



Citius Pharmaceuticals, Inc.
(NASDAQ: CTXR)

CORPORATE OVERVIEW
AUTUMN 2021



FORWARD-LOOKING STATEMENTS

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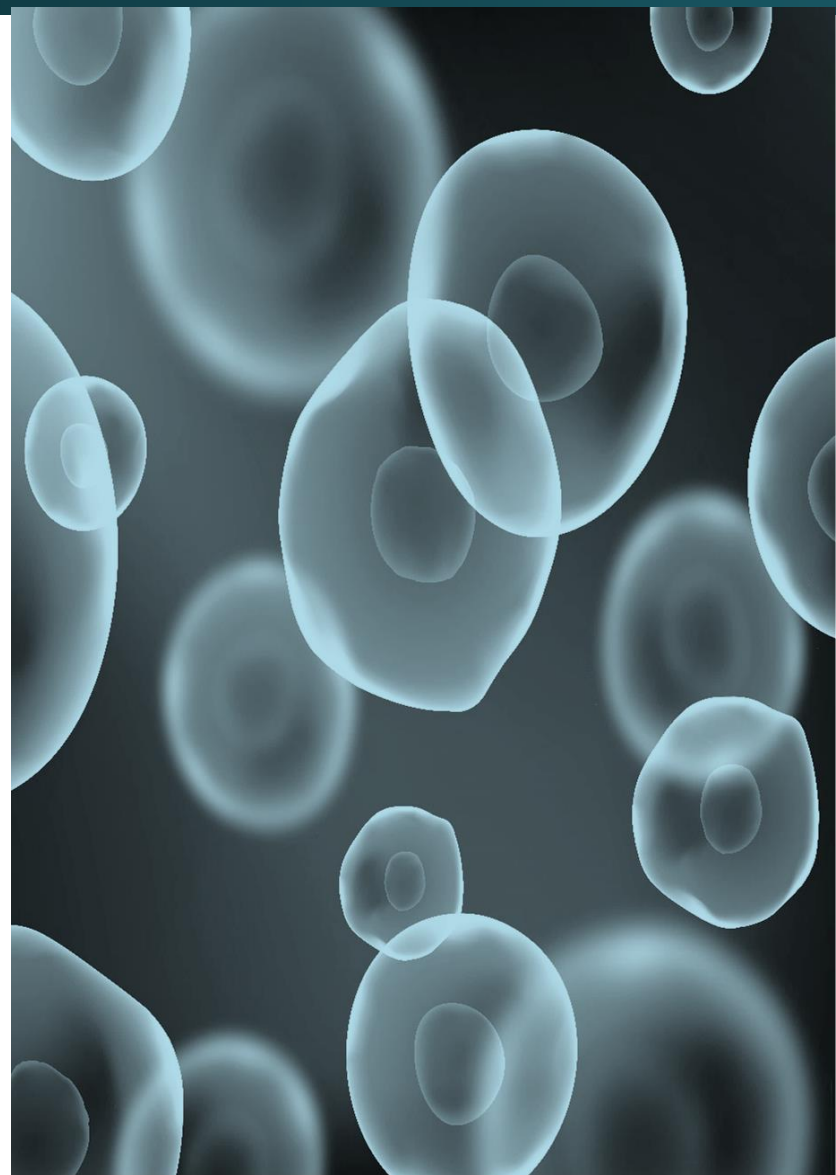
OVERVIEW

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 ASSETS

- **Diversified Pipeline with Five Active Programs**

- E7777 "I/ONTAK": purified reformulation of IL-2 diphtheria toxin fusion protein immunotoxin for CTCL
- Mino-Lok® (Phase 3): potential to be **first and only** FDA-approved product to salvage infected CVCs causing CRBSI/CLABSI
- NC i-MSC™: novel 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



LARGE ADDRESSABLE MARKETS

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

- CTCL market est. >\$300M with larger potential in PTCL and immuno-oncology (I/O)
- 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



