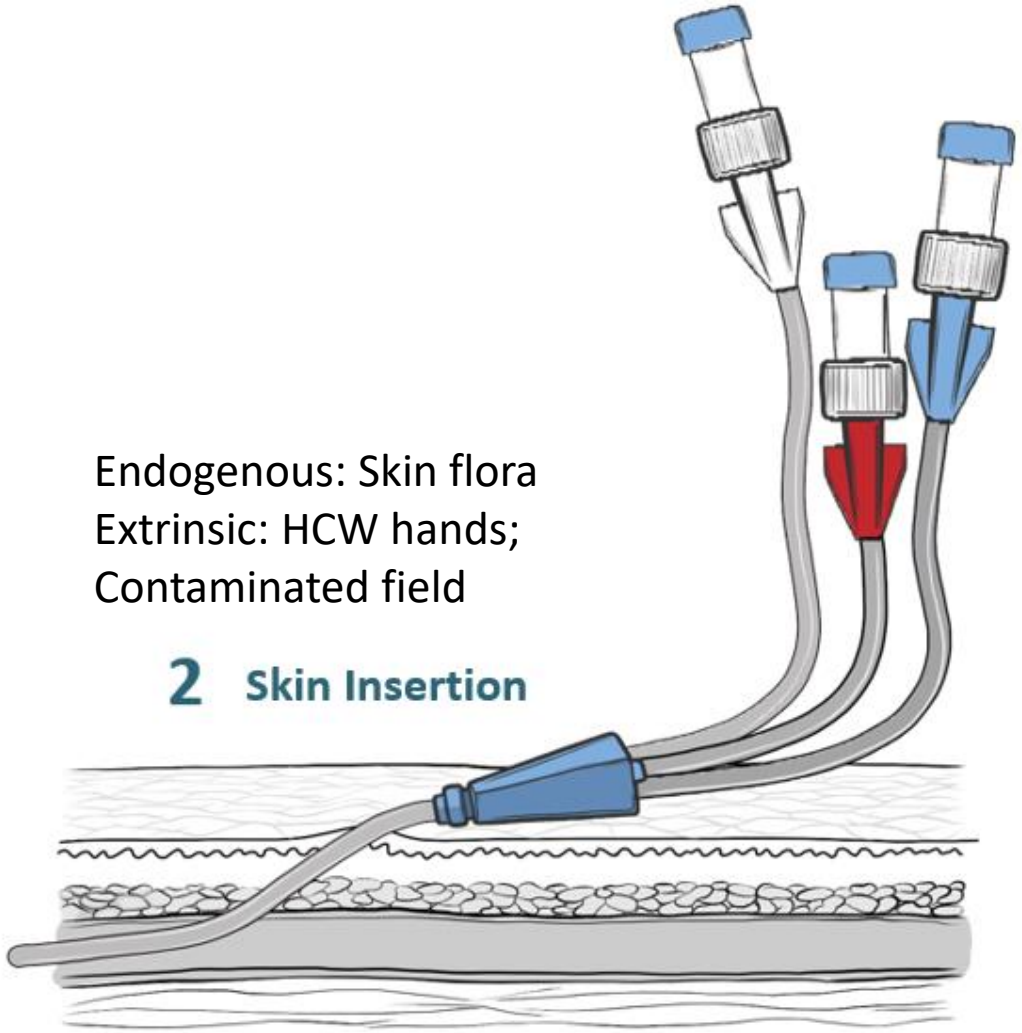








Pathogenesis of CRBSI



1 Contaminated Catheter Hub

Endogenous: Skin flora
Extrinsic: HCW hands

Endogenous: Skin flora
Extrinsic: HCW hands;
Contaminated field

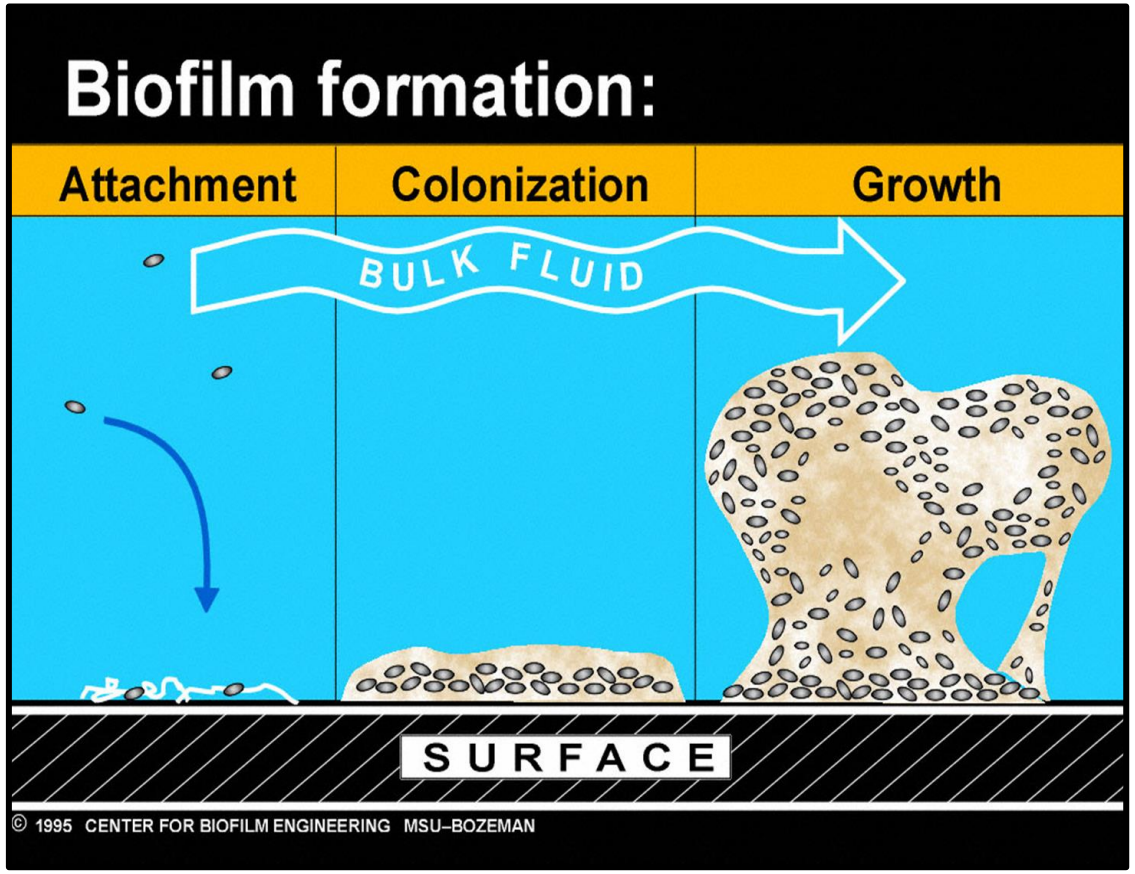
2 Skin Insertion

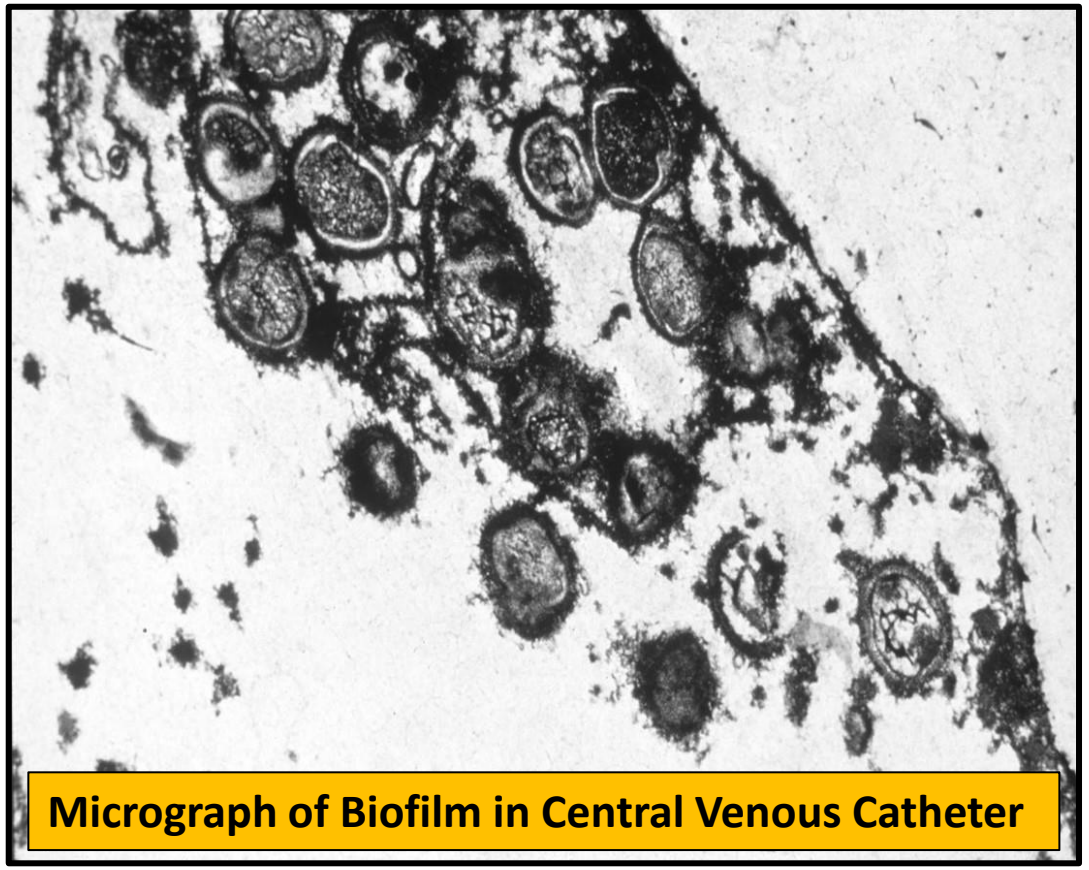
3 Hematogenous

From distant Infection (<10%)

Safdar N, Maki DG. The pathogenesis of catheter-related bloodstream infection with noncuffed short-term central venous catheters. *Int Care Med*. 2004;30:62-67.

Biofilm Formation Protects Colonies





- Pathogens attach to the surface of the lumen in a central venous catheter and form colonies.
- Colonies grow and exude a fibrous glycocalyx that protects the organisms from antibiotics, even when shown to be sensitive *in vitro*

THE PROBLEM: CVCs are a Lifeline for Cancer Patients

BUT Infection Rates + Poor SOC Leads to Death & Morbidity

Infections are Common & Dangerous

- Of the 7,000,000 CVCs used annually in US, up to 472,000 become infected leading to serious, life threatening infections called CRBSI/CLABSI.[1]
- These infections are associated with 12-25% mortality and morbidity.[2]
- Hospitals are penalized for reporting high infection rates, not to mention, incur an attributable cost of $46,000 to $65,000 per episode

+

SOC is a Poor Option for Patients & Hospitals

- Current SOC is to remove and replace (R&R) the CVC, while treating with systemic antibiotics
- Catheter R&R causes physical and psychological symptoms in 57% to 67% of patients.[3]
- R&R is difficult for many patients, due to unavailability of other accessible vascular sites and the need to maintain infusion therapy
- Cost for just the R&R procedure is ~$10,000

Mino-Lok is the first – *and only* – therapy under investigation that can be used to sterilize and salvage the infected CVC avoiding the complications, discomfort and costs of removal and replacement.

