Citius Pharmaceuticals, Inc.

Corporate Presentation

Summer 2021

NASDAQ: CTXR

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CTXR 10 Q and 8-K with Press Release filed this morning (5/13)

Company Overview

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

Four Active Programs with a Late Stage Lead Asset	Lead 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); superior efficacy review in Q2 2021 (DMC).
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 successful pharma/biotech history; Advisors are KOL's in infectious disease, pulmonology (ARDS), breast surgery
Financing and Management Commitment	Citius is well funded for execution of the Business Plan; Management/Founders have invested $26.5 million into the company

MANAGEMENT TEAM WITH PROVEN TRACK RECORD



LEONARD MAZUR
EXECUTIVE CHAIRMAN, DIRECTOR



MYRON HOLUBIAK
PRESIDENT & CEO, DIRECTOR



JAMIE BARTUSHAK
EVP, CFO



DR. MYRON CZUCZMAN
EVP, CHIEF MEDICAL OFFICER



DR. ALAN LADER
VP, CLINICAL OPERATIONS



GARY TALARICO
EVP, OPERATIONS



ILANIT ALLEN
VP, INVESTOR RELATIONS

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

Ilanit Allen, VP, Corporate Communications & Investor Relations

- Over 20 years of experience in investor relations, corporate communications, finance and strategy with Fortune 500 companies, startups and two dozen private and public life science companies
- MBA, Harvard Business School; BA in Finance and International Relations, The Wharton School

FOUR ACTIVE PIPELINE PROGRAMS

PROGRAM	INVESTIGATIONAL INDICATION	ESTIMATED MARKET (WW)	PRECLINICAL	PHASE I	PHASE II	PHASE III	ANTICIPATED MILESTONES
MINO-LOK®	TREAT CVC INFECTIONS	> $1.8B					• DMC review • NDA
HALO-LIDO (CITI-002)	RX THERAPY FOR HEMORRHOIDS	> $2B					• IND • Phase 2b
MINO-WRAP (CITI-001)	PREVENT INFECTIONS ASSOCIATED WITH BREAST IMPLANTS	> $400M					• IND
NC *I*-MSC (CITI-401)	TREAT ARDS	Multi-billion					• IND

CITIUS PHARMA



Mino-Lok®



LEAD PRODUCT

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

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

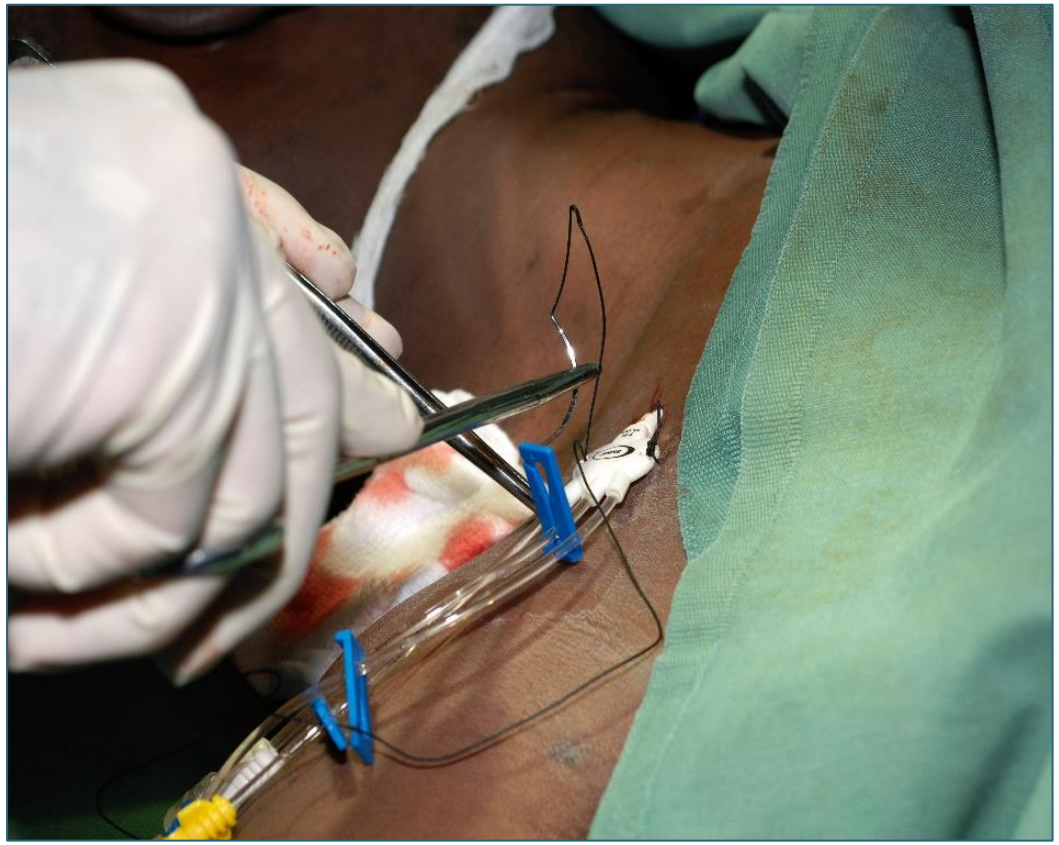
R&R Procedures are costly and usually require additional hospital stay.