SEASONED MANAGEMENT & ADVISORS

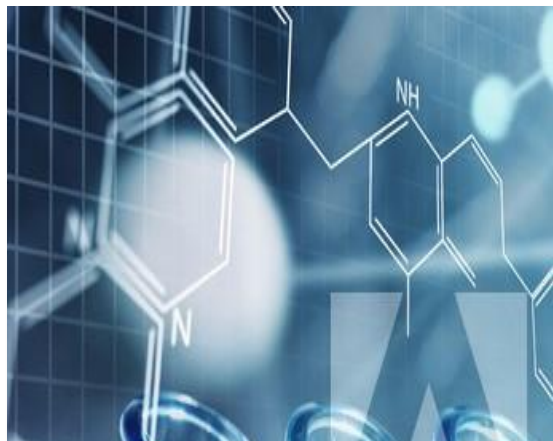
- **Extensive pharma operational and financial track record**
- **History of multi-billion \$ in successfully completed transactions (pre-Citius)**
- **Scientific Advisory Boards of leading KOL's in infectious disease, pulmonology (ARDS), and breast surgery**



STRONG FINANCIAL PLATFORM

- **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



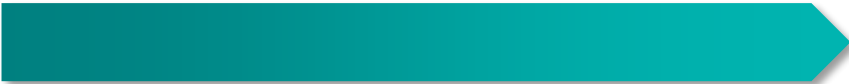
RECENT DEVELOPMENTS

- Secured exclusive worldwide* license of Eisai's late-stage cancer immunotherapy "I/ONTAK" (E7777)
- Completed characterization and expansion of NoveCite's *i*-MSC accession cell bank (ACB) at Waisman Biomanufacturing at the University of Wisconsin-Madison to create a cGMP master cell bank (MCB)
- Advanced Mino-Lok[®] Phase 3 trial following interim review and recommendation of independent Data Monitoring Committee

* Excludes Japan and certain other Asian countries

FIVE ACTIVE PIPELINE PROGRAMS

Unlocking Potential. Faster.

PROGRAM	INVESTIGATIONAL INDICATION	ESTIMATED MARKET (WW)	PRECLINICAL	PHASE I	PHASE II	PHASE III	ANTICIPATED MILESTONES
I/ONTAK (E7777)	IL-2R CANCER IMMUNOTHERAPY	>\$300M					BLA 2022
MINO-LOK® (CITI-001)	TREAT CVC INFECTIONS	> \$1.8B					NDA 2022
HALO-LIDO (CITI-002)	Rx THERAPY FOR HEMORRHOIDS	> \$2B					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

* Anti-IL-2R receptor

As of 9/2021, best estimate subject to impact of COVID-19 pandemic on operations

LATE-STAGE ONCOLOGY ASSET ADDED TO PIPELINE



- Secured exclusive worldwide* license of Eisai's cancer immunotherapy E7777 (I/ONTAK)
- Initial indication in cutaneous T-cell lymphoma (CTCL)
- Additional potential indications in peripheral T-cell lymphoma (PTCL) and immuno-oncology
- Near BLA-ready asset expands Citius's late-stage pipeline

* Excludes Japan and certain other Asian countries



- \$40 million upfront cash payment to Dr. Reddy's (DRL) funded with existing capital
- Development and commercial milestone payments to DRL and Eisai
- Tiered royalties to DRL on net product sales



- Assigns exclusive license from DRL to CTXR for all markets excluding Japan and certain parts of Asia; with option for India
- Completes CTCL Pivotal Phase 3 trial work through BLA filing



- Pivotal trial of E7777 for CTCL completion expected by end of 2021
- Anticipated BLA submission by the end of 2022

I/ONTAK (E7777) TRANSACTION RATIONALE

I/ONTAK (E7777) is a novel oncology asset with an attractive near-term revenue opportunity and substantially de-risked path to support commercial success

IMPROVED FORMULATION OF PROVEN DRUG

Enhanced formulation of ONTAK®, previously FDA-approved and marketed for CTCL

Improved purity and 1.5-2X greater specific bioactivity compared with ONTAK

Well-known safety and efficacy profile

PHASE 3 TRIAL NEAR COMPLETION

Enrollment in Pivotal trial for CTCL completed (last patient in)