Sources:

1. Shah H., Bosch W., Hellinger W. C., Thompson K. M. (2013). Intravascular catheter-related bloodstream infection. Neurohospitalist 3, 144–151. doi: 10.1177/1941874413476043.
2. Antoňáková Němčíková A, Bednárovská E. Catheter-related bloodstream infections: do we know all of it? Klin Onkol. 2017;30(6):405–411. doi: 10.14735/amko2017405.
3. Chaftari, AM et al,. Unnecessary Removal of CVCs in Cancer Patients with CRBSI: Impact on Symptom Burden. Poster presentation at ID Week 2017, Infectious Diseases Society of America (IDSA)Oct 04 - 08, 2017

CVC Remove and Replace (R&R) Complications

R&R procedures are invasive and discomforting to patient

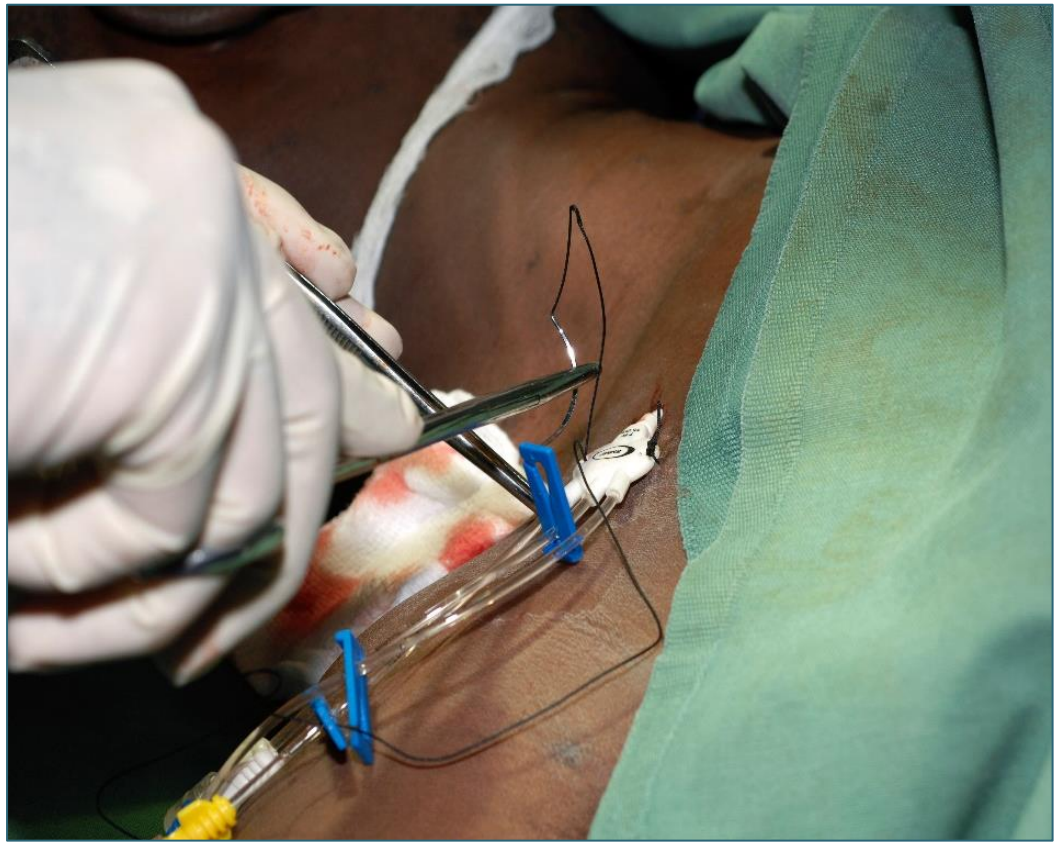
R&R Procedures are costly and usually require additional hospital stay.

Complications include infection, thrombosis, occlusion, and mechanical complications.

- Infectious complications are reported to occur in 5% to 26% of patients;
- Mechanical complications in 5% to 19%; and,
- Thrombotic complications in 2% to 26%.[1,2]

Mechanical complications associated with the insertion of CVCs include arterial puncture, hematoma, hemothorax, pneumothorax, arterial-venous fistula, venous air embolism, nerve injury, thoracic duct injury (left side only), intraluminal dissection, and puncture of the aorta.[3]

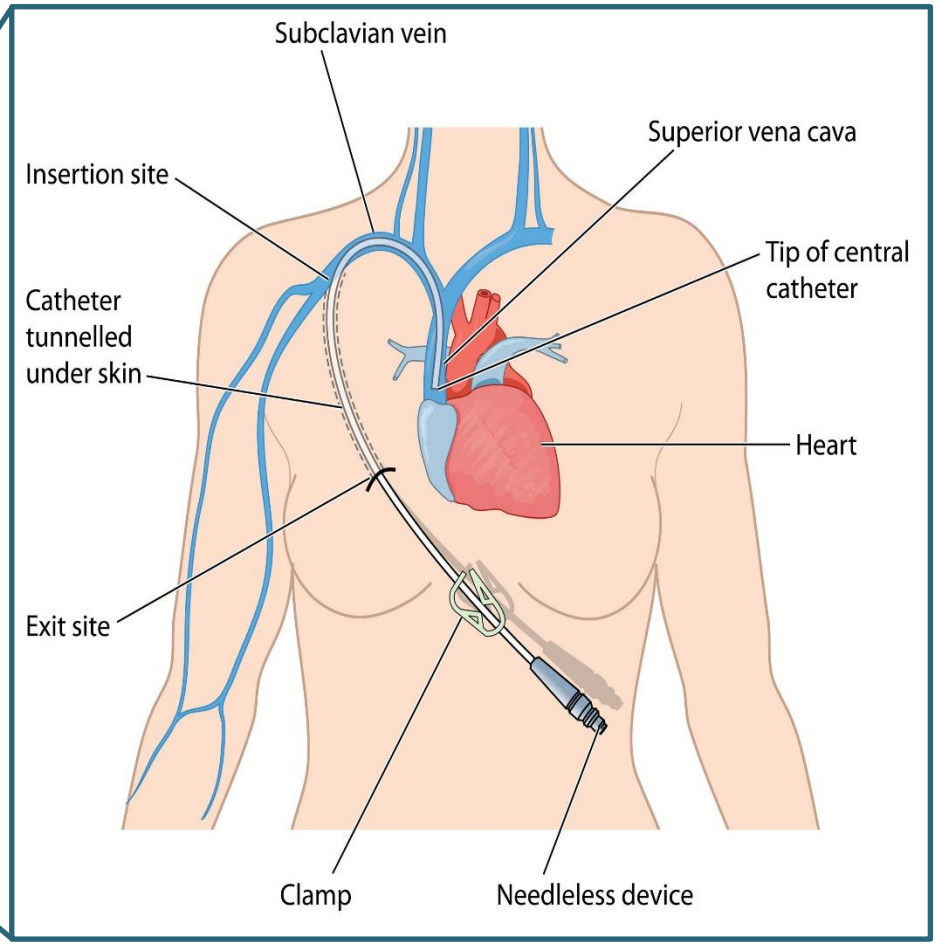
Catheter removal and reinsertion causes physical and psychological symptoms in 57% to 67% of patients, respectively.[4]



Sources (NCBI: Annals of Translational Medicine):

1. McGee DC, Gould MK.. Preventing complications of central venous catheterization. N Engl J Med 2003;348:1123-33.
2. Merrer J, De Jonghe B, Golliot F, et al. Complications of femoral and subclavian venous catheterization in critically ill patients: a randomized controlled trial. JAMA 2001;286:700-7.
3. Polderman KH, Girbes AJ.. Central venous catheter use. Part 1: mechanical complications. Intensive Care Med 2002;28:1-17.
4. Chaftari, AM et al,. Unnecessary Removal of CVCs in Cancer Patients with CRBSI: Impact on Symptom Burden. Poster presentation at ID Week 2017, Infectious Diseases Society of America (IDSA)Oct 04 - 08, 2017

Locking a Central Venous Line with Mino-Lok®



**Mino-Lok™ is not flushed into the venous system.*

Locking a Catheter is a Standard Operating Procedure

1. Using Mino-Lok does not require any novel methodologies.
2. Any RN or LPN or Technician can perform the procedure.
3. There is no change in normal workflow and does not require exceptional training.
4. The patient does not experience any sensations similar to the threading of a central line through a vein or artery.
5. The procedure does not require any change to the tunneling or change in placement of the central line.
6. No anesthesia (general or local) is needed.
7. Standard sterile techniques still apply.

Phase 2b Trial Results

Parameter	Mino-Lok Arm N	(%)	Control Arm N	(%)
Patients	30	(100%)	60	(100%)
Cancer Type				
- Hematologic	20	(67)	48	(80)
- Solid tumor	10	(33)	12	(20)
ICU Admission	4	(13)	4	(7)
Mech. Ventilator	3	(10)	0	(0)
Bacteremia				
- Gram+	17	(57)*	32	(53)
- Gram -	14	(47)*	28	(47)
Neutropenia (<500)	19	(63)	36	(60)
Microbiologic Eradication	30	(100)	60	(100)
- Relapse	0	(0)	3	(5)***
Complications	0	(0)	8	(13)
SAEs related to R&R	0	(0)	6	(10)
Overall Complication Rate	**0**	**(0%)**	**11****	**(18%)**

***1 polymicrobial patient had Gr+ and Gr – organism cultured; ** 6 patients had >1 complication; ***all 3 CVCs were removed within 1 month.**

Mino-Lok® Phase 3 Pivotal Trial Design

Multi-center, randomized, open label, blinded assessor, active control superiority study
(80% powered)

Adjunct in CLABSI/CRBSI

Patients with CRBSI/CLABSI (n~ 144)

R

Active Arm (n=72)
Mino-Lok® Solution

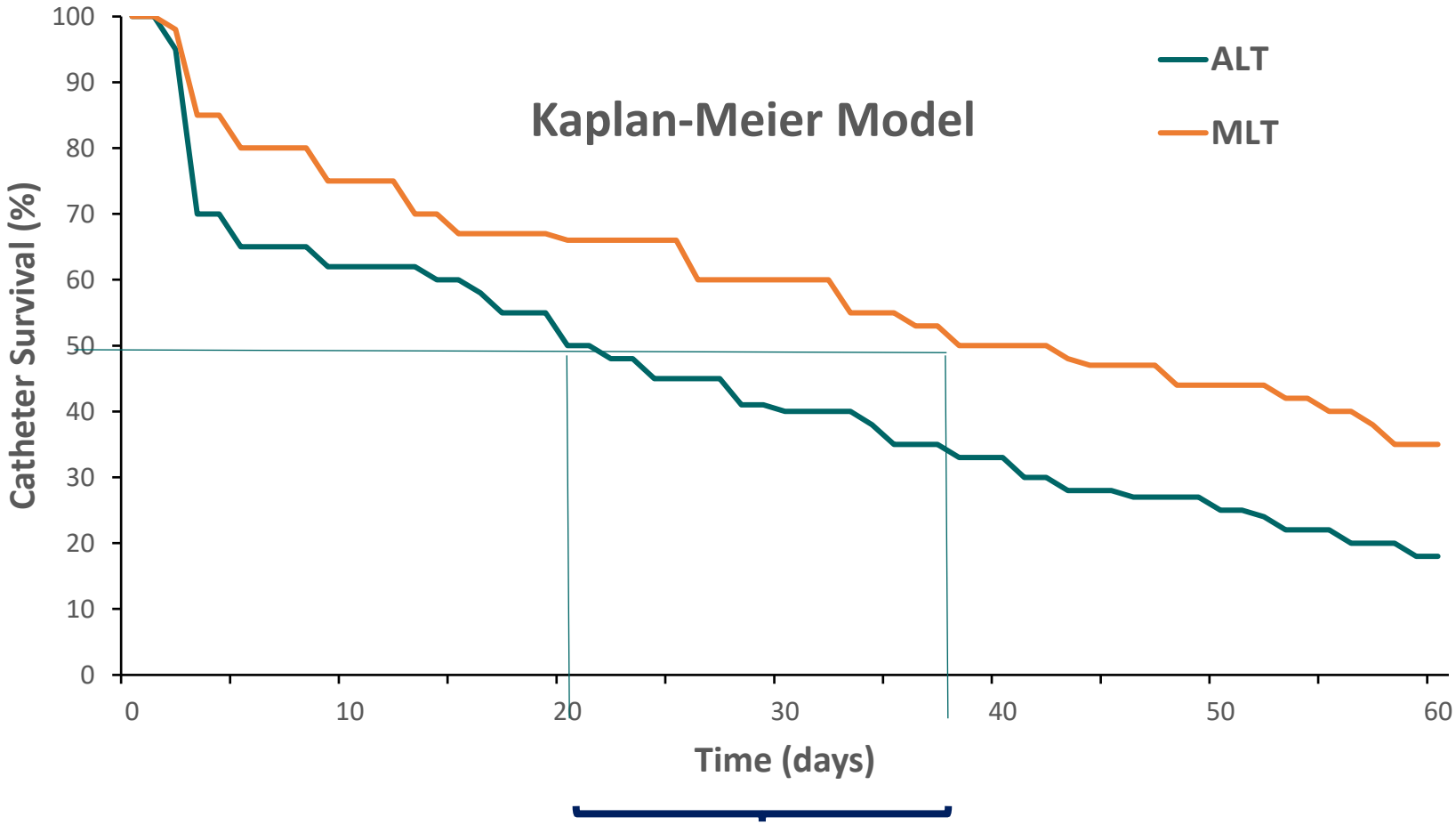
Control Arm (n=72)
Antibiotic Lock

Anticipated median time of 21 days vs. 38 days to achieve significance

Interim Analysis
Futility Performed at 35-40 Events and 60-70 Events for Superior Efficacy