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]

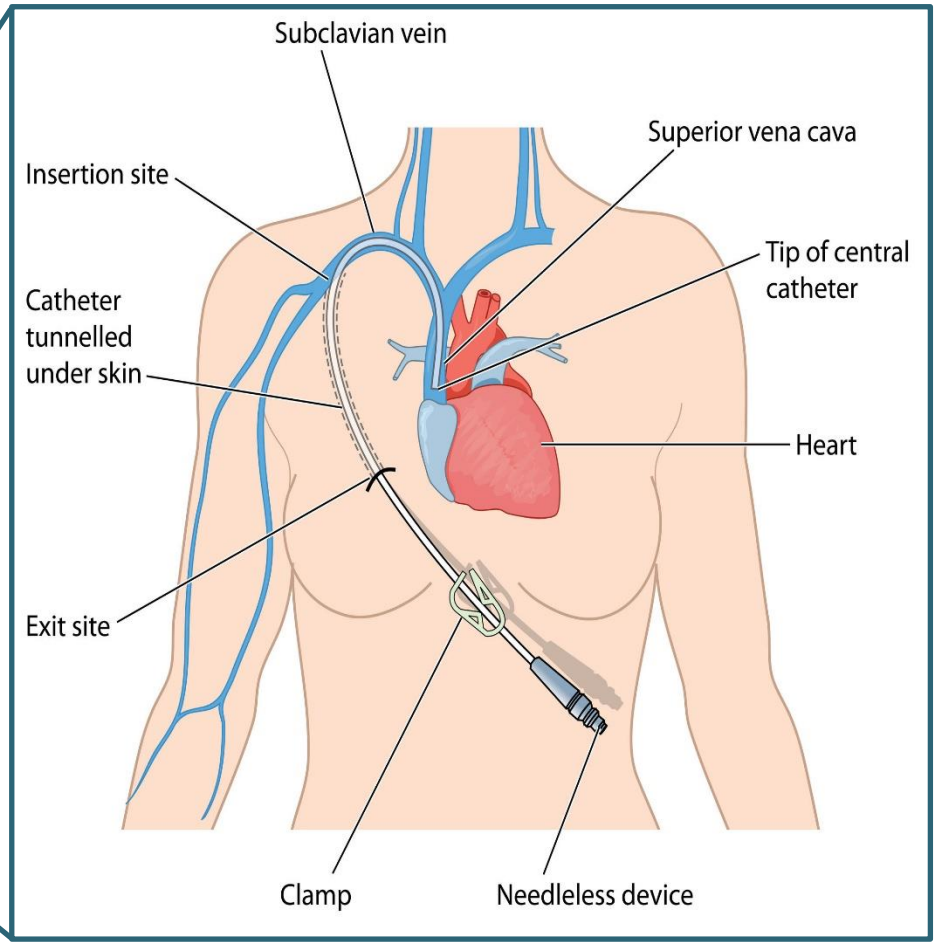


Sources (NCBI: Annals of Translational Medicine):