Top line results expected 1H 2022

BLA submission expected Q4 2022

MULTIPLE MARKET OPPORTUNITIES

CTCL market estimated to be >\$300 million in the U.S. alone

Upside potential in additional indications (PTCL & I/O) and OUS

Limited efficacy of current CTCL/PTCL therapies

FULLY FUNDED TRANSACTION

\$115.7 M in cash on balance sheet as of 6/30/21 to fund transaction and ongoing programs

No additional financing required at this time, based on current plans

MULTIPLE SHOTS ON GOAL

Near-term opportunity in CTCL with significant upside potential in PTCL and I/O

	CTCL	PTCL	Immuno-Oncology (I/O)
ADDRESSABLE MARKET	• Monotherapy in relapsed / refractory CTCL	• Monotherapy in relapsed / refractory (R/R) systemic therapy setting	• Combination with Checkpoint Inhibitors and Adoptive Cell Therapy in various cancers
KEY FEATURES	• ONTAK® was highly regarded by KOLs for treatment of CTCL • Established MOA • Granted ODD in US	• Granted ODD in US • Strong clinical evidence of ONTAK activity in PTCL	• In various preclinical studies, denileukin diftitox has shown immuno-therapeutic potential through selective depletion of Tregs
STATUS	• US Pivotal trial completion expected by end of 2021 • Approved in Japan in 2021	• Approved in Japan in 2021	• Preclinical studies in combination with anti-PD-1 completed • Phase I study in combination with CAR-T ongoing • Investigator-initiated study for use in comb. with pembrolizumab (anti-PD-1) in solid tumors finalize

WHAT IS CUTANEOUS T-CELL LYMPHOMA (CTCL)?



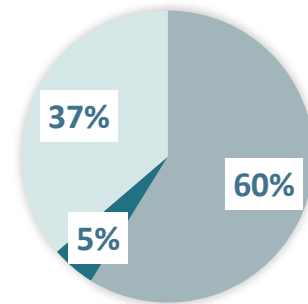
Considered to be incurable, CTCL is a general term for T-cell lymphoma that involve the skin, but may also involve the blood, lymph nodes, and internal organs



More prevalent in men than women and usually appears in patients in their 50s and 60s



CTCL accounts for approximately 4% of all non-Hodgkin lymphoma (NHL)



- Mycosis Fungoides
- Sezary Syndrome
- Other CTCL



Plaque Stage



Tumor Stage

I/ONTAK PIVOTAL TRIAL IN CTCL NEARING COMPLETION

PIVOTAL TRIAL DESIGN	Global, multicenter, open label single arm pivotal clinical trial for the treatment of patients with persistent or recurrent CTCL	Inclusion Criteria: - CTCL (MF or SS) - CD25+ - Stage IA-IVA - At least 1 prior CTCL therapy - ECOG PS ≥ 2 - Visceral metastasis and prior denileukin diftitox therapy excluded
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2 PHASES	Lead In: Completed FPI: May 2013 LPO: Aug 2015	Subjects: N=21 Dose finding by CRM: 6,9,12,15mcg/kg/d IV for 5 consecutive days in 21 day cycle PK and immunogenicity
	Pivotal Study: Ongoing Enrollment completed FPI: Jun 2016 LPO: exp. 2021	Subjects: N=70 Dose: 9 mcg/kg/d IV for 5 consecutive days in 21 day cycle PK and immunogenicity