Primary End Point
Comparison of "Time to Catheter Failure", TOC = 6 weeks

Mino-Lok® Time-To-Catheter Failure Trial Design



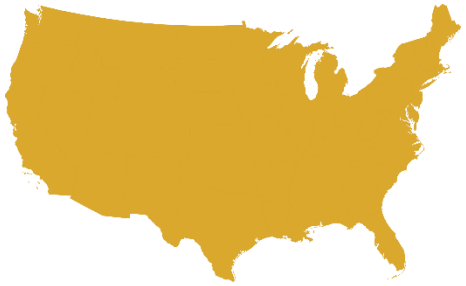
21 vs. 38 Day Difference in Median Number of Catheter Failures

Mino-Lok® Development Plan (estimated as of 12/2020*)

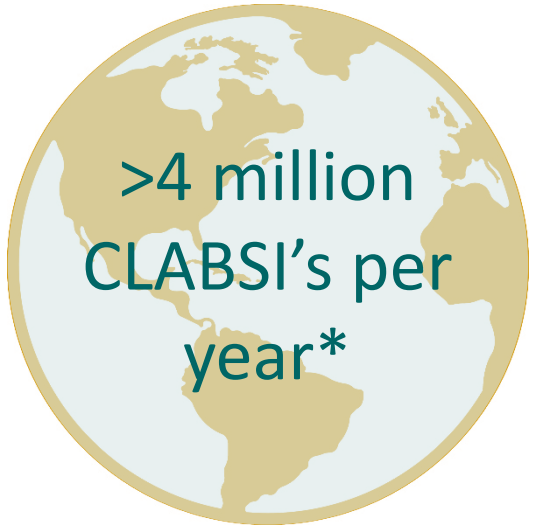
* Best estimate, subject to impact of Covid pandemic on clinical trial conduct.

Market Opportunity

Pursue Directly



United States



Worldwide

Partnerable

Ex-US

With modest penetration at conservative pricing, we believe that >$500M peak year U.S. sales is achievable.

Regulatory Updates

DISARM Act is pending in the Senate, which would create a DRG carveout for QIDP products. This would allow for full reimbursement for CMS programs and not be part of the payment bundle.

Reimbursement

Company will apply for NTAP, which was just increased to 75% of list price, which would apply to all QIDP products

Company will apply for transitional pass-through

Pricing

Conservative pricing to allow for rapid market uptake would be ~$1.4k treatment

Pricing should have elasticity upwards, given the alternative, R&R (~$10k)

*DelveInsight "Catheter-Related Blood Stream Infections (CRBSI)-Market Insights, Epidemiology & Market Forecast–2028"

Intellectual Property

Mino-Lok™ is supported by a robust intellectual property portfolio ***Composition of Matter patent*** *that provides protection until* ***June 7, 2024****.* ***Formulation Patent*** *has been issued and will add protection through* ***2036.***

Creators	Description of Patent	All U.S. and Foreign Patent Applications / Patent Numbers
Issam Raad, M.D. et al	Antimicrobials in Combination with Chelators and Ethanol for the Rapid Eradication of Micro-organisms Embedded in Biofilm (Composition of Matter)	• U.S. Patent No.: 7,601,731; • EP Ser. No.: 04754538.9; • CA Ser. No.: 2,528,522;
Issam Raad, M.D. Joel Rosenblatt, Ph.D. et al	Antimicrobial Catheter Lock / Flush Solutions with Enhanced Stability (Formulation)	• Pub.No.: US 2017/051373 A1 • Global IP: UTFC.P1283WO

U.S. Patent No. 7,601,731 (Composition of Matter) was filed on June 7, 2004 priority date of Provisional Application No. 60/476,555 of June 6, 2003 and issued on October 13, 2009. The expiration date is **June 7, 2024**.
U.S. Patent No. 9,078,441 (Method of Use) was issued on July 14, 2015. The expiration date is **June 7, 2024**.
There are corresponding patents granted in Europe and Canada (European Patent No. EP 1644024, and Canadian Patent No. 2528522).
U.S. Patent No. 10,086,114 (Formulation/Enhanced Stability) was filed on November 4, 2016 and issued on Oct. 2, 2018. The expiration date is **November 4, 2036.**
Patent applications for Global IP filed on June 12, 2018 incl. Canada, China, Japan, Korea, European Patent Office.

Regulatory Protection

Qualified Infectious Disease Product (US)

- Eligibility for Fast Track Status, enables frequent communication and collaboration with FDA;
- Priority Review, reduces the NDA review time from 12 to 6 months; and,
- Market Exclusivity, grants an additional 5 years of market exclusivity at NDA, combined with Hatch-Waxman.

Fast Track Designation (US)

- Fast Track expedites review of drugs which treat a serious or life-threatening condition and fills an unmet medical need.
  - More frequent meetings with FDA to discuss the development plan and ensure collection of appropriate data needed to support approval;
  - More frequent correspondence with FDA about the design of the clinical trials;
- Rolling review allows for completed sections of the New Drug Application (NDA) to be submitted and reviewed by FDA rather than waiting until the entire application is compiled and submitted for review.

Supplementary Protection Certificate (EU)

- Extends patent protection up to 5 years for medicinal products which must undergo lengthy testing and clinical trials.

Competitive Landscape

*There are **no products** being developed for **treatment** of infected central venous lines.*

Company/Source	Product/Components	Status	Features/Weaknesses
CorMedix	DefenCath™ (Neutrolin®) taurolidine, citrate, heparin	NDA accepted by the FDA in August 2020 PDUFA date 2/28/2021 Available in Europe (CE Mark)	**Prevention only** Anti-infective only being used in prophylaxis

No company has United States regulatory approval. CorMedix is focused on development of lock solutions for the prevention of CRBSI in hemodialysis (HD) patients. There are no lock solutions in development for treating CRBSI patients and salvaging indwelling, infected CVCs. The current standard-of-care is to treat the bacteremia while removing and replacing the CVC usually in a new vascular access site.

Mino-Lok® (minocycline/disodium EDTA/ethyl alcohol)

- **Treats** catheter-related blood stream infections (CRBSIs).
- **Penetrates** biofilm, eradicates bacteria and salvages infected, indwelling vascular catheters while providing anti-clotting properties.
- **Salvages** central venous access in patients highly dependent on central lines and avoids the serious and expensive complications and morbidities associated with catheter removal and reinsertion.
- **Expected to be indicated** as adjunctive therapy for the treatment of Catheter-Related Blood Stream Infections (CRBSI) in combination with appropriate systemic antibiotic(s).
- **Would have worldwide rights** with appx. **16 years of exclusivity** at time of launch.

A major step forward in addressing a serious unmet medical need.

NoveCite *induced* Mesenchymal Stem Cells ("*i*-MSCs")

PLUS

Citius Pharmaceuticals, Inc.

- late-stage specialty pharmaceutical company
- critical care products (anti-infectives and cancer care)
  - Mino-Lok, Mino-Wrap, and Halo-Lido.

NASDAQ (CTXR)

Novellus Therapeutics

- pre-clinical stage biotechnology company
- patented non-immunogenic mRNA technology
  - gene editing, mutation-free & footprint-free cell reprogramming.
- Novellus is privately held.

NoveCite Biotherapeutics

- Worldwide license for *i*-MSCs for acute respiratory conditions
- main focus is on ARDS associated with COVID-19
- developing the next generation of mesenchymal stem cells
- NoveCite cells are called *i*-MSCs
  - derived from an *i*-PSC master cell bank
- NoveCite is a subsidiary of Citius

NoveCite *i*-MSC Compelling Unique Advantages

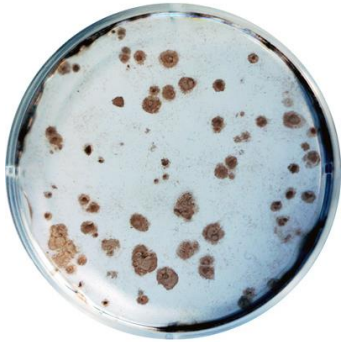
- Novellus mRNA cell reprogramming efficiently creates *i*-PSC cells (*i*-PSCs are an ideal building-block for cell-based therapies)
- Clonal *i*-PSC master cell bank is created – no batch-to-batch variation and footprint-free (no viral vectors)
- Rapid production of *i*-MSCs (4 week differentiation from *i*-PSC master cell bank)
- Significantly greater expansion ability than donor-derived cells
- Higher level secretion of many immunomodulatory proteins (vs. donor-derived MSCs) results in higher potency and anti-inflammatory effects
- NoveCite *i*-MSCs will be allogeneic (‘off-the-shelf’) and supplied in frozen, ready-to-use IV bags.

Novellus mRNA Cell Reprogramming

Proprietary *induced* Pluripotent Stem Cell Platform

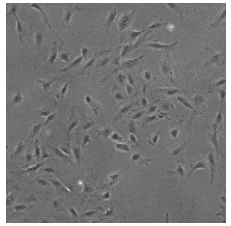
- Single donor, **NO** repeat harvesting adult-derived cells; **NO** repeat donor testing
- Clonal *i*-PSCs differentiated into clonal *i*-MSCs for genetically identical manufacturing batches
- *i*-MSCs exhibit enormous expansion potential (trillions of cells)
- Footprint-free ("viral-vector free") *i*-MSCs
- Allogeneic cells ('off-the-shelf")
- mRNA process restores telomeres (rejuvenated embryonic-like cells)
- *i*-MSCs secrete higher levels of immunomodulatory proteins

Typical Results

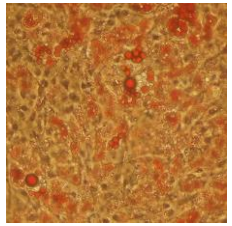


- iPSC colonies from dermal fibroblasts
- 6 daily transfections, 5 mRNA constructs expressing reprogramming factors
- animal-component free

Mesenchymal Stem Cells (MSCs)

