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**Citius Pharmaceuticals, Inc.**  
(NASDAQ: CTXR)

**CORPORATE OVERVIEW**  
AUTUMN 2021



# FORWARD-LOOKING STATEMENTS

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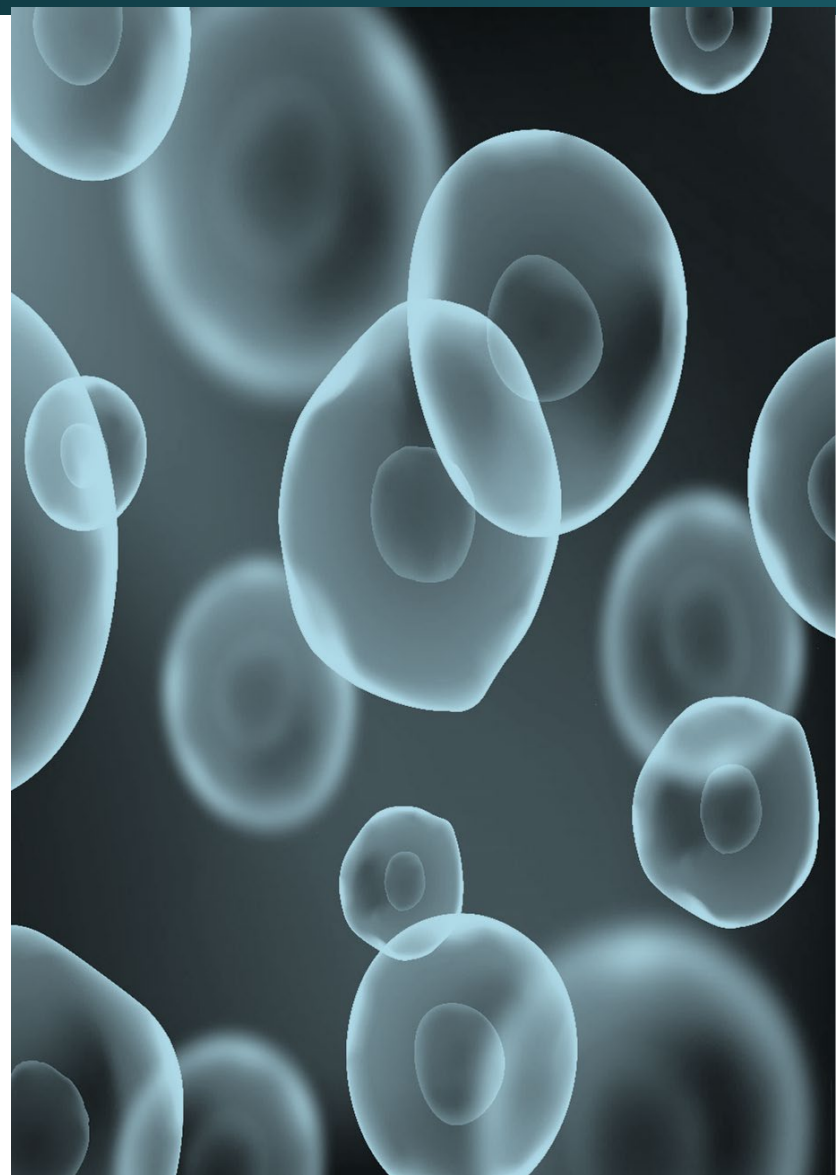
# OVERVIEW

Citius is a late-stage biopharmaceutical company focused on the development and commercialization of first-in-class critical care products, with a pipeline of anti-infectives in adjunct cancer care, stem cell therapy and unique prescription products

Olympic Motto

**Citius | Altius | Fortius**

**Faster | Higher | Stronger**



# INVESTMENT HIGHLIGHTS



## GROWING PIPELINE WITH LATE STAGE LEAD ASSET



## LARGE ADDRESSABLE MARKETS



## SEASONED MANAGEMENT & ADVISORS



## STRONG FINANCIAL PLATFORM

- **Diversified Pipeline with Four Active Programs**

- Mino-Lok® (Phase 3): potential to be **first and only** FDA-approved product to salvage infected CVCs causing CRBSI/CLABSI
- NC i-MSC™: novel mRNA stem cell therapy for acute respiratory distress syndrome (ARDS)
- Mino-Wrap: potential to be **first and only** FDA-approved product to prevent infections associated with post mastectomy breast implants
- Halo-Lido Rx: potential to be **first and only** FDA-approved Rx therapy for hemorrhoids

- **Multi-billion \$ global market opportunities**

- CRBSI/CLABSI market est. >\$1.8B worldwide
- ARDS market large with no approved therapies
- Tissue expander infection prevention est. \$400M worldwide
- Rx hemorrhoid market est. >\$2B US

- **Extensive pharma operational and financial track record**

- **Experienced “Blue Ribbon” Board of Directors**

- **Scientific Advisory Board of leading KOL’s in infectious disease, pulmonology (ARDS), and breast surgery**

- **Multi-billion \$ in successfully completed transactions pre-Citius**

- **Cash runway into 2023 (\$115.7M cash as of 6/30/21)**

- **\$26.5M invested by management / founders**



# THREE PILLARS OF OUR STRATEGY



## FASTER TO MARKET

Advance therapies with unique commercial advantages



## NEW CHEMICAL ENTITY BENEFITS

Invest in assets with differentiated upside potential







## FINANCIAL STEWARDSHIP

Create long-term sustainable value for shareholders

# FOUR ACTIVE PIPELINE PROGRAMS

Unlocking Potential. Faster.