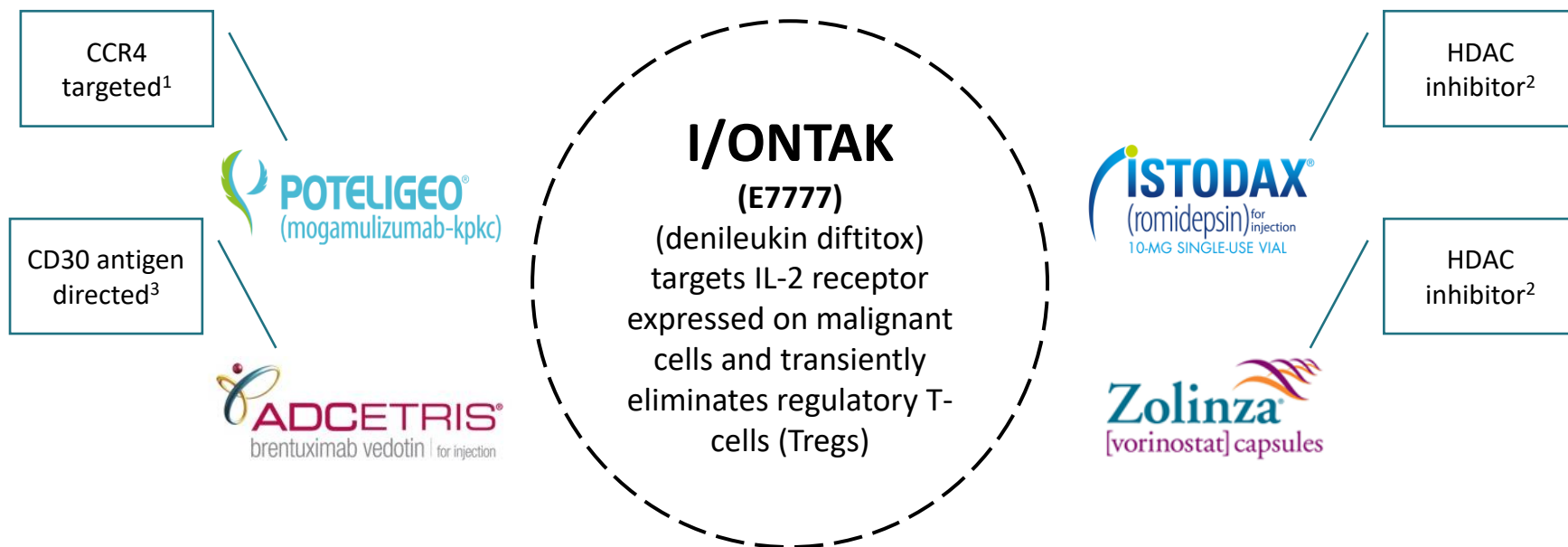
ENDPOINTS	Primary: ORR (Olsen 2001) ¹	Secondary: Overall DOR, TTR Skin RR, DOR, TTR ORR (Prince 2010) ² PK and immunogenicity
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1. Objective Response is Complete Response and Partial Response, according to the ISCL/EORTC Global Response Score (Olsen 2001)

2. Assess ORR for I/ONTAK (E7777) using the alternate response assessment criteria of Prince (2010)

I/ONTAK (E7777): UNIQUE MOA

I/ONTAK expected to be an important option, especially when existing targeted therapies are poorly tolerated or have limited efficacy



LIMITATIONS OF EXISTING TARGETED THERAPIES

Often discontinued due to toxicity / AEs

Limited duration of response / Development of resistance

“non-curative”

1. CCR4 - C-C chemokine receptor type 4 is a protein that in humans is encoded by the CCR4 gene
2. HDAC - Histone deacetylase inhibitors are believed to induce death, apoptosis, and cell cycle arrest in cancer cells
3. CD30 - cell membrane protein of the tumor necrosis factor receptor superfamily (TNFRSF) and a tumor marker