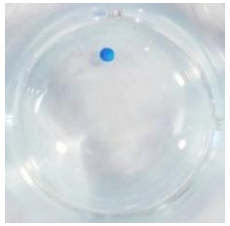


Adipocytes
Oil Red O stain

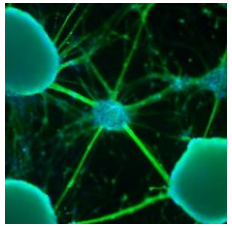


Osteoblasts
Alizarin Red S stain

Chondrocytes
Alcian Blue stain

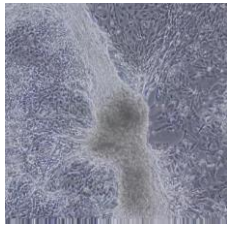


Neurons
β-*tubulin*



Retinal Pigment Epithelial Cells

Cardiomyocytes

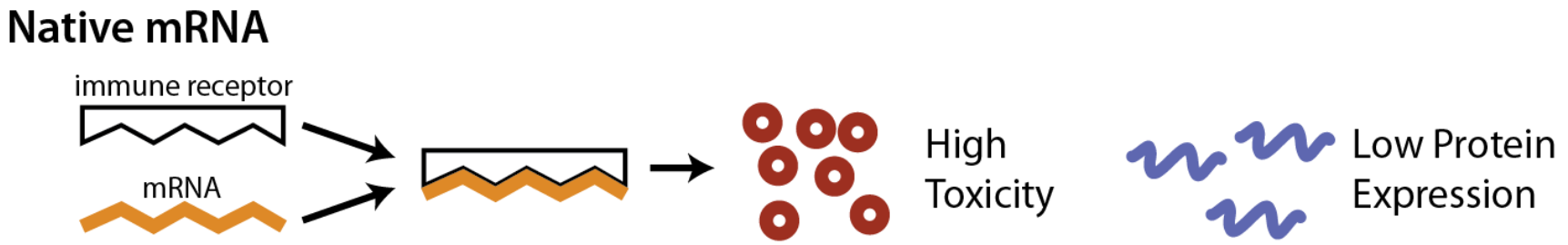


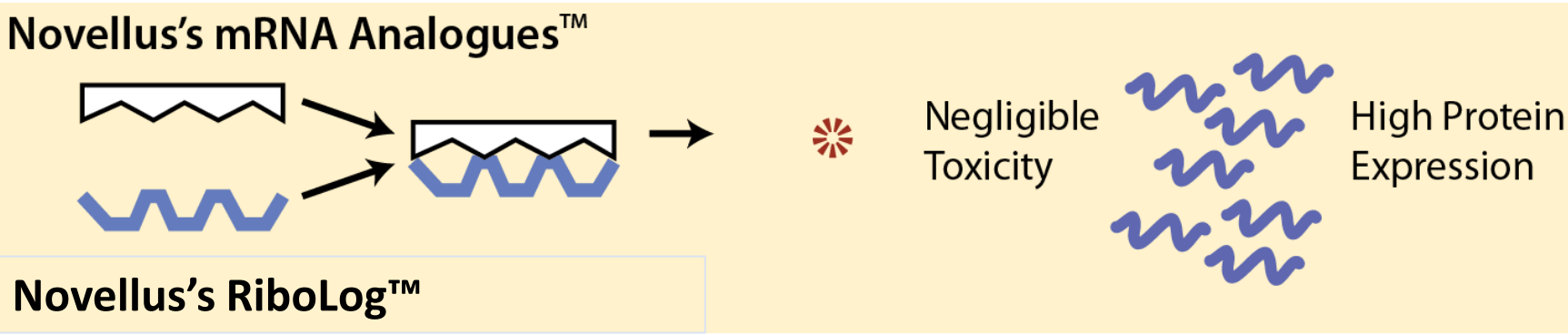
"The main advantages of the RNA method are speed of colony emergence, high efficiency, a complete absence of integration, a very low aneuploidy rate and a low donor cell requirement" *– Thorsten M Schlaeger, PhD, Boston Children's Hospital*

Schlaeger, et al. A comparison of non-integrating reprogramming methods. Nature Biotechnology. 2015.

Proprietary mRNA Technology – *Non-Immunogenic*

Native mRNA is recognized by the innate immune system so is highly immunogenic, resulting in lower protein expression and no ability for repeat dose



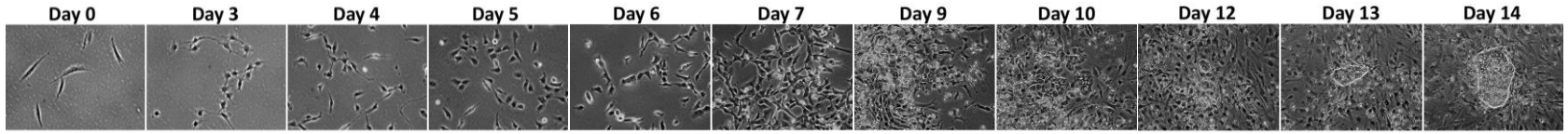


Ribolog™ evades the innate immune system and is recognized by the ribosome as mRNA, resulting in no immunogenicity, high protein expression and ability for repeat dose

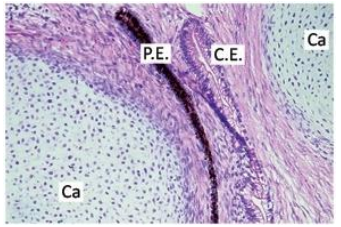
i-MSC Advantages: Production in 30 Days

i-PSC Production Process & Proof of *i*-PSCs

- **6 days of 5 non-immunogenic mRNAs encoding reprogramming factors**
- **Mutation-free, extensively characterized *i*-PSCs, unlimited supply**



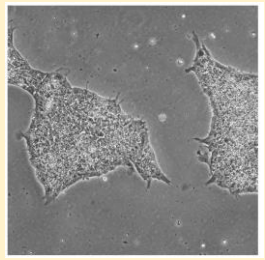
Proof of iPSC Pluripotency* Demonstrated

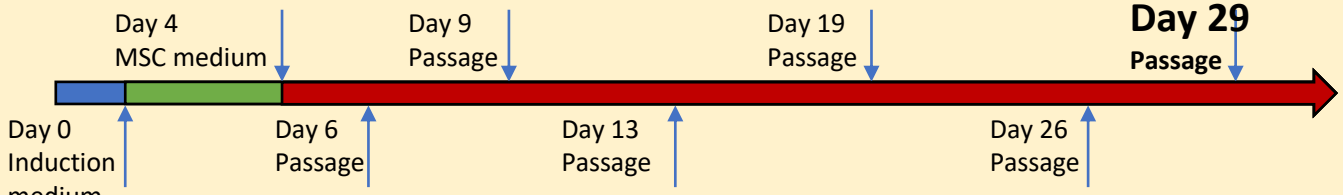


*formation of the three "germ layers"

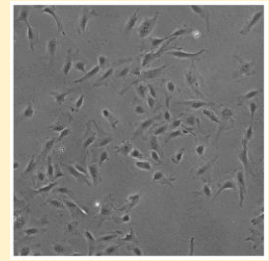
i-MSC Production Process & Proof of MSCs

i-PSCs

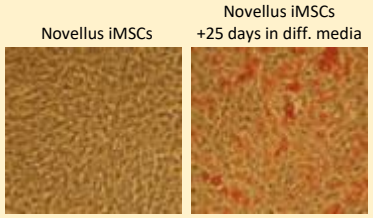




i-MSCs



- **mRNA generated**
- **Consistent**
- **Single-source**
- **Mutation-free**
- **Near unlimited supply**



Adipocytes
Oil Red O stain

Osteoblasts
Alizarin Red S stain

Chondrocytes
Alcian Blue stain

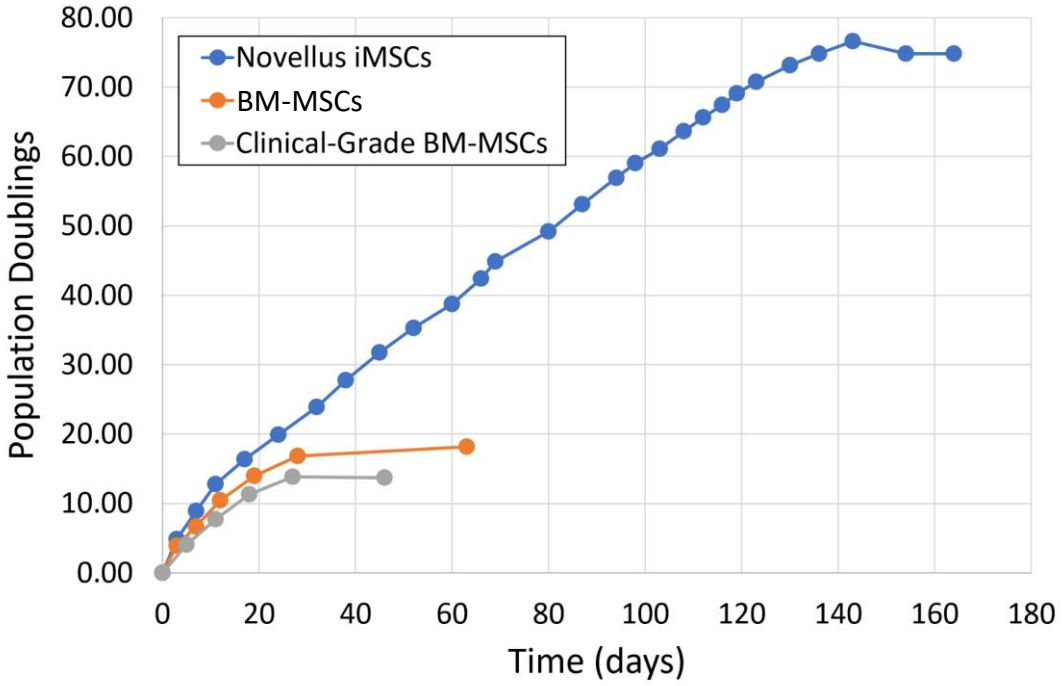
- **Single-source**
- **Viral vector free**
- **"Pristine" (less senescent)**
- **More potent**
- **Can be genetically modified**

i-MSCs Advantages: Greater Expansion Potential

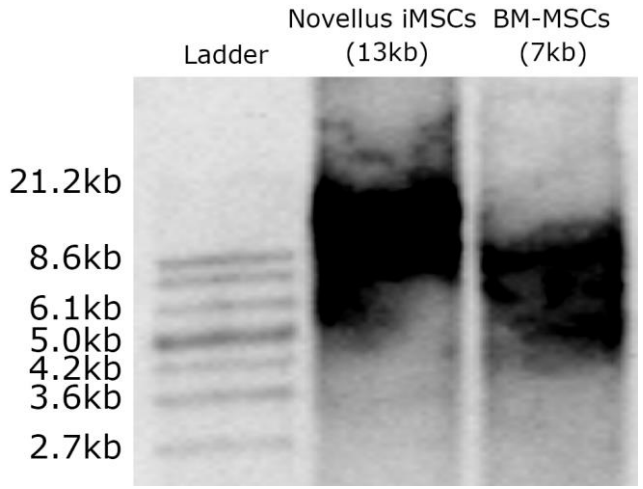
i-MSCs exhibit greater expansion potential