PROGRAM	INVESTIGATIONAL INDICATION	ESTIMATED MARKET (WW)	PRECLINICAL	PHASE I	PHASE II	PHASE III	ANTICIPATED MILESTONES
MINO-LOK®	TREAT CVC INFECTIONS	> \$1.8B					• NDA 2022
HALO-LIDO (CITI-002)	Rx THERAPY FOR HEMORRHOIDS	> \$2B					• IND 2021 • Ph 2b 2021
MINO-WRAP (CITI-101)	PREVENT INFECTIONS ASSOCIATED WITH BREAST IMPLANTS	> \$400M					• IND 2022
NC i-MSC™ (CITI-401)	TREAT ARDS	Multi-billion					• IND 2022

\*As of 8/2021, best estimate subject to impact of COVID-19 pandemic on operations

# LEAD PRODUCT CANDIDATE: MINO-LOK<sup>®</sup>

First and Only antibiotic lock  
therapy under investigation to  
sterilize and salvage infected  
Central Venous Catheters (CVCs)



**7 Million**

Central Venous Catheters  
(CVCs) used annually in  
the U.S.\*



**4 Million**

Long-term CVCs  
(>1 month) in the U.S.

**~500,000**

CRBSI/CLABSI infections  
annually in the U.S.\*\*

**12-25%**

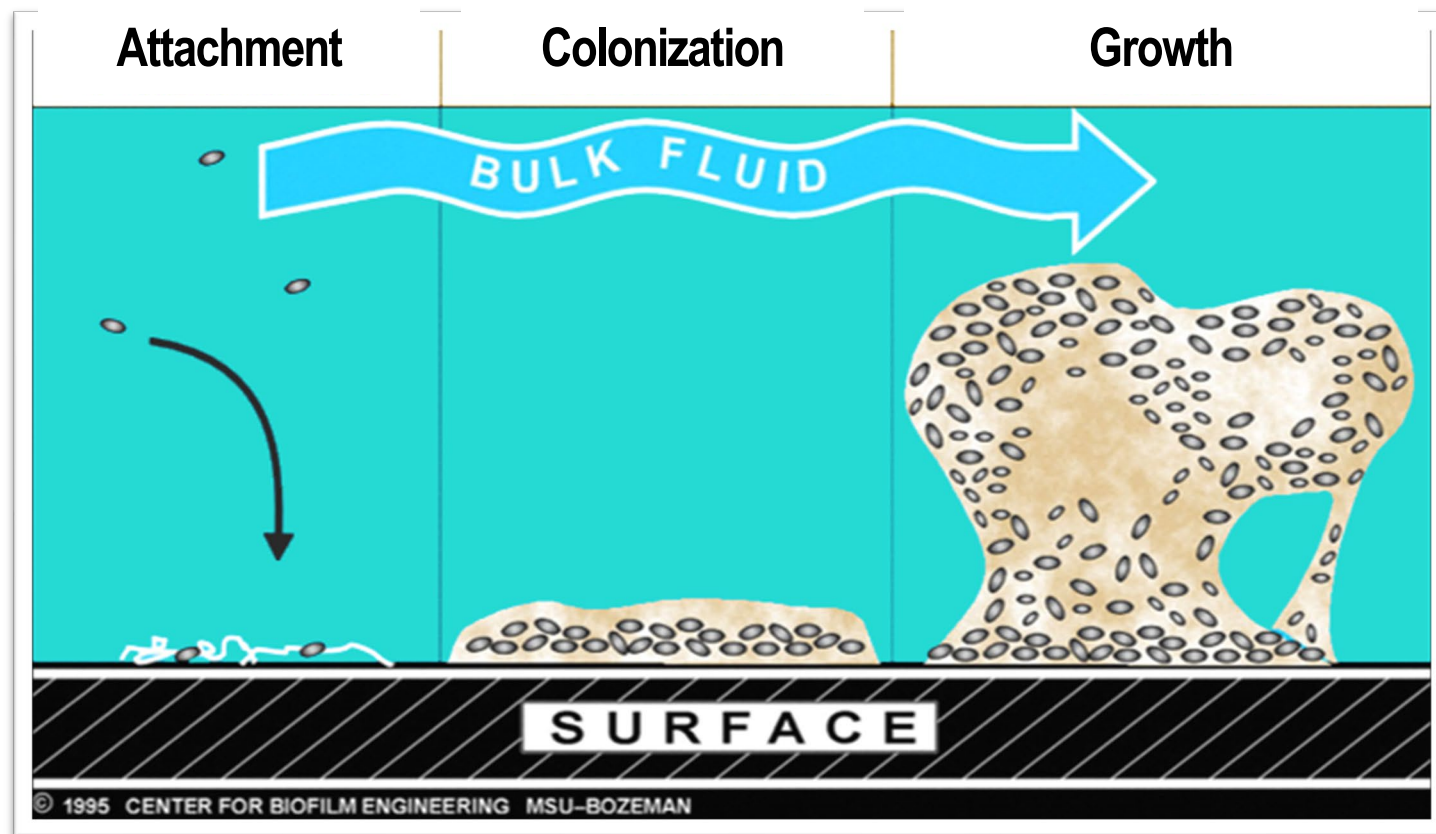
CRBSI/CLABSI  
associated mortality &  
morbidity\*\*

\* Shah H., Bosch W., Hellinger W. C., Thompson K. M. (2013). Intravascular catheter-related bloodstream infection. Neurohospitalist 3, 144–151. doi: 10.1177/1941874413476043.