PRELIMINARY PIVOTAL TRIAL RESULTS

No new safety signals identified with I/ONTAK compared to ONTAK

PHASE 3
PIVOTAL
SINGLE ARM
TRIAL



N=70



DAY 1 DAY 2 DAY 3 DAY 4 DAY 5

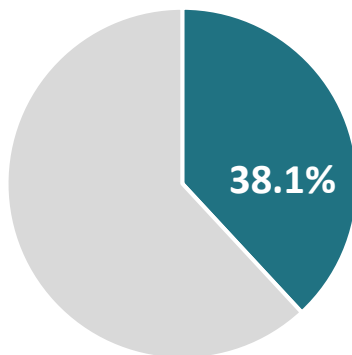
CYCLE DOSING: 9mcg/kg/day IV



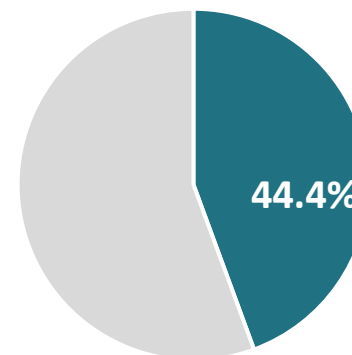
CYCLE

LEAD IN
STUDY
RESULTS

ORR*
in ITT population
n=21



ORR*
in "efficacy-evaluable" population
n=18



* Objective Response is Complete Response and Partial Response, according to the ISCL/EORTC Global Response Score (Olsen 2001)

MULTI-LAYERED PROTECTION THROUGH IP AND EXCLUSIVITY

**Proprietary Manufacturing
Process**
trade secret

Orphan Drug Designation
granted for CTCL and PTCL
(eligible for 7 years of marketing
exclusivity)

BLA Exclusivity
limits competition
(12 years)

Patents Pending
for I/O use as combination
therapy with check point
inhibitors

ATTRACTIVE NEAR-TERM OPPORTUNITY IN CTCL

PATIENTS LIVING WITH
CTCL IN THE U.S.¹

30-40k

EST. 3,000 NEW CASES PER
YEAR²

PATIENTS WITH ADVANCED,
RELAPSED OR
REFRACTORY CTCL

10k

THAT REQUIRE SYSTEMIC
THERAPY¹

ADDRESSABLE U.S.
MARKET¹

**\$300+
MILLION**

PHASE 3 TRIAL TOPLINE
RESULTS EXPECTED

1H 2022

BLA FILING WITH US FDA
ANTICIPATED

Q4 2022

LIKELIHOOD OF RX FOR
ADVANCED STAGE DISEASE

HIGH

SOURCES:

1. Company estimate
2. <https://www.clfoundation.org/cutaneous-t-cell-lymphoma>

ANTICIPATED I/ONTAK MILESTONES (12-18 MONTHS)