– mRNA process restores telomeres to yield >70 population doublings

Growth Curve



Telomere Length



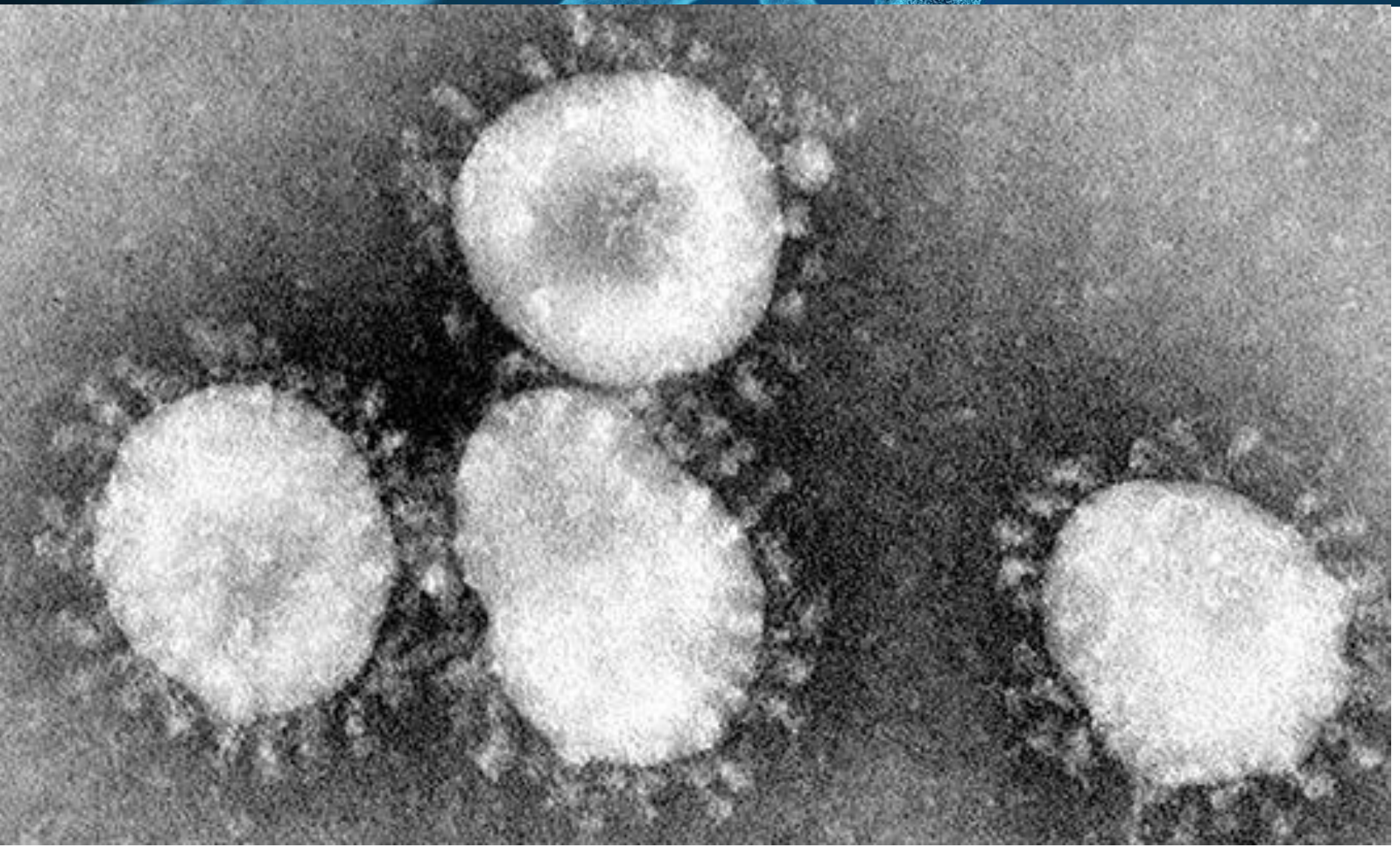
"BM-MSCs" = bone marrow-derived MSCs

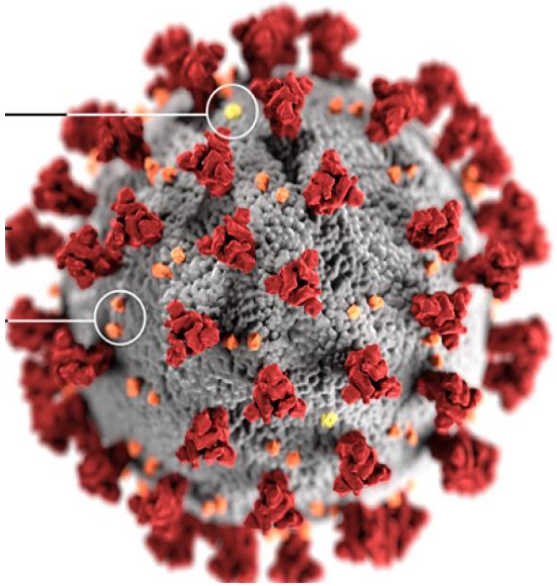
*Data on file (Novellus)

NoveCite *i*-MSC Summary

- Novellus mRNA cell reprogramming efficiently creates *i*-PSC cells (*i*-PSCs are an ideal building-block for cell-based therapies)
- Clonal *i*-PSC master cell bank is created – no batch-to-batch variation and footprint-free (no viral vectors)
- Rapid production of *i*-MSCs (4 week differentiation from *i*-PSC master cell bank)
- Significantly greater expansion ability than donor-derived cells
- Higher level secretion of many immunomodulatory proteins (vs. donor-derived MSCs) results in higher potency and anti-inflammatory effects
- NoveCite *i*-MSCs will be allogeneic (‘off-the-shelf’) and supplied in frozen, ready-to-use IV bags.

NoveCite *i*-MSCs: ARDS in COVID-19

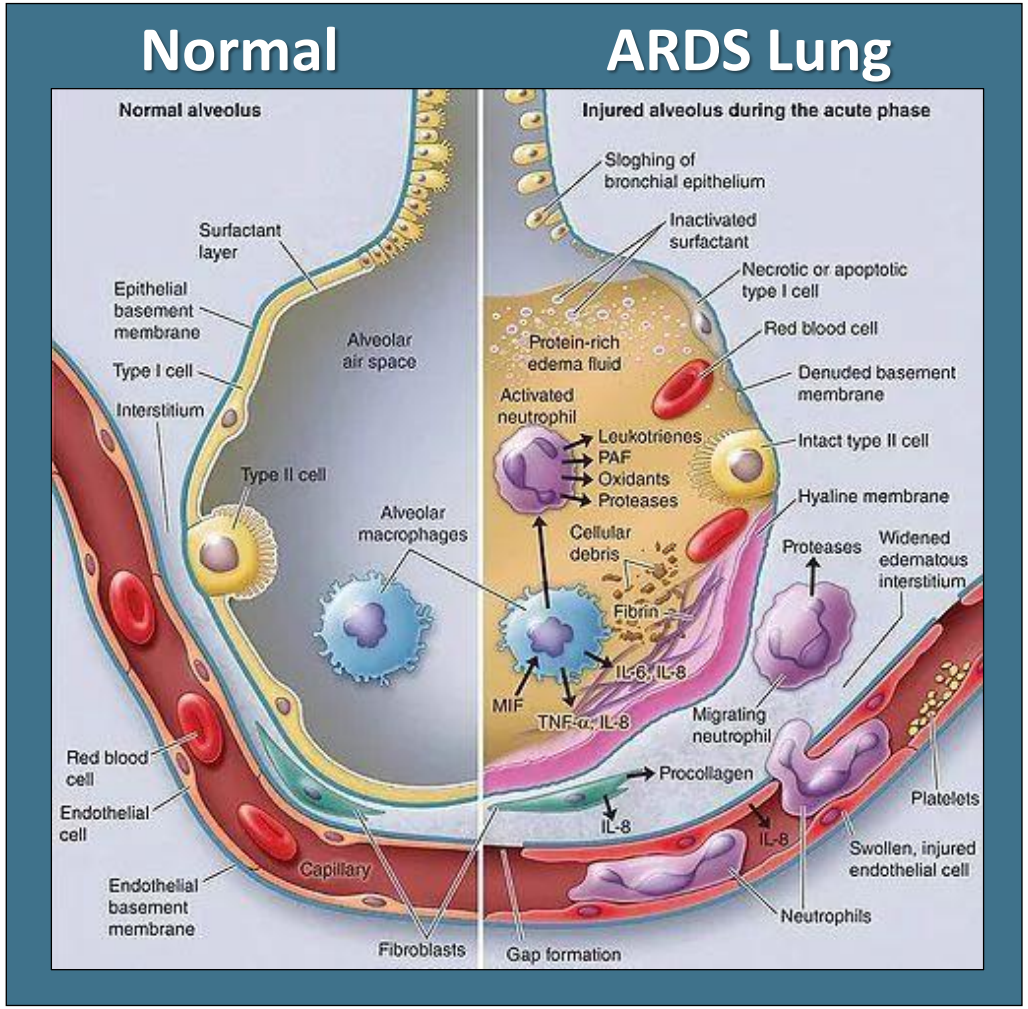




SARS-CoV-2

Severe acute respiratory syndrome coronavirus 2

Acute Respiratory Distress Syndrome (ARDS)



ARDS

a type of respiratory failure characterized by rapid onset of widespread inflammation and fluid accumulation in the lungs. ARDS impairs the lungs' ability to exchange oxygen for carbon dioxide

Symptoms

includes shortness of breath, rapid breathing, and bluish skin coloration; for those who survive, a decreased quality of life is common

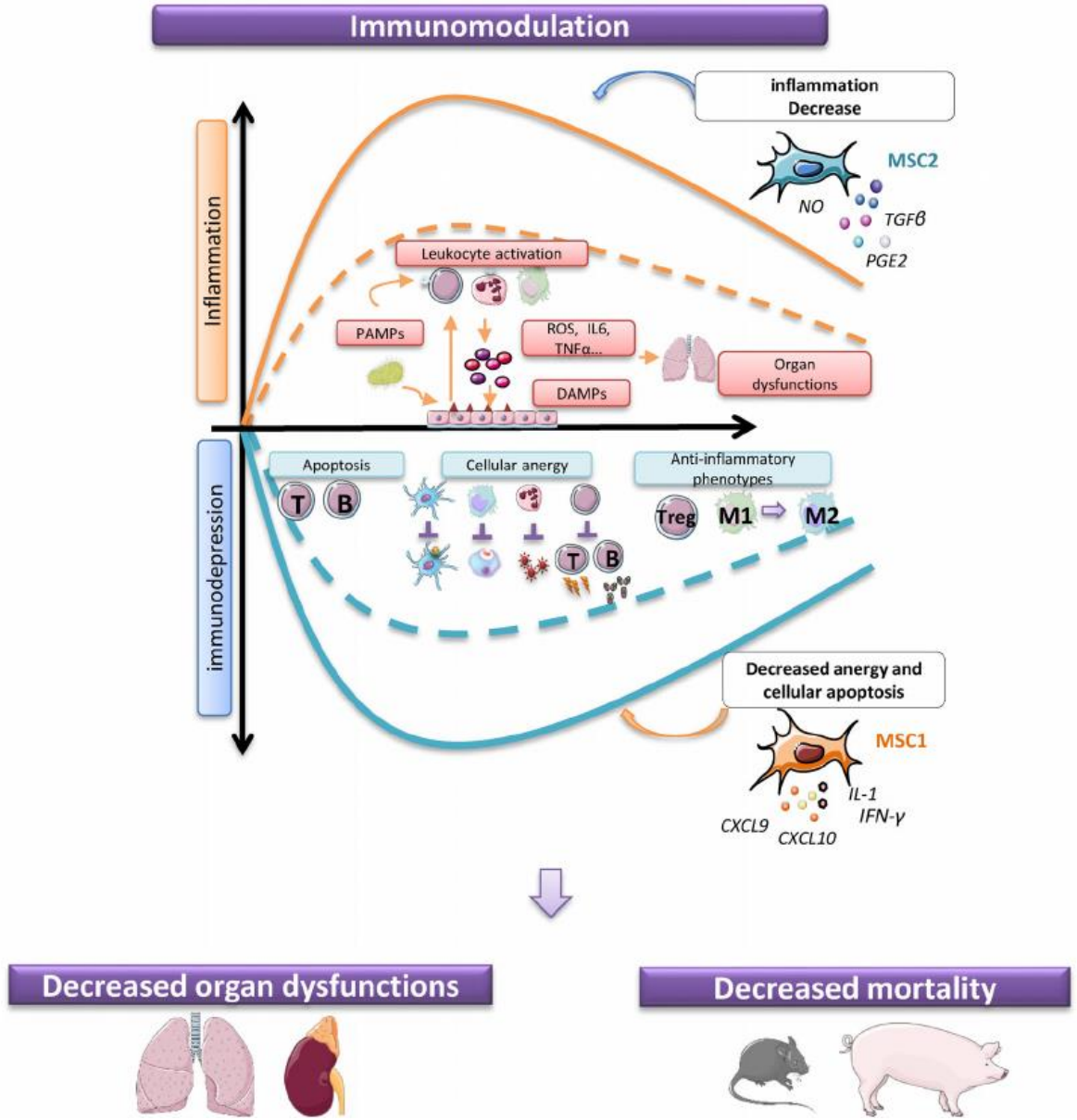
Drug Treatments

No FDA approved drug therapy for ARDS

Clinical Management

supportive care, through the use of ventilator, as well as fluid management, and in *some* instances, extracorporeal membrane oxygenation and/or glucocorticoids