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

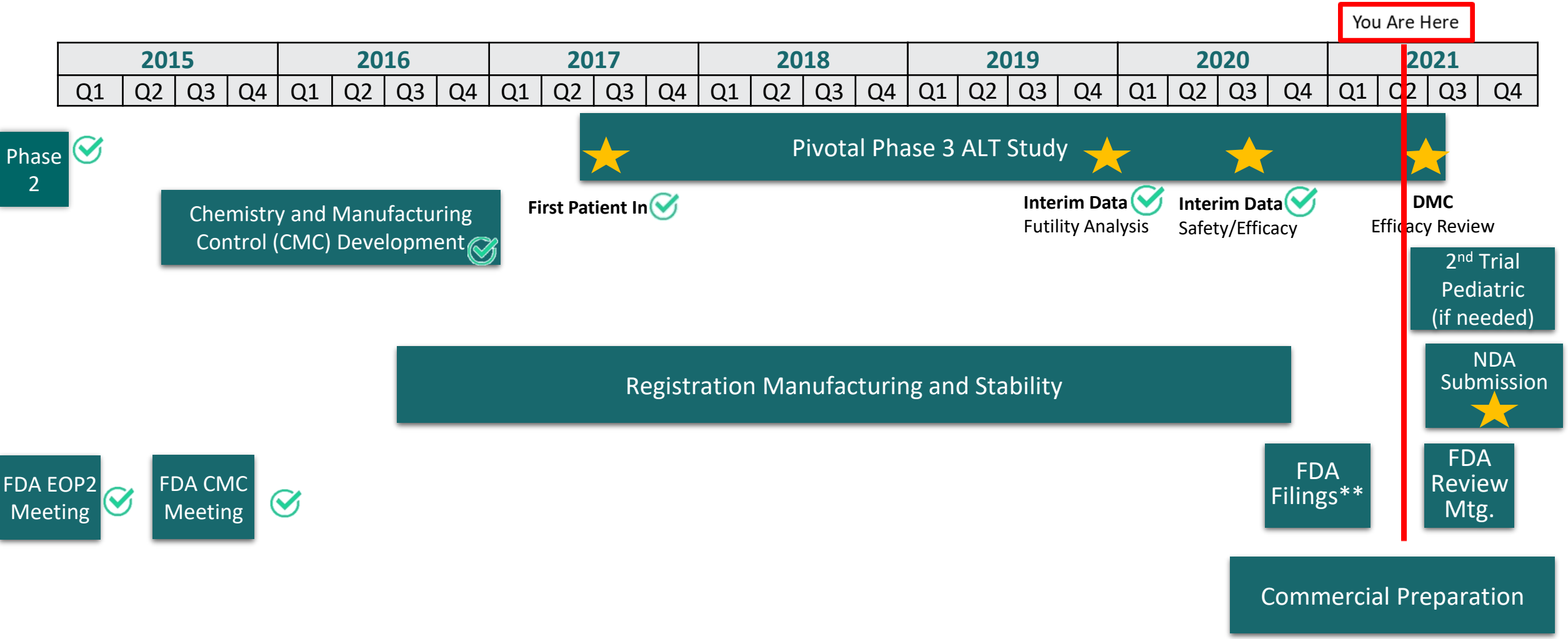
Control Arm (n=72)
Antibiotic Lock

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

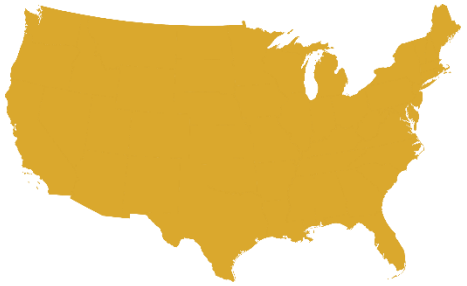
Mino-Lok® Development Plan (estimated as of 2/2021*)



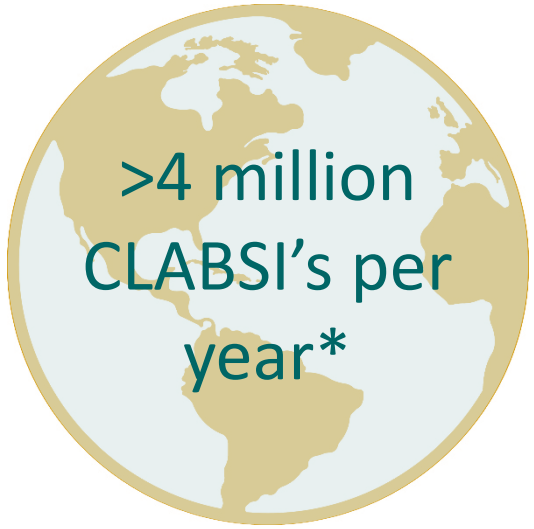
* best estimate, subject to impact of COVID-19 pandemic on clinical trial conduct.
** *in vitro* disc study…catheter integrity protocol

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")