\*\* Antoňáková Nĕmčíková A, Bednárovská E. Catheter-related bloodstream infections: do we know all of it? Klin Onkol. 2017;30(6):405–411. doi: 10.14735/amko2017405.

# MINO-LOK<sup>®</sup> PENETRATES BIOFILM

Biofilm prevents penetration of pathogen colonies by most traditional antibiotics



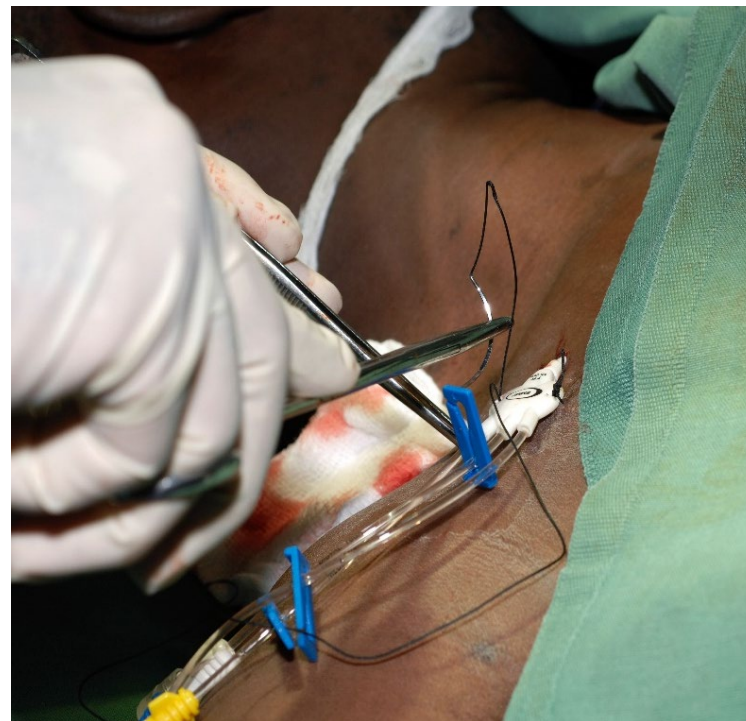
Biofilm Formation



# CURRENT STANDARD OF CARE IS A POOR OPTION

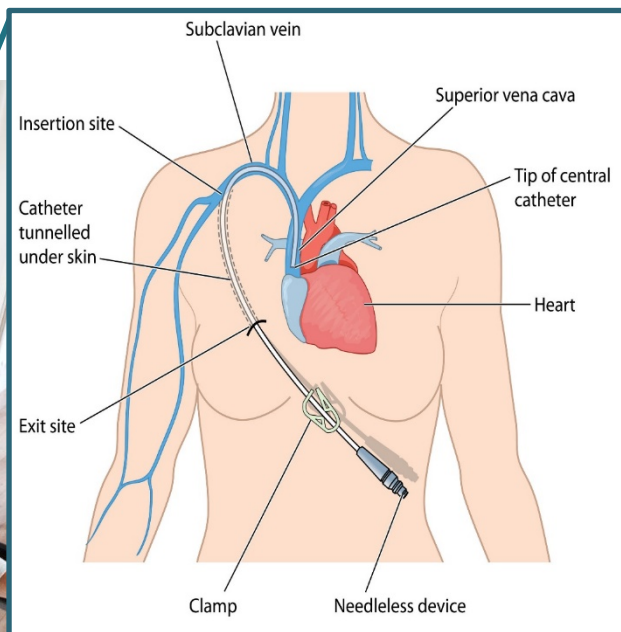
## Removing & replacing infected CVCs has multiple limitations

- Limited availability of other vascular sites
- Does not address need to maintain infusion therapy
- Potential for complications: infectious, thrombotic and mechanical
- 57%-67% of patients experience adverse physical and psychological symptoms from catheter R&R\*
- High cost
  - ~\$10K cost of R&R procedure
  - \$46K-\$65K cost of CRBSI/CLABSI episode




# POTENTIAL GOLD STANDARD IN CLABSI TREATMENT

Mino-Lok® addresses the complications, discomfort and cost of CVC removal and replacement



✓ Limited duration IV therapy

 **× 5-7 DAYS**

✓ Limits disruption of infusion therapy

✓ Ease of Administration

- Locking a catheter is a well known SOP
- Procedure can be performed by any healthcare provider