2021

Complete Pivotal trial for CTCL indication by end of year

Support start of investigator initiated study of I/ONTAK for I/O indications

1H 2022

Readout of top line Pivotal trial results

Initiate program planning to explore relapsed/refractory PTCL indication

2H 2022

Submit BLA for CTCL indication

LATE-STAGE PRODUCT CANDIDATE: MINO-LOK®

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%

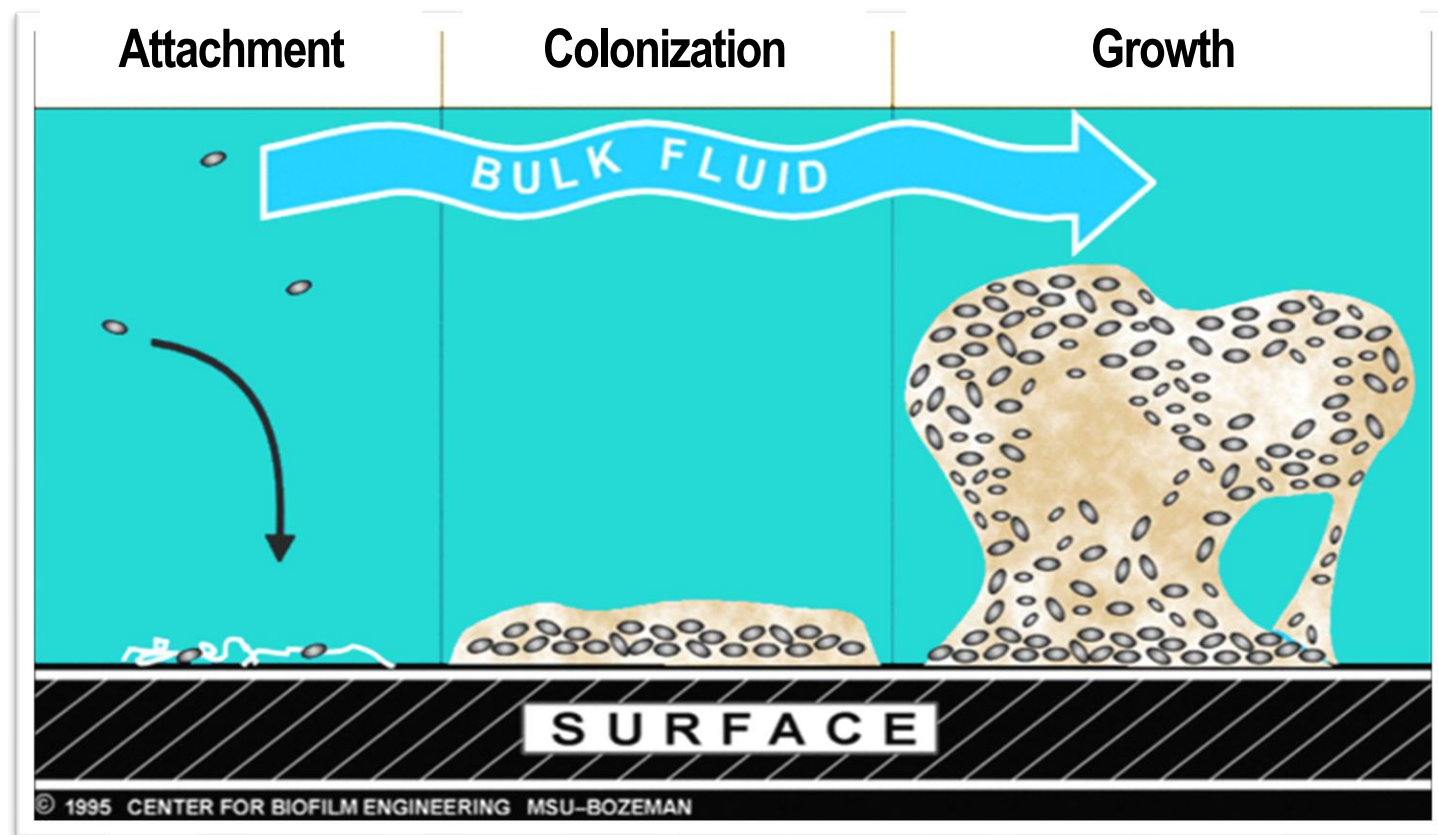
CRBSI/CLABSI associated mortality & morbidity**

* 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 Némčíková 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[®] PENETRATES BIOFILM

Biofilm prevents penetration of pathogen colonies by most traditional antibiotics