CITIUS PHARMA

PLUS

Novellus™
Engineered Cellular Medicines

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

NoveCite Biotherapeutics

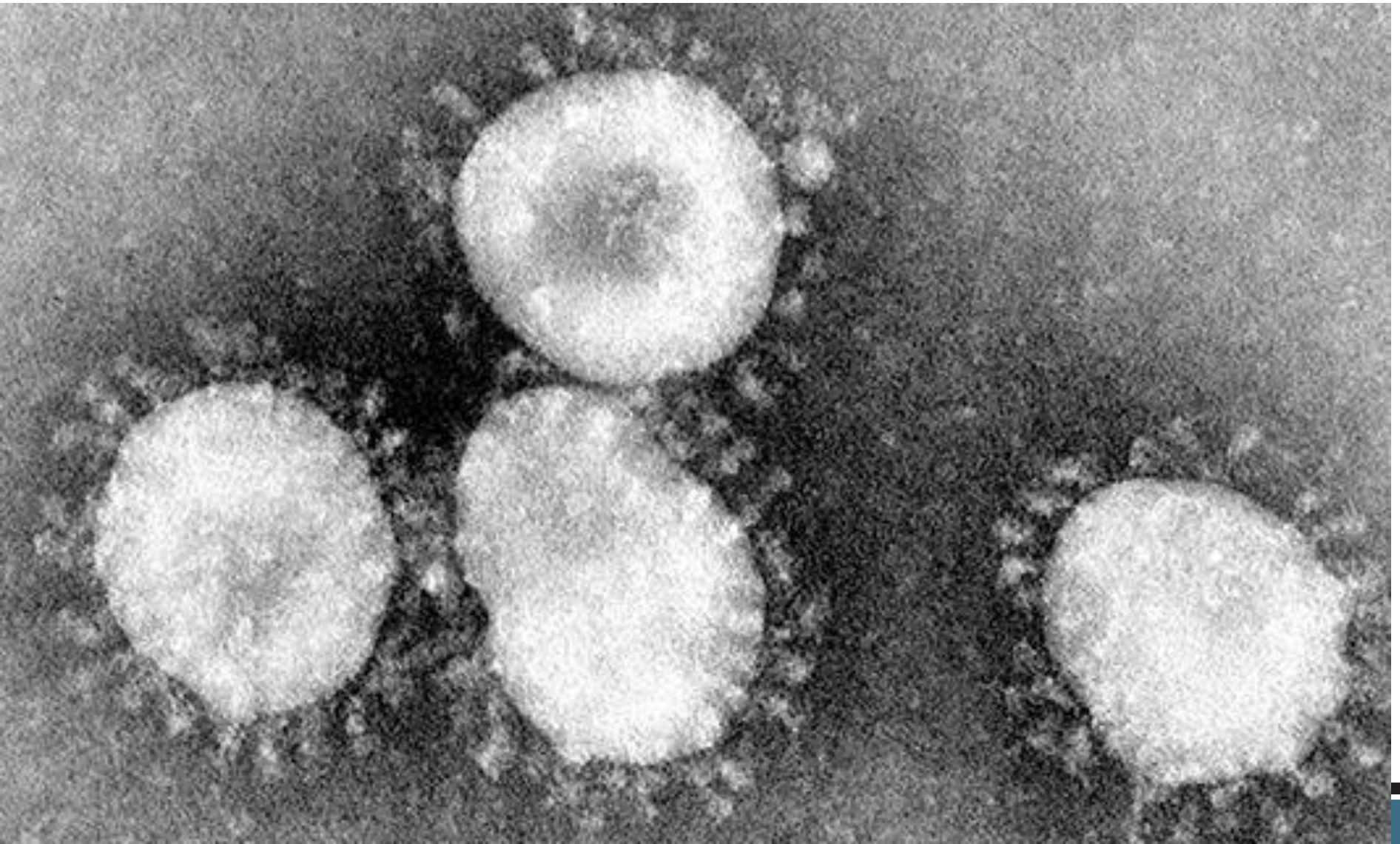
- Worldwide license for *i*-MSCs for acute respiratory conditions
- main focus is on ARDS associated with COVID-19
- developing the next generation of mesenchymal stem cells
- NoveCite cells are called *i*-MSCs
  - derived from an *i*-PSC master cell bank
- NoveCite is a subsidiary of Citius

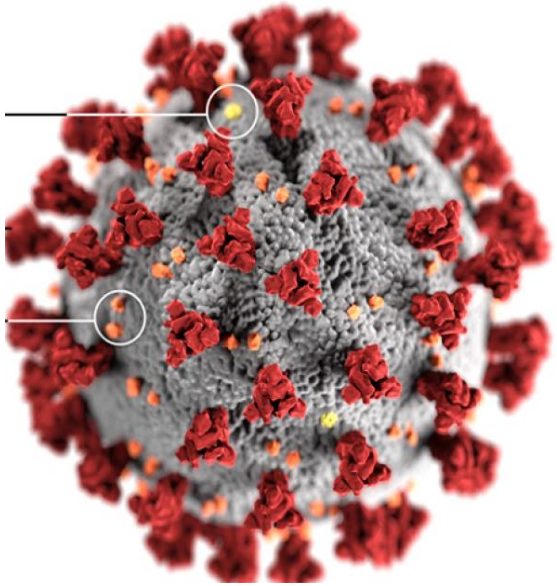
NoveCite *i*-MSC Compelling Unique Advantages