✓ Not flushed into the venous system

✓ Lower cost alternative

- Significantly < R&R

# MINO-LOK® PHASE 2B TRIAL RESULTS

**100%** Effective in salvaging CVCs in all patients treated with Mino-Lok®

**100%** Patients treated with Mino-Lok® all had complete microbiologic eradication with no relapse

**0%** No SAEs in patients treated with Mino-Lok®

**0%** Complication rate for Mino-Lok® patients was 0% vs. 18% for control arm patients

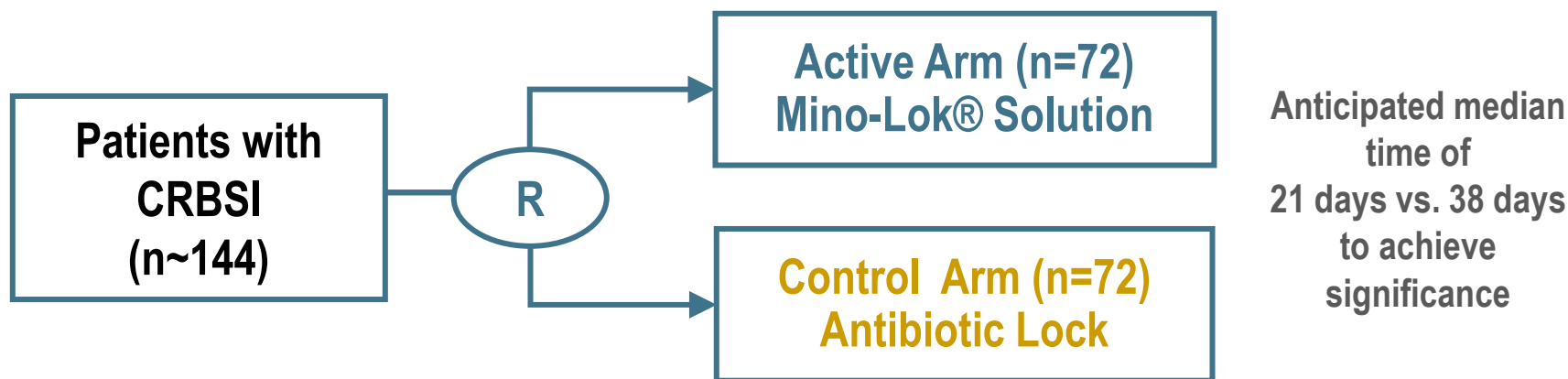
Mino-Lok® demonstrated a strong safety and efficacy signal

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

\*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 UNDERWAY

Multi-center, randomized, open label, blinded assessor, active control superiority study



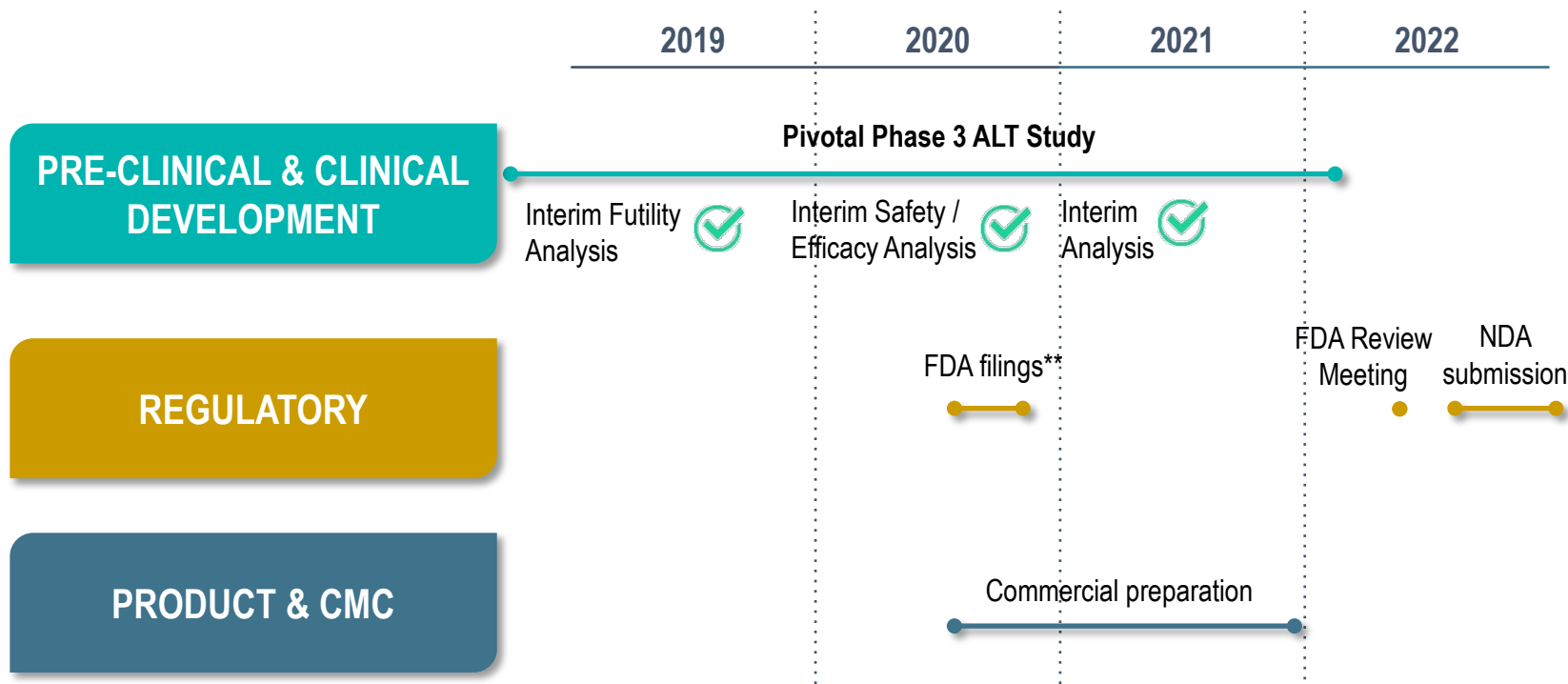
Primary Endpoint: Comparison of “Time to Catheter Failure” TOC = 6 weeks (42 days)

## Interim Analyses:

- Futility performed at 35-40 events; superior efficacy and futility at 50% and 65% of anticipated events
- DMC recommended proceeding with trial without modification following all 3 reviews

# MINO-LOK<sup>®</sup> DEVELOPMENT PLAN\*

## Completing Phase 3 pivotal superiority trial



\*As of 8/2021, best estimate subject to impact of COVID-19 pandemic on operations

\*\* in vitro disc study...catheter integrity protocol



# IP PROTECTION THROUGH 2036

Mino-Lok® is supported by a robust intellectual property portfolio

- Composition of Matter and Method of Use patents that provide protection until June 2024
- Formulation patent has been issued and will add protection through 2036