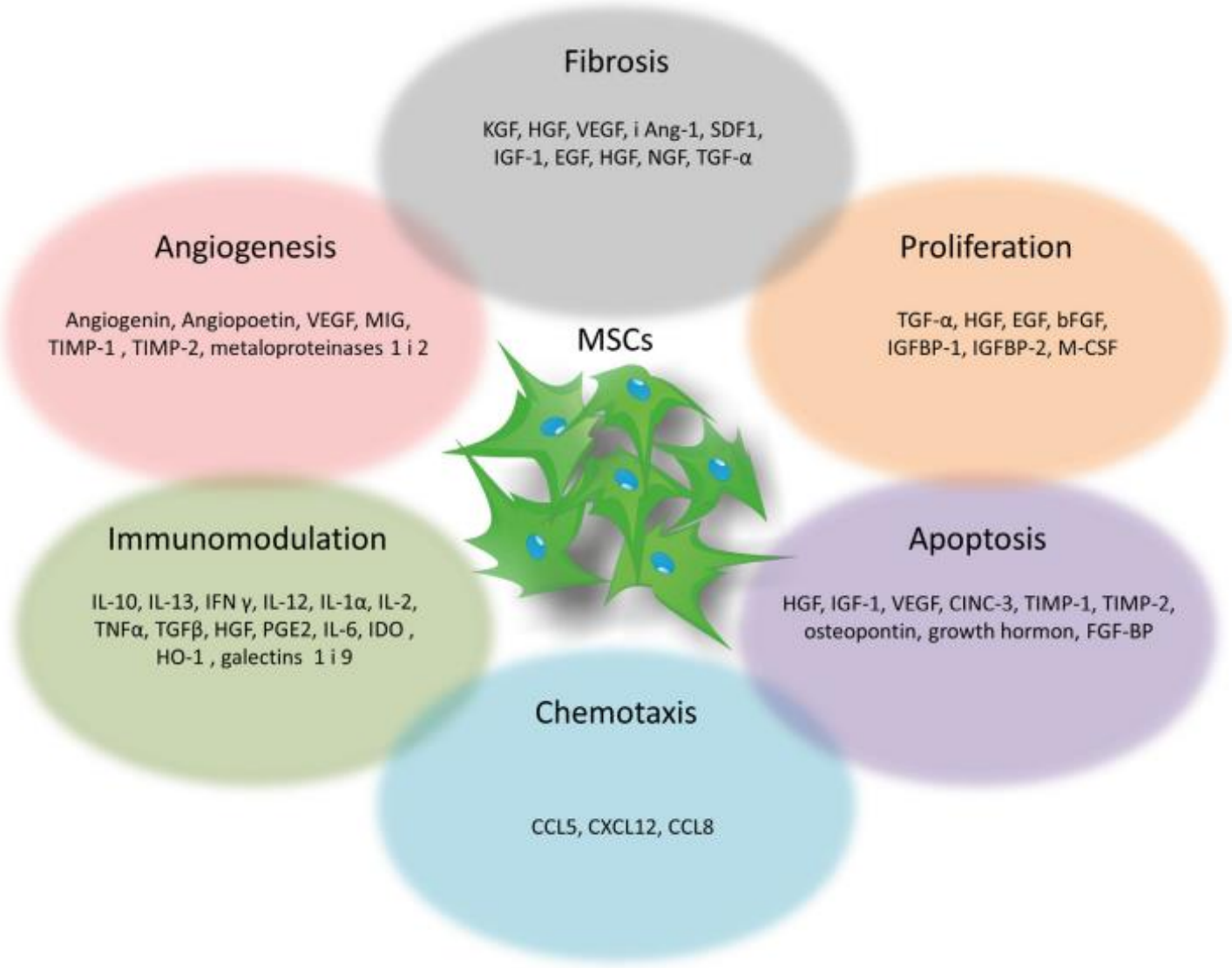
Immune Response to MSCs in SARS-CoV-2 Infected Lung



ARDS (and sepsis) is a dysfunction of the immune system with the concomitant presence of pro-inflammatory and anti-inflammatory states. A post infection immunosuppressive state is evidenced by the development of anergy: increase in lymphocyte apoptosis, alteration of immune cell functions with less antigen presentation by dendritic cells, and promotion of reactive oxygen species (ROS) neutrophil production or phagocytic activities and anti-inflammatory phenotypes. To be effective, therapeutic management should be able to adapt to this inflammatory context and at the same time, improve organ failures and survival. Mesenchymal stromal cell (MSC) capacities to switch to MSC1 or MSC2 phenotypes can be interesting in sepsis indication

Reference: Laroye C, Gibot S, Huselstein C,Bensoussan D. Mesenchymal stromal cells for sepsis andseptic shock: Lessons for treatment of COVID-19. STEMCELLS Transl Med. 2020;9:1488–1494.https://doi.org/10.1002/sctm.20-02391494 LAROYE ET AL.

Immunomodulatory Mechanisms of MSCs



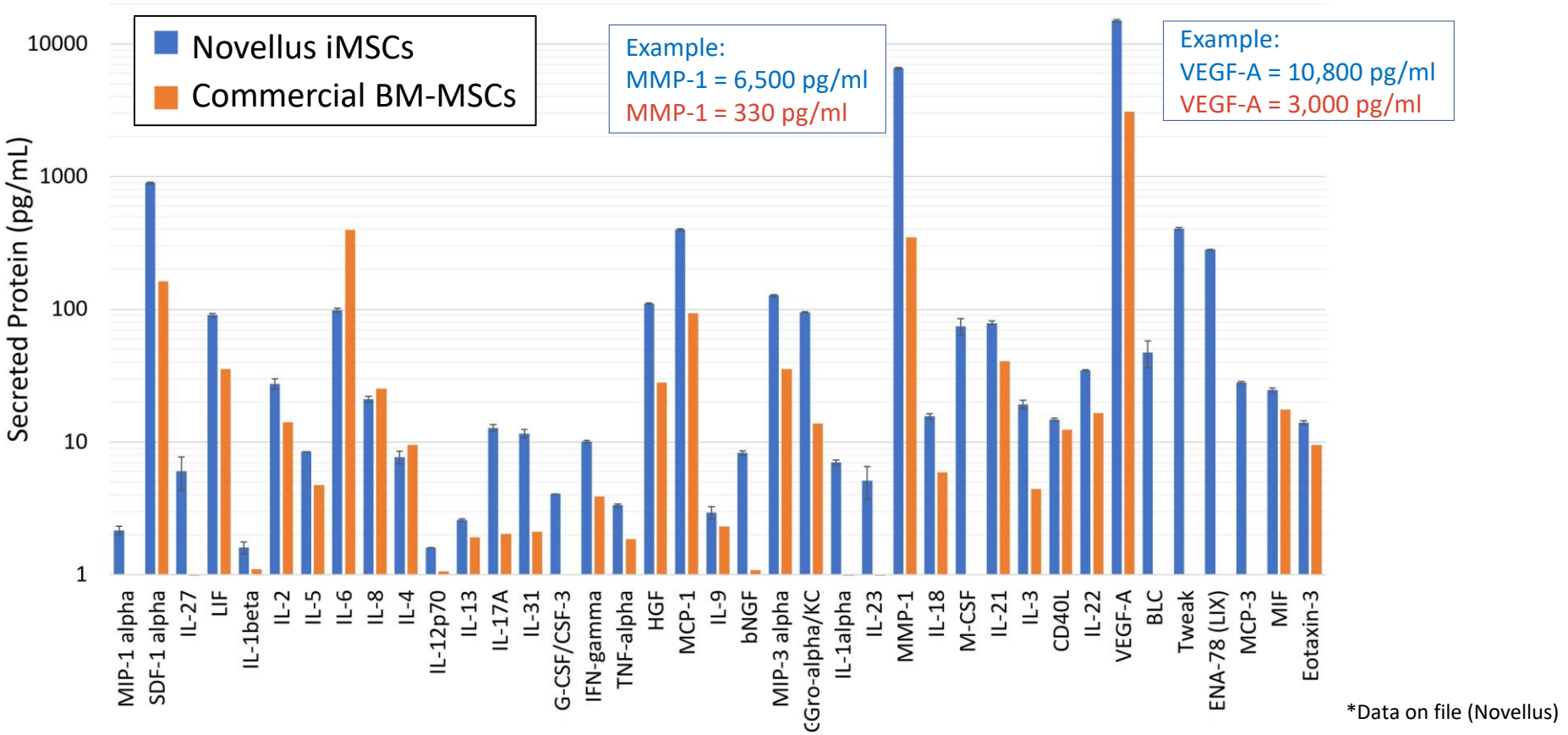
MSCs secrete a wide range of paracrine factors (secretome) that play an important role in the regulation of biologic functions, homeostasis, inflammation, and immune response, including…

- regeneration of cells,
- protection of cells against apoptosis,
- prevention of excessive fibrosis
- stimulation of angiogenesis.

Source: Andrzejewski, Anna, et.al., “Concise Review: Mesenchymal Stem Cells…”, STEM CELLS 2019;37:855-864 www.StemCells.com

i-MSC Advantages: Levels of Immunomodulator Secretion

i-MSCs secrete higher levels of many immunomodulatory proteins



*Data on file (Novellus)

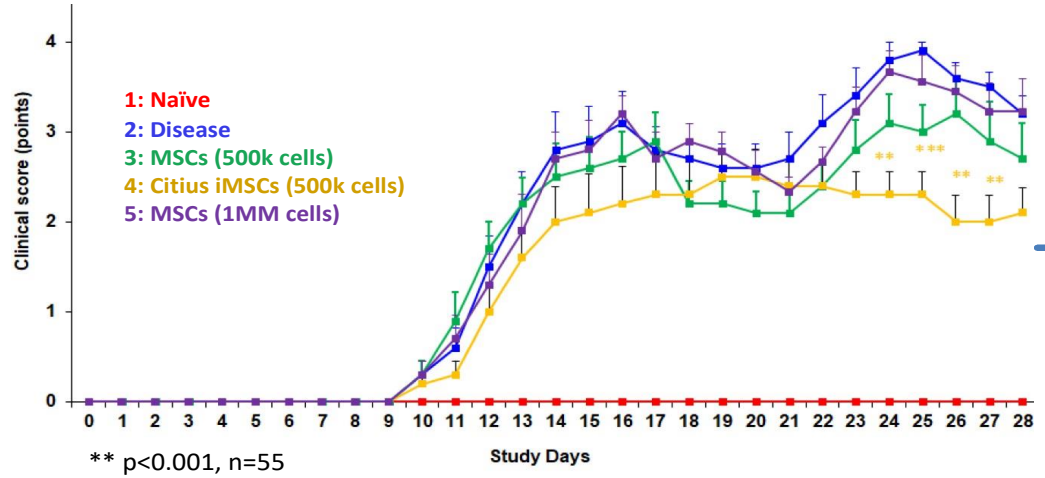
***MMP-1: member of the MMP family which contribute to homeostasis and a variety of physiological processes (e.g. immunity, wound healing, angiogenesis)**
****VEGF-A: mediates the growth of new blood vessels from pre-existing vessels (angiogenesis)**

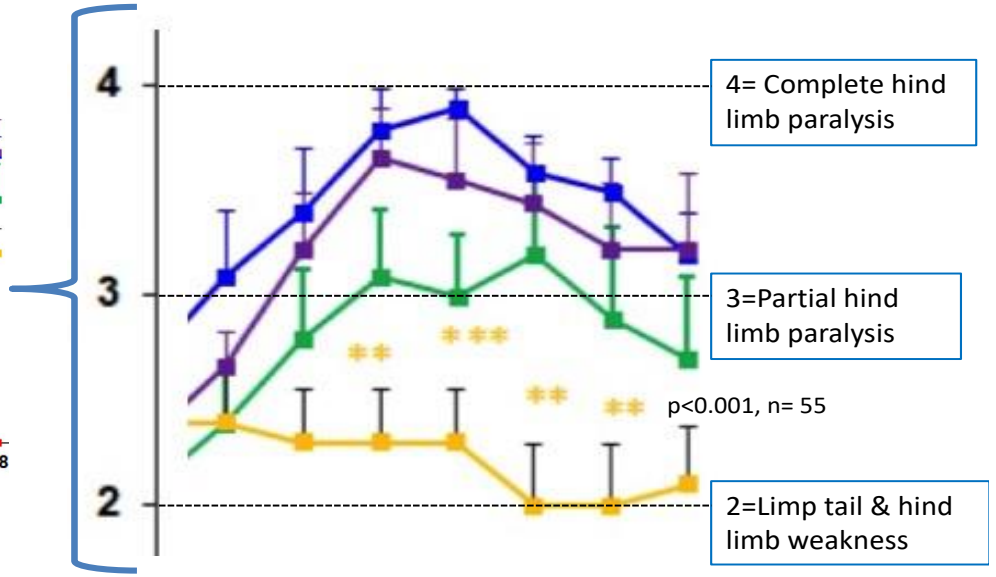
NoveCite *i*-MSC Mouse Study

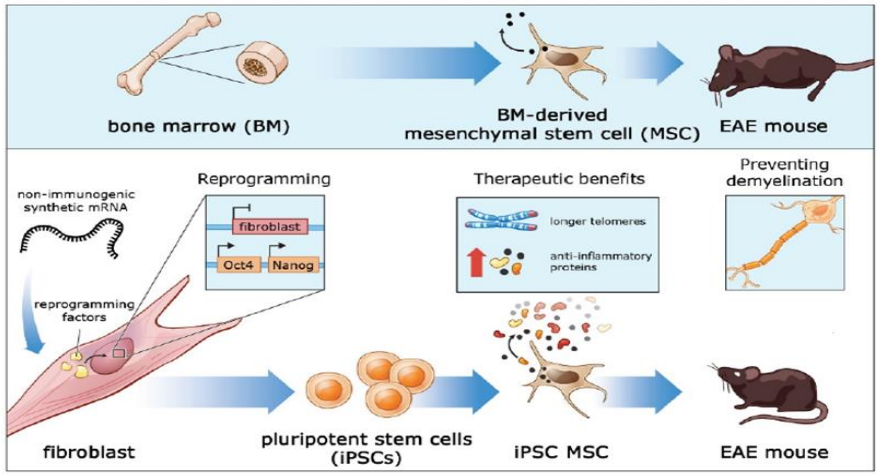
i-MSCs vs. MSCs: Therapeutic Effect in MS Mouse Model