- 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 – consistent cell source - 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

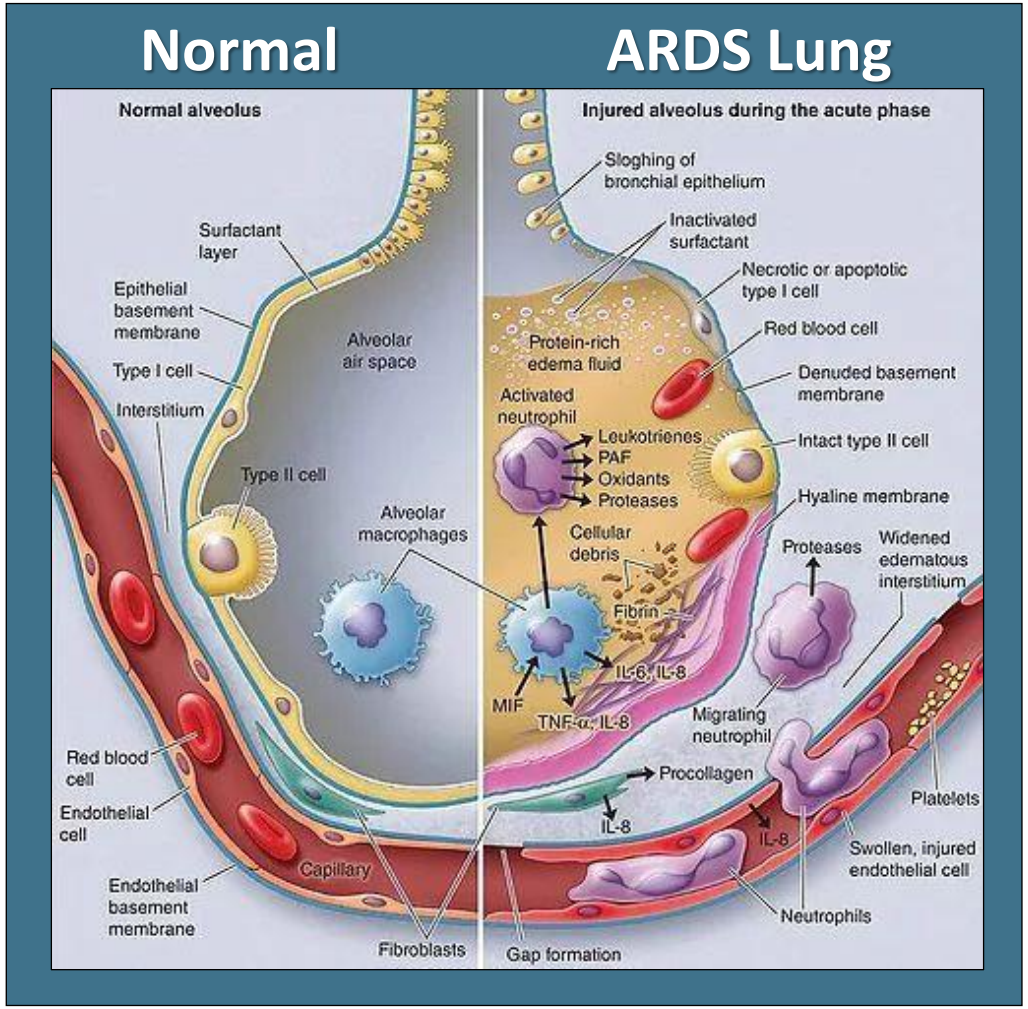
Severe acute respiratory syndrome coronavirus 2