Creators	Description of Patent	Patent Numbers	Issued	Expiry
Issam Raad, M.D. et al	Composition of Matter	<ul style="list-style-type: none"><li>• US: 7,601,731</li><li>• EP: 04754538.9</li><li>• CA: 2,528,522</li></ul>	2009	2024
Issam Raad, M.D. Joel Rosenblatt, Ph.D. et al	Formulation/Enhanced Stability	<ul style="list-style-type: none"><li>• US: 10,086,114</li><li>• Pub.No.: US 2017/051373 A1</li><li>• Global IP: UTFC.P1283WO</li></ul>	2018	2036
Issam Raad, M.D. et al	Method of Use	<ul style="list-style-type: none"><li>• US: 9,078,441</li><li>• EP: 1644024</li><li>• CA: 2528522</li></ul>	2015	2024



# REGULATORY PROTECTIONS

## Qualified Infectious Disease Product (US)

- Priority Review reduces NDA review time from 12 to 6 months
- Additional 5 years of market exclusivity upon approval, combined with Hatch-Waxman

## Fast Track Designation (US)

- Expedites review of drugs which treat a serious or life-threatening condition and fills an unmet medical need
- Rolling review allows for completed sections of the New Drug Application (NDA) to be submitted when ready


## Supplementary Protection Certificate (EU)

- Extends patent protection up to 5 years

# COMPETITIVE LANDSCAPE

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

- No company has US regulatory approval
- There are no lock solutions in development for treating CRBSI patients and salvaging indwelling, infected CVCs
- CorMedix is focused on development of lock solutions for the prevention of CRBSI in hemodialysis patients

Company	Product	Status	Limitation
 CorMedix™	Defencath™	NDA accepted by the FDA in August 2020 CRL received from FDA in March 2021 Available in Europe (CE Mark)	<b>Prevention only</b> Anti-infective only being used in prophylaxis

# MARKET OPPORTUNITY

With modest penetration at conservative pricing >\$500M peak year US sales achievable with a worldwide opportunity of \$1.8B

## United States



**PURSUE DIRECTLY**

**>4 million CLABSI's  
per year\***

## Ex-US



**PARTNER**

### Regulatory Environment

DISARM Act pending

- create a DRG carveout for QIDP products
- Allow for full reimbursement for CMS programs; not part of the payment bundle

### Reimbursement

Apply for NTAP (all QDIP), increased to 75% of list price

Apply for transitional pass-through reimbursement

### Commercial

#### Pricing

Cost-Saving Mino-Lok will be < R&R

Targeting Accounts with high CLABSI medical claims

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

# MINO-LOK<sup>®</sup> SUMMARY

Potential market-leading antibiotic lock therapy to salvage the CVC in patients with CRBSI/CLABSI

## Patented solution



- Breaks down biofilm barriers
- Provides anti-clotting properties to maintain CVC patency
- Worldwide license from The University of Texas MD Anderson Cancer Center (MDACC)
- Patent protection through 2036

## Market Opportunity



- First and only therapy under investigation to salvage infected CVCs
- Est. >\$1.8B WW sales opportunity
- Cost advantage over current SOC
- No direct competition
- ~16 years of exclusivity at time of launch

## Clinical & regulatory milestones



- Phase 2b trial: 100% effective in salvaging CVCs with no SAEs
- Phase 3 multicenter trial is currently enrolling patients
- QIDP & Fast Track designation

## Key Advantages



- Effective at penetrating biofilm
- Avoids R&R complications
- Shorter treatment time
- Lower cost to providers and patients
- Benefits support rapid and sustained market penetration



# EXPANDING PORTFOLIO: ENGINEERED STEM CELL THERAPY



Privately-held pre-clinical stage biotechnology company with patented non-immunogenic mRNA technology for gene editing (acquired by Brooklyn ImmunoTherapeutics, Inc. (NYSE American: BTX) in July 2021)



**Majority-owned subsidiary of Citius**

**Developing next generation mesenchymal stem cells (NC *i*-MSCs™)**

**Derived from an iPSC master cell bank**

**Primary focus is ARDS**

**Worldwide license for respiratory conditions associated with acute inflammation**

**Strong patent protection**



# DIFFERENTIATED STEM CELL PLATFORM

Next generation allogeneic engineered stem cell platform under development for the treatment of ARDS

## SINGLE DONOR / CLONAL

- Genetically identical *i*-MSCs™ derived from mutation-free iPSCs
- One homogeneous, validated source for all future cells
- NO repeat harvesting from multiple donors; NO repeat donor testing