Novellus *i*-MSCs improve clinical score in an EAE mouse model

- **Tail-vein injection of 20 million *i*-MSCs/kg improved score (p<0.001)**
- **Donor-derived MSCs had little/no effect at 20 million and 40 million cells/kg**







i-MSCs delayed disease progression and improved clinical score 43% improvement as compared to donor MSCs

EAE = Experimental Autoimmune Encephalomyelitis (resembles multiple sclerosis [MS])

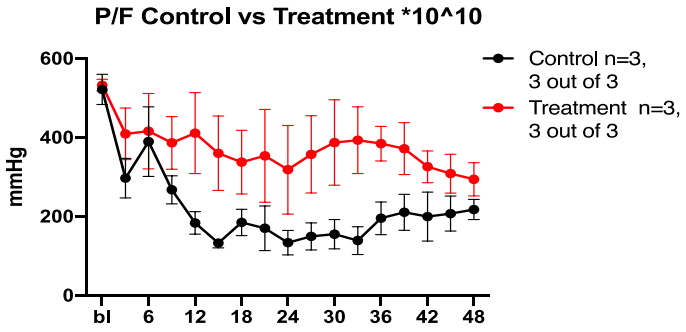
Abstract 830: ***"Mesenchymal Stem Cells (MSCs) Generated Using mRNA Reprogramming Show Enhanced Growth Potential, Secretome,and Therapeutic Efficacy in a Demyelinating Disease Model"*** presented by Harris et al at ASGCT 23rd Annual Meeting, May 13, 2020

*Data on file (Novellus)

ARDS Sheep Study

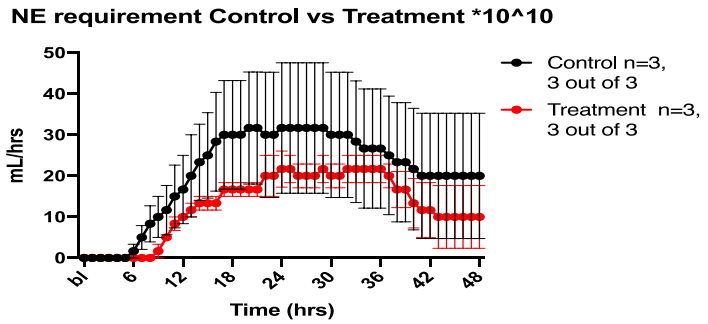
Interim Results: Very Strong Beneficial Effect of *i*-MSCs in Sheep Model of ARDS

P/F ratio



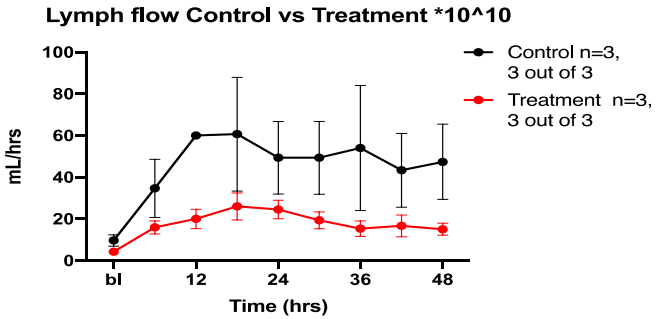
Improved Oxygenation

Norepinephrine Requirement

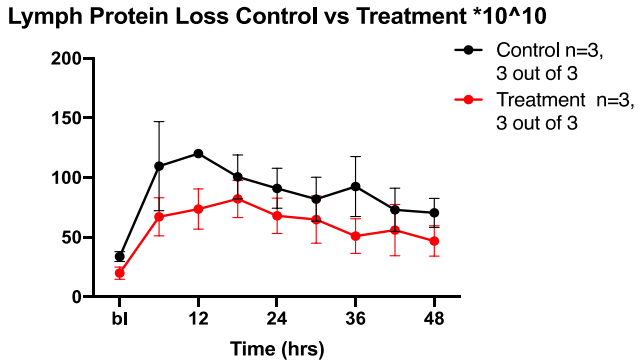


Less systemic shock

Pulmonary Lymph Flow



Pulmonary Lymph Protein Loss



Reduced Lung Vascular Injury

Overview of findings: In this ovine model of severe ARDS the animals receiving *i*-MSCs demonstrated clear improvement over control animals of several critical clinical parameters: 1) oxygenation (improved); 2) systemic BP (less shock/less pressor support); and 3) lung/alveolar permeability (decrease in production of excess lung lymph flow and associated protein loss) which persisted throughout the 48 hour course of the experiment

Our Solution – NoveCite *i*-MSCs

Description:

- Allogeneic (“off-the-shelf”) *i*-PSC-derived *induced* Mesenchymal Stem Cells
- High potency *i*-MSCs – *in vitro* data showing exponentially higher secretion of immunomodulatory proteins vs. BM-derived MSCs
- Footprint-free *i*-PSCs created using patented non-immunogenic mRNA process
- Clonal cells, telomere restored, unlimited supply, lower COGs
- “Superior” MSCs

How Supplied/Administered:

- Cells cryo-frozen 250 ml IV bag (saline), thawed and reconstituted with Plasmalyte prior to use
- IV infusion: will evaluate dosing range between 1-10 million cells/kg to determine OBD (optimal biological dose); a second dose may be given, at 48-96 hours, based on patient’s clinical status

Target Indication:

- Treatment of ARDS in Covid-19 patients

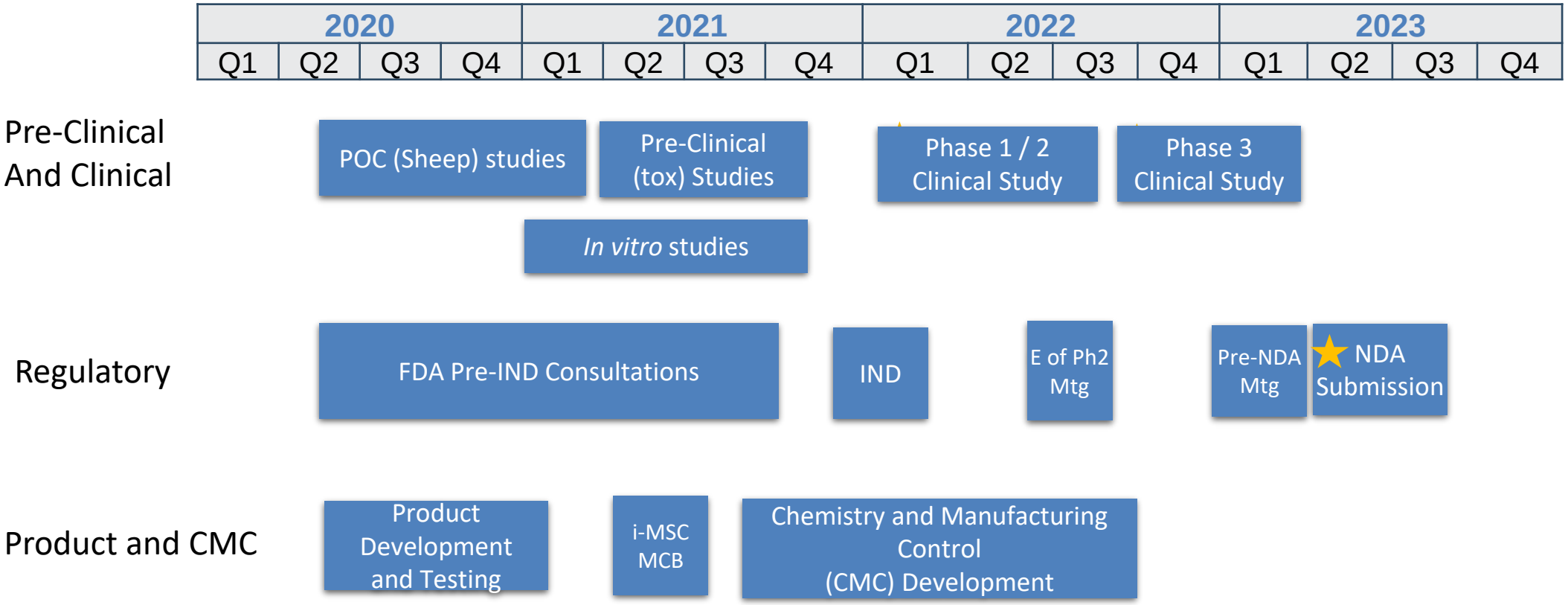
Future Indications:

- Treatment of acute inflammatory respiratory conditions

Clinical Development Plan (as of 12/2020)

Phase	Type	n	Description
1/2	Multi-center Phase 1 dose-finding study followed by a randomized placebo-controlled Phase 2 expansion phase to assess the safety, tolerability, and efficacy of iMSCs in patients with moderate to severe ARDS due to COVID-19	40 in phase 1 and 200 in phase 2	This is an adaptive design trial. The first part of the trial will serve as the phase 1 portion of the trial and will serve to establish safety in human subjects. The phase 1 portion will also serve as a dose-finding study. The phase 2 portion of the trial will take the selected dose forward into a larger patient population. The phase 2 portion will serve to establish safety of the selected dose in a larger population as well as an evaluation of efficacy endpoints. The results of this study will serve to establish the primary endpoint and help determine the sample size for the phase 3 study.
3	Multi-centered randomized placebo-controlled safety and efficacy evaluation of iMSCs for treatment of acute respiratory distress syndrome in patients with COVID-19	TBD	The primary objectives of the Phase 3 study are to confirm and expand on safety and effectiveness results from the Phase 1/2 studies of iMSCs as a treatment for subjects with moderate to severe ARDS due to COVID-19. The secondary objectives of this study are to evaluate tolerability, pulmonary function, mortality, and quality of life among survivors associated with iMSCs therapy as a treatment for subjects with moderate to severe ARDS due to COVID-19. This trial to serve as a pivotal trial for the NDA.