SARS-CoV-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

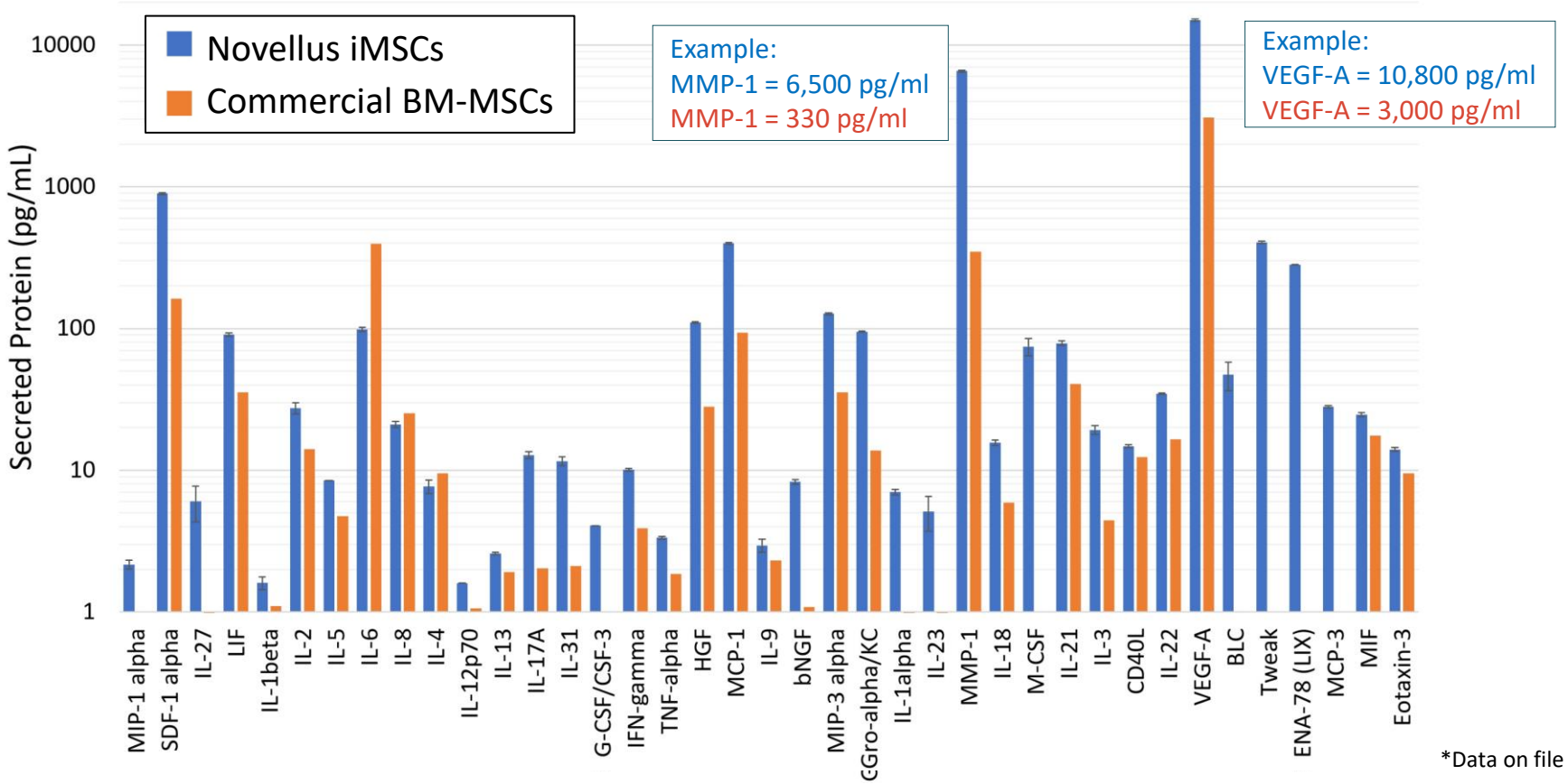
No FDA approved drug therapy for ARDS

Clinical Management

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

i-MSC Advantages: Levels of Immunomodulator Secretion

i-MSCs secrete higher levels of many immunomodulatory proteins



*Data on file (Novellus)

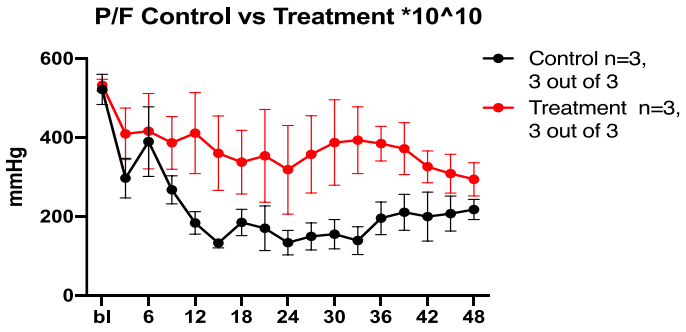
***MMP-1: member of the MMP family which contribute to homeostasis and a variety of physiological processes (e.g. immunity, wound healing, angiogenesis)**