## MORE POTENT

- Higher levels of therapeutic proteins compared to donor-derived cells

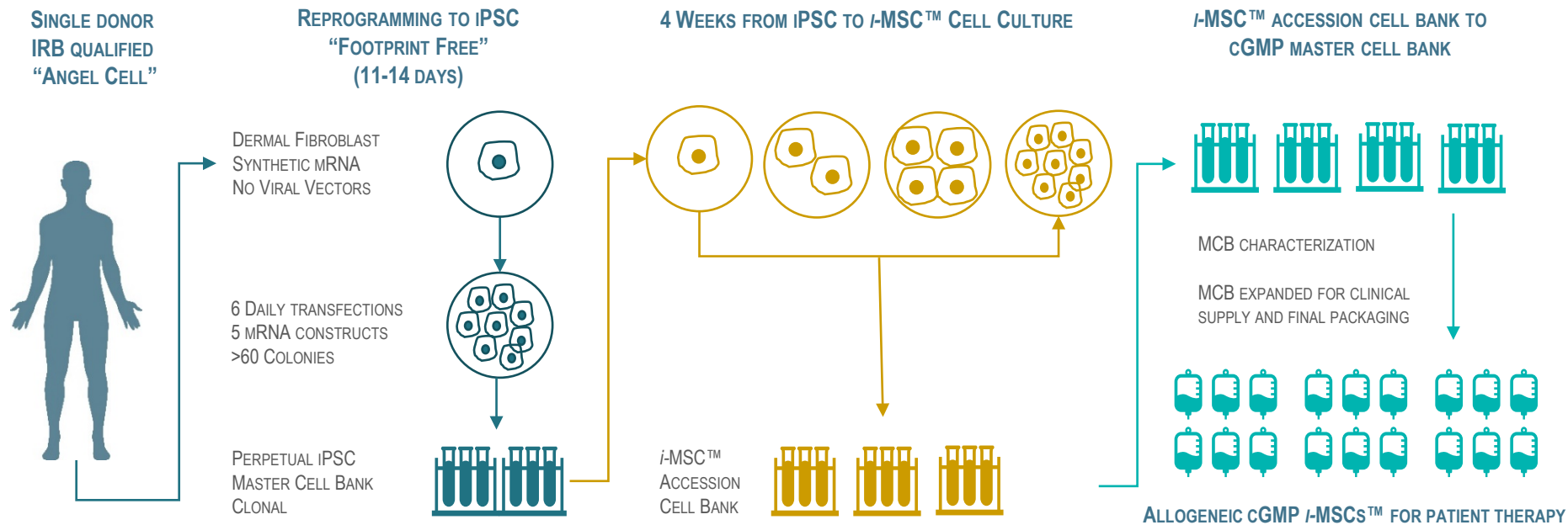
## RESTORED TELOMERES

- Result in longer therapeutic lifespan compared to donor-derived cells

## SCALABLE MFG

- Rapid production from master *i*-MSC™ cell bank
- Substantial expansion potential (trillions of cells for higher and repeat doses)

# *i*-MSCs™: FROM ONE CELL TO TRILLIONS



One homogeneous, validated source for all future cells

Patented synthetic, non-immunogenic mRNA high efficiency cell reprogramming

Virtually limitless number of cells from "Angel Cell"

Rapid 4-week production process from iPSC cell bank

Performance enhanced with longer therapeutic lifespan *i*-MSCs

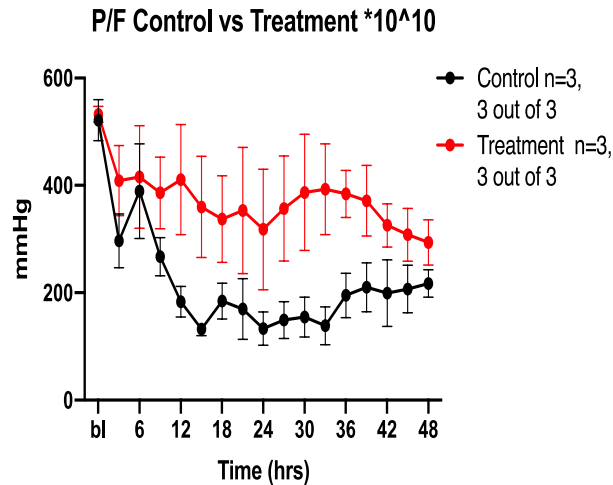
cGMP compliant scalable manufacturing for preclinical and clinical studies

*i*-MSCs™ packaged in cryopreserved mini-bags

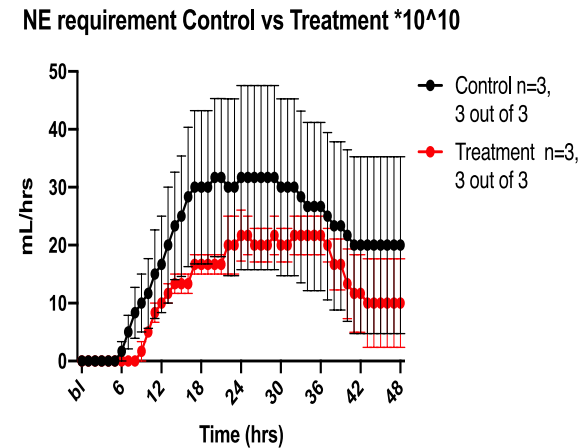
# INTERIM RESULTS OF *i*-MSC™ STUDY IN SHEEP MODEL OF ARDS

Animals receiving *i*-MSCs™  
demonstrated stronger  
therapeutic effects v. control