Clinical Development Plan (estimated as of 12/2020*)



*Best estimate subject to impact of Covid pandemic on operations

CITIUS PHARMA

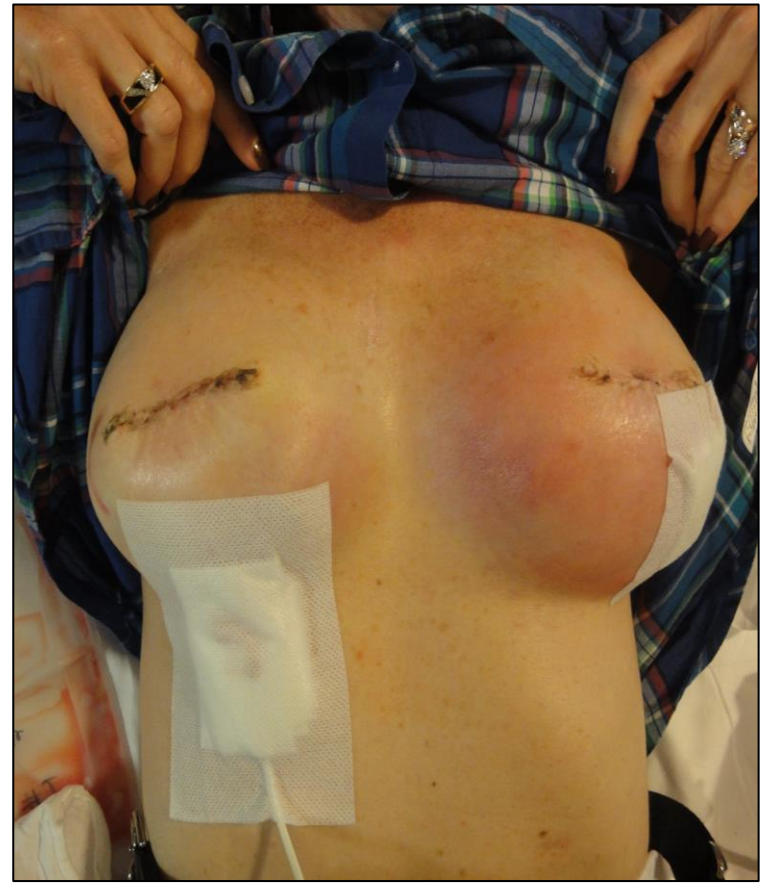
Mino-Wrap

CITI-101

Minocycline/Rifampin (M/R) Gelatin Film
Bioabsorbable Extended Release Antimicrobial Wrap for the
Prevention of Breast Tissue Expander Infections

Background: Rate of Infection Post-Mastectomy

- The rate of infection following mastectomy with tissue expander (TE) is 2.4 to 24%. Estimated mean is 12-14%*.
- Once the implant becomes infected, the patient is usually hospitalized requiring approximate 2 weeks of IV and/or oral antimicrobials; and the TE is removed leading to a delay of lifesaving chemoradiation therapy, and a more complex reconstruction in the future.
- The preventive measures used to decrease the rate of TE infections are (a) systemic perioperative antimicrobial agents, (b) perioperative immersion of the implant or irrigation of the surgical pocket with an antimicrobial solution prior to insertion of the device, and (c) immediate postoperative oral antimicrobials. Except for (a), all of the other preventive modalities are of debatable use.



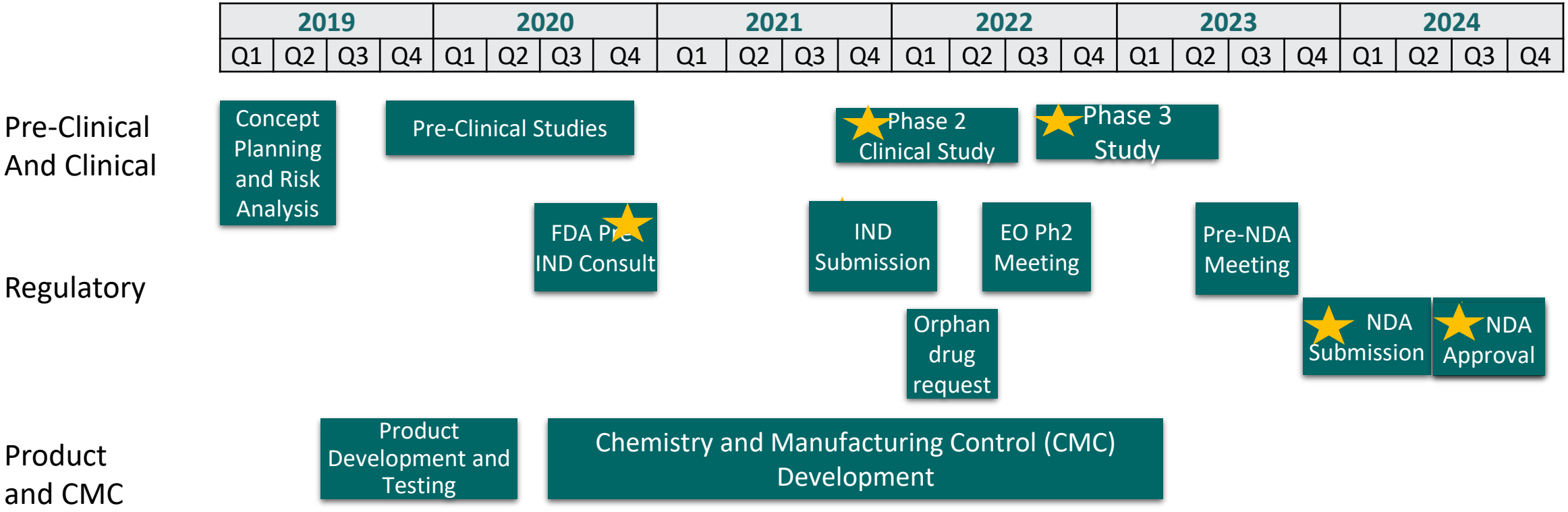
Armstrong RW. Ann Plast Surg 1989;23:284-8
Francis SH. Plast Reconstr Surg 2009;124:1790-6
Rosenblatt et al. 2015. Novel in situ liquefying antimicrobial wrap for preventing tissue expander infections following breast reconstructive surgeries. J Biomed Mater Res Part B 2015:00B.

*__Please note that the 12-14% estimate for mean infection rates is an estimate from clinicians and is not a published data point.__

Mino-Wrap: Thesis

- The highest risk for TE-related infections occurs at the time of surgery and as long as drains remain in place (about two weeks post-operatively) and there are portals for microbial colonization.
- Mino-Wrap is a malleable, bioabsorbable, antimicrobial wrap that is placed over the TE in the surgical pocket as a solid film. It swells and liquefies in situ for a specified period of time providing extended protection against infection from the most likely pathogens.
- Mino-Wrap is designed to allow the temporary tissue expander to be inflated without any restrictions, and to prevent infection and biofilm formation on the implant over longer durations than current practice.
- The current standard of care (SOC) appears to be inadequate as the mean infection rate is very high compared to common surgical infection rates.

Mino-Wrap Development Plan (estimated as of 12/2020*)



* Best estimate, subject to impact of Covid pandemic on operations.

Halo-Lido

CITI-002

Halobetasol/Lidocaine
Prescription Strength Topical for Symptomatic Hemorrhoid Treatment

CITI-002 (halobetasol + lidocaine)

Citius' product candidate would be the first FDA-approved prescription product to treat hemorrhoids in the US

OTC Products are the Mainstay for Treatment of Grade I and II

- Up to 5% of the U.S. population suffers from hemorrhoids, but there are no FDA-approved prescription products on the market
- Over 10 million patients admit to symptoms of hemorrhoidal disease and one-third of them seek physician treatment
- OTC hemorrhoid product sales are approximately 20 million units annually

Existing Rx Treatments: "Grandfathered Products"

- Several DESI topical cream formulations containing hydrocortisone and lidocaine are commonly prescribed to treat grade I and II hemorrhoids, but none are FDA-approved
- In 2011, more than 4 million prescriptions were written in the U.S. for hemorrhoidal medications
- Other topical DESI products for hemorrhoids contain hydrocortisone and pramoxine and have annual sales in excess of $80 million

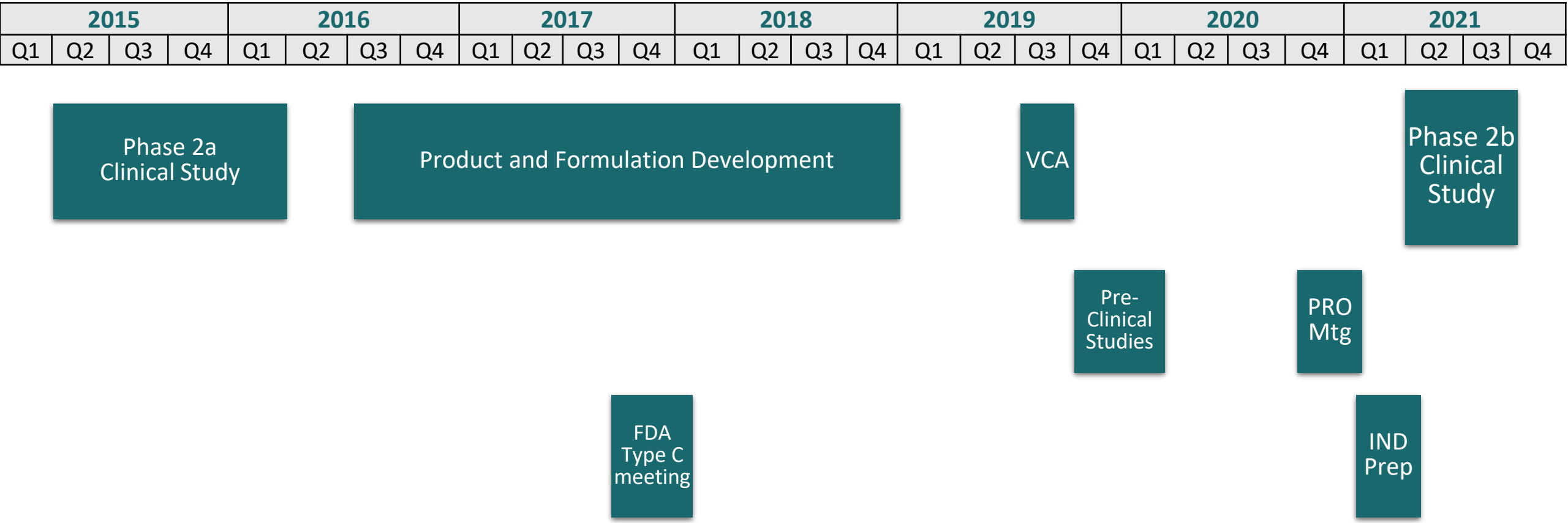
Commonly Used OTC Treatments

Prescription, Non-approved Treatments

Current Status

- Based on the results of phase 2 trial in 240 patients, CTXR elected to use super potent steroid Halobetasol propionate (HBP), maintained Lidocaine HCl (LH) and developed 10 prototype formulations
- Two formulations selected for Vasoconstriction Assay (VCA) studies
- A cream formulation containing novel excipient selected for phase 2b study
- Formulation met chemical, physical and stability criteria
- Manufacturing scale-up completed
- Pre-clinical toxicology testing in progress, initial results show acceptable profile
- IP evaluation in progress

Halo/Lido Development Plan (estimated as of 12/2020*)



* Best estimate, subject to impact of Covid pandemic on operations.

CITIUS Corporate Summary

- Addressing attractive diversified multi-billion dollar opportunities – Adjunctive Cancer Care/Infectious Disease and Gastrointestinal Disease
- Partnership with Novellus partnership and developing highly promising *i*-MSC product
- Partnership with MD Anderson Cancer Center in developing novel anti-infectives in cancer
- Portfolio addressing recognized unmet medical needs with cost-saving or cost-effective solutions with low risk development pathways
- Multiple staged near-term milestones anticipated
- Highly experienced and successful Management Team, Board of Directors, and Scientific Advisory Board

Financial Summary (as of 12/31/20)

Current Cap Table	Shares	% of Fully Diluted
Basic Shares Outstanding	55,576,996	64.7%
Warrants	26,831,988	31.3%
Options	3,390,166	3.9%
Unit Purchase Options	100,667	0.1%
Fully Diluted Shares Outstanding	**85,899,817**	**100%**

Principal Insider and Former Insider Shareholders (1)	
Leonard Mazur	(28.4%)
Myron Holubiak	(6.4%)
Reinier Beeuwkes, PhD	(1.1%)
Geoffrey Clark	(1.1%)

Stock Price	
Current Price	$1.02
52 Week High	$1.97
52 Week Low	$0.415

(1) Beneficial stock ownership as calculated under rules of the Securities Exchange Commission.

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