****VEGF-A: mediates the growth of new blood vessels from pre-existing vessels (angiogenesis)**

ARDS Sheep Study

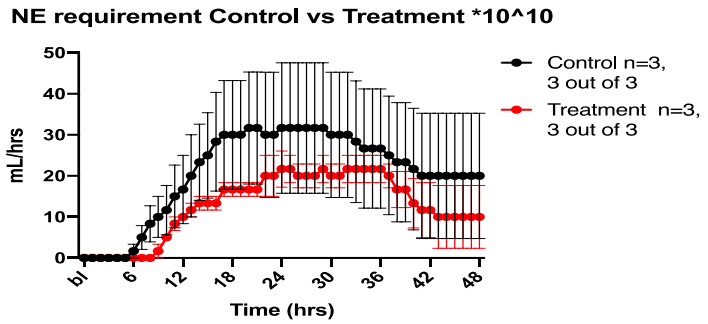
Interim Results: Very Strong Beneficial Effect of *i*-MSCs in Sheep Model of ARDS

P/F ratio



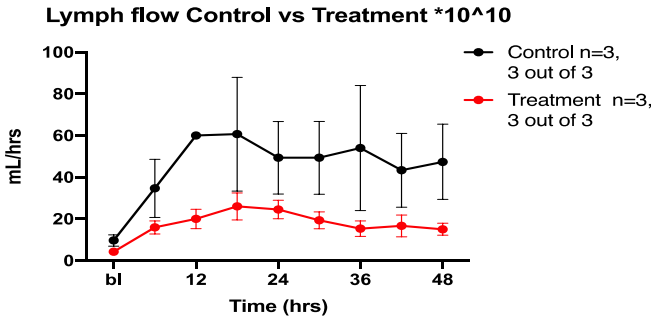
Improved Oxygenation

Norepinephrine Requirement

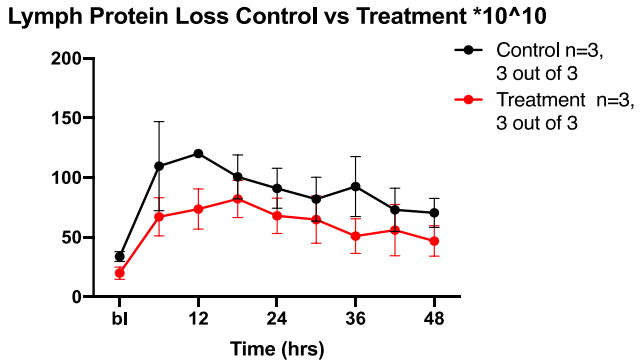


Less systemic shock

Pulmonary Lymph Flow



Pulmonary Lymph Protein Loss



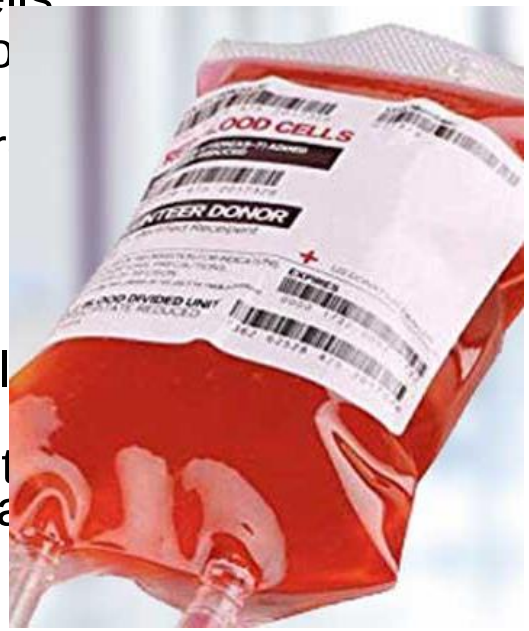
Reduced Lung Vascular Injury

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 secretio immunomodulatory proteins vs. BM-derived MSCs
- Footprint-free *i*-PSCs created using patented non-immunogenic mRNA pr
- 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 Pl use
- IV infusion: will evaluate dosing range between 1-10 million cells/kg to det (optimal biological dose); a second dose may be given, at 48-96 hours, ba clinical status