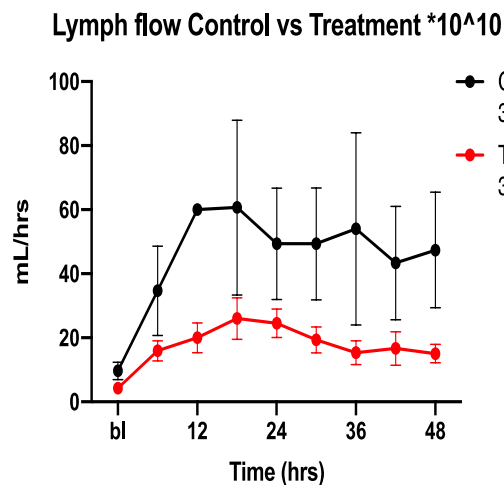
## Improved Oxygenation



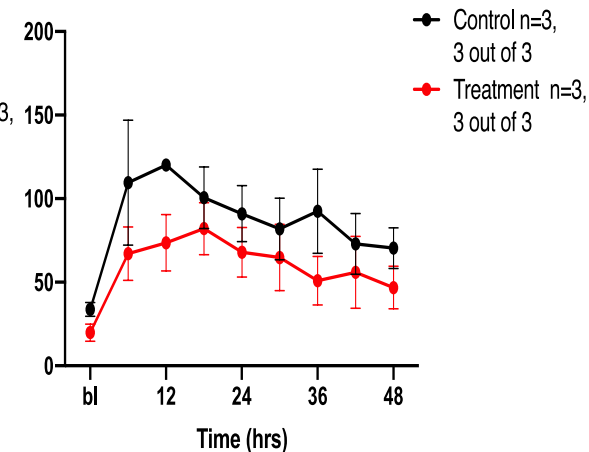
## Less Systemic Shock



## Reduced Lung Vascular Injury

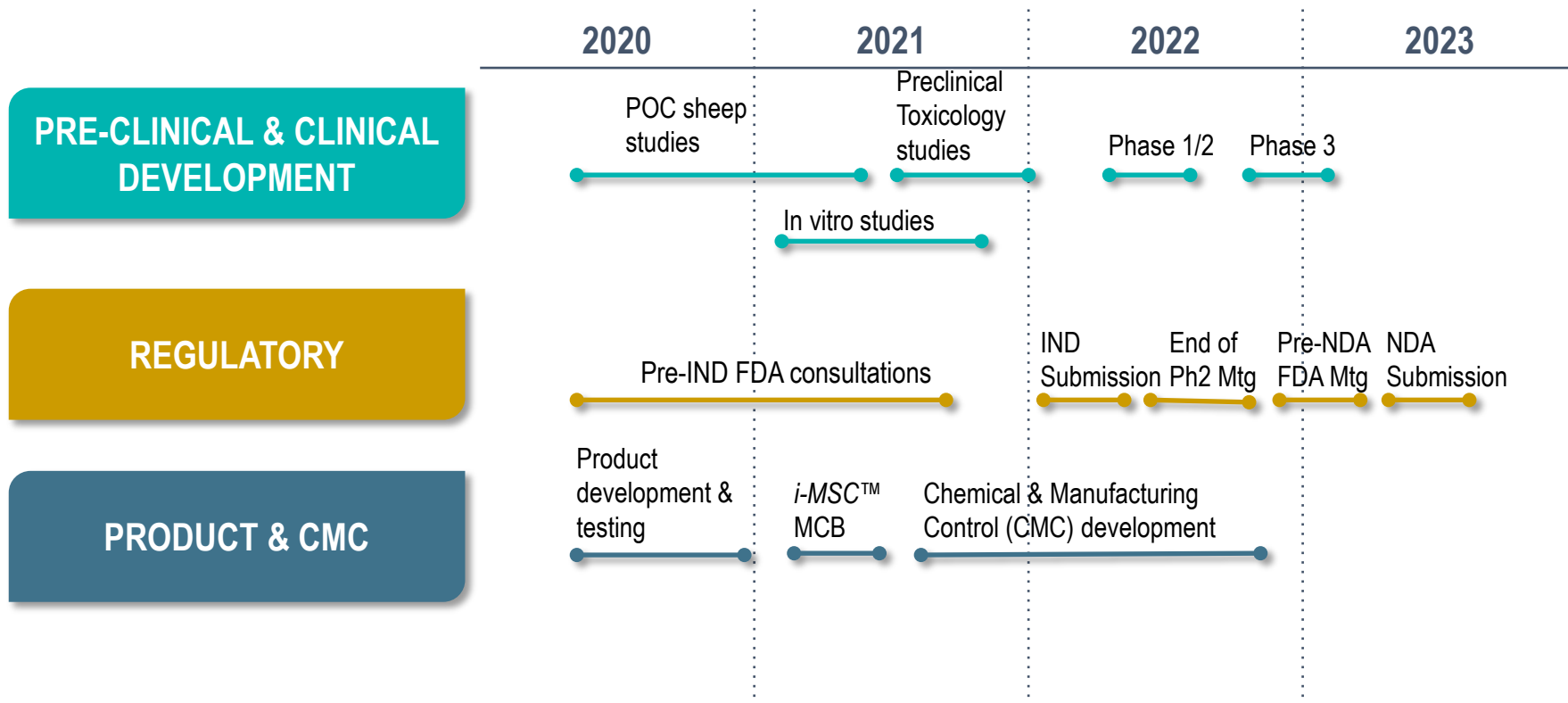


## Lymph Protein Loss Control vs Treatment \*10<sup>10</sup>



# NC *i*-MSC™ DEVELOPMENT PLAN\*

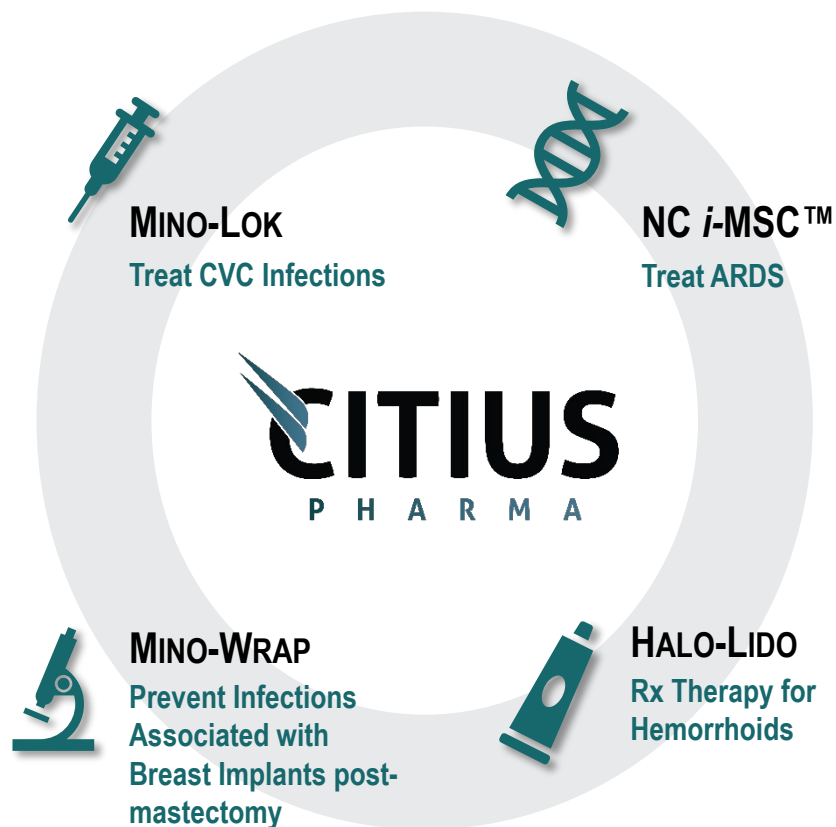
Preparing cGMP NC *i*-MSC™ Master Cell Bank to support future trials, with IND submission planned for 2022



\*As of 8/2021, best estimate subject to impact of COVID-19 pandemic on operations



# DIVERSIFIED PIPELINE WITH NEAR TERM CATALYSTS



Q3 2021

- Mino-Lok® trial proceeding as planned following DMC recommendation

Q4 2021

- Halo-Lido (CITI-002) IND filing
- Halo-Lido (CITI-002) Phase 2b trial start

2022

- Mino-Lok® NDA filing
- Mino-Wrap (CITI-101) IND filing
- NC *i*-MSC™ (CITI-401) IND filing

\*As of 8/2021, best estimate subject to impact of COVID-19 pandemic on operations

# MANAGEMENT TEAM WITH PROVEN TRACK RECORD



LEONARD MAZUR  
EXEC. CHAIRMAN, DIRECTOR



MYRON HOLUBIAK  
PRESIDENT & CEO, DIRECTOR



JAIME BARTUSHAK  
EVP, CFO



DR. MYRON CZUCZMAN  
EVP, CHIEF MEDICAL OFFICER



GARY TALARICO  
EVP, OPERATIONS



JAY WADEKAR  
VP, BUSINESS STRATEGY



DR. ALAN LADER  
VP, CLINICAL OPERATIONS



PAUL SOWYRDA  
VP, PROGRAM DIR., ONCOLOGY



JOHN WESTMAN  
VP, PROGRAM MANAGEMENT



ILANIT ALLEN  
INVESTOR RELATIONS



# SCIENTIFIC ADVISORY BOARD OF LEADING KOLS

## INFECTIOUS DISEASE / CANCER ADVISORS

**Isaam Raad, MD**

University of Texas MD Anderson Cancer Center

**Mark Rupp, MD**

University of Nebraska Medical Center

**Leonard A. Mermel, DO**

US Dept. of Health & Human Services

**Jesse Selber, MD**

University of Texas MD Anderson Cancer Center

**George Viola, MD**

The University of Texas MD Anderson Cancer Center,  
Baylor College of Medicine

**Joel Rosenblatt, PhD**

The University of Texas MD Anderson Cancer Center