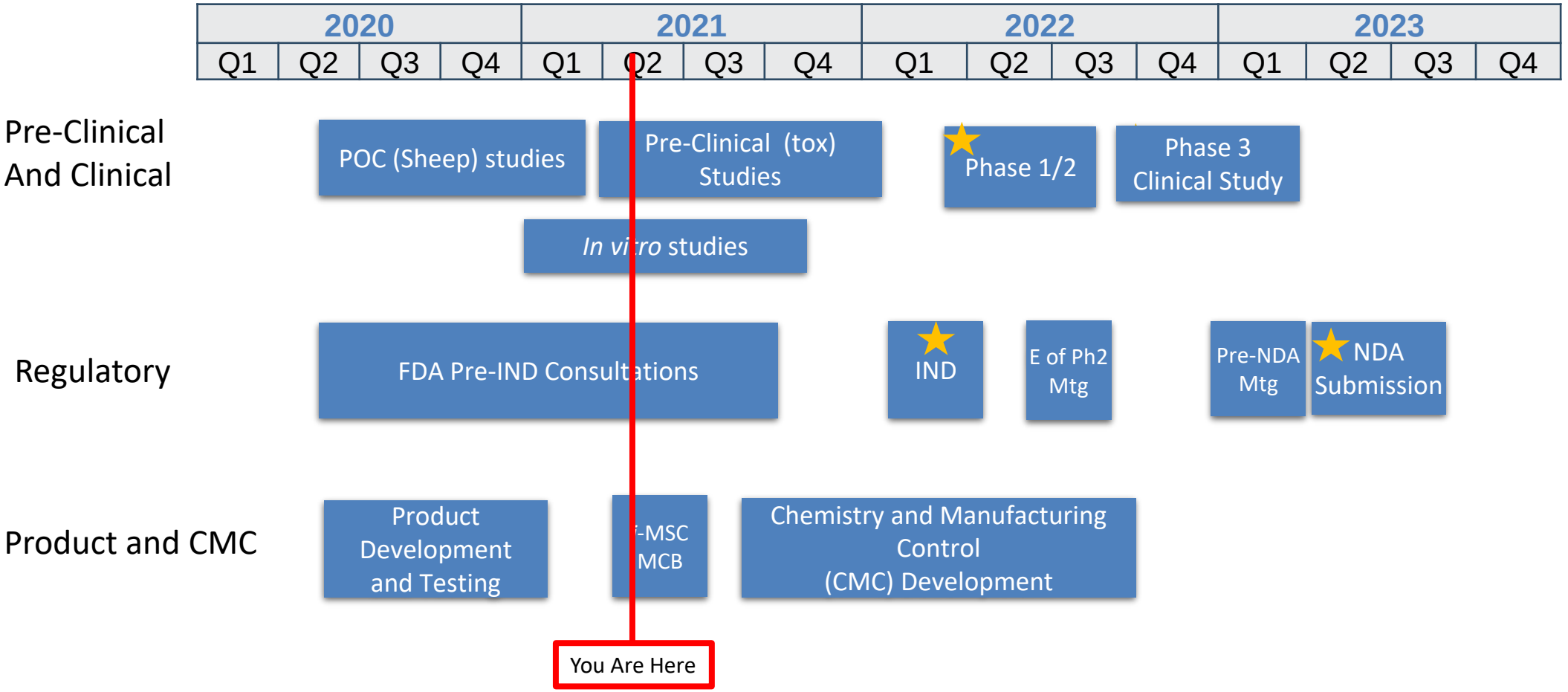
Target Indication:

- Treatment of ARDS in Covid-19 patients

Future Indications:

- Treatment of acute inflammatory respiratory conditions

CLINICAL DEVELOPMENT PLAN (ESTIMATED AS OF 2/2021*)



*Best estimate subject to impact of COVID-19 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.



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

FINANCIAL SUMMARY
(AS OF 03/31/21)

Bandwidth to Execute

- $103.7M in cash as of 3/31/21
- 1H 2021 R&D expense of $7.7M
- Runway into 2023
- $26.5M invested by insiders

CTXR STOCK PRICE*	
MARKET CAP	$290M
CURRENT PRICE	$2.18
52 WEEK HIGH	$2.90
52 WEEK LOW	$0.77

*As of May 6, 2021

CURRENT CAPITALIZATION	SHARES	% OF FULLY DILUTED
BASIC SHARES OUTSTANDING	134,701,219	70.6%
WARRANTS	51,569,059	27.0%
OPTIONS	4,615,171	2.4%
FULLY DILUTED SHARES OUTSTANDING	**190,885,449**	**100%**

PRINCIPAL INSIDER SHAREHOLDERS (1)	
LEONARD MAZUR	(12.6%)
MYRON HOLUBIAK	(2.7%)

(1) Beneficial stock ownership as calculated under rules of the Securities Exchange Commission as filed with the Citius Def 14 A Proxy Statement in April 2021.

Citius: why invest? Why now?

01 Portfolio addressing recognized unmet medical needs with cost-saving or cost-effective solutions with potential first-in-class products

02 Attractive diversified multi-billion dollar opportunities – Adjunctive Cancer Care/Infectious Disease and Gastrointestinal Disease

03 Strong research partnerships to advance pipeline
- MD Anderson Cancer Center in developing novel anti-infectives in cancer
- Novellus developing highly promising i-MSC product

04 Multiple staged near-term milestones anticipated

05 Well capitalized to advance pipeline and invest in long-term growth
- $103.7M in cash as of 3/31/21; runway into 2023
- $26.5M invested by management/founders

06 Seasoned executives with successful track record



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