## CELL THERAPY ADVISORS

**Michael A. Matthay, MD**

University of California at San Francisco (UCSF)

**Lorraine B. Ware, MD**

Vanderbilt University

**Mitchell M. Levy, MD**

Brown University, Rhode Island Hospital

**John Laffey MD, MA, FCAI, FJFICMI**

National University of Ireland (NUI Galway)

**Perenlei Enkhbaatar MD, PhD, FAHA**

University of Texas

# FINANCIAL SUMMARY\*

## Bandwidth to Execute

- \$127.6M Financing activities 1H 2021
- \$7.7M R&D expense 1H 2021
- Runway into 2023
- \$26.5M invested by insiders

\*As of 06/30/21 unless otherwise noted.

CURRENT CAPITALIZATION	SHARES	% OF FULLY DILUTED
BASIC SHARES OUTSTANDING	145,979,429	76.5%
WARRANTS	40,234,172	21.1%
OPTIONS	4,655,166	2.4%
FULLY DILUTED SHARES OUTSTANDING	190,868,767	100%


## PRINCIPAL INSIDER SHAREHOLDERS <sup>(1)</sup>

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?



Diversified pipeline of potential first-in-class products addressing recognized unmet medical needs



Attractive diversified multi-billion dollar opportunities in adjunctive cancer care, infectious disease and gastrointestinal disease



Strong research partnerships to advance pipeline

- MD Anderson Cancer Center in developing novel anti-infectives in cancer
- Novellus developing promising *i*-MSC™ therapy



Multiple staged near-term catalysts anticipated



Well capitalized to advance pipeline and invest in long-term growth

- \$115.7M in cash as of 6/30/21; runway into 2023
- \$26.5M invested by insiders



Seasoned executives with successful execution-focused track record



The background of the slide features a glowing blue DNA double helix structure, composed of numerous small dots connected by lines. Overlaid on this are several thin, golden-yellow wavy lines that resemble chemical pathways or molecular structures. The overall color scheme is dark blue with bright blue and golden-yellow highlights.

# CITIUS

P H A R M A

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