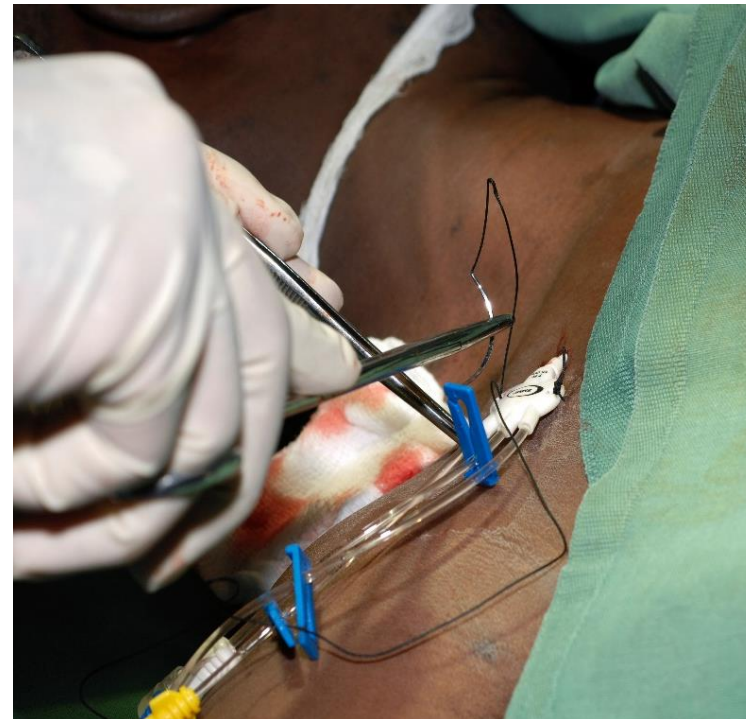


Biofilm Formation

CURRENT STANDARD OF CARE IS A POOR OPTION

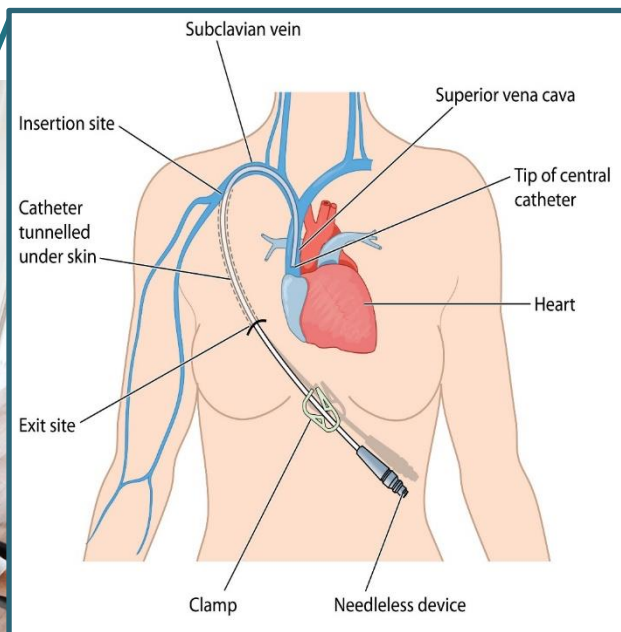
Removing & replacing infected CVCs has multiple limitations

- 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

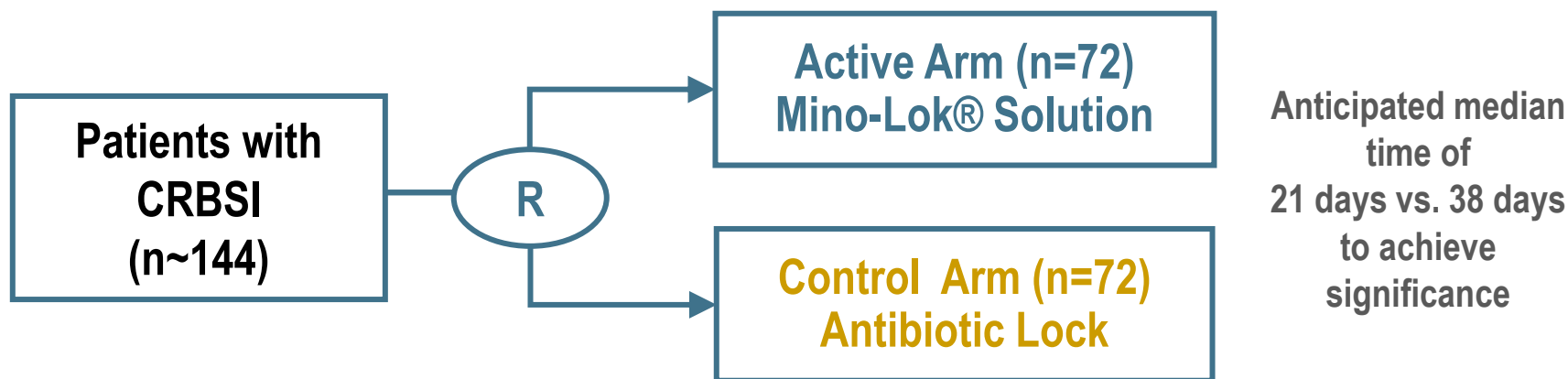
Mino-Lok® demonstrated a strong safety and efficacy signal

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%
Overall Complication Rate	-	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 UNDERWAY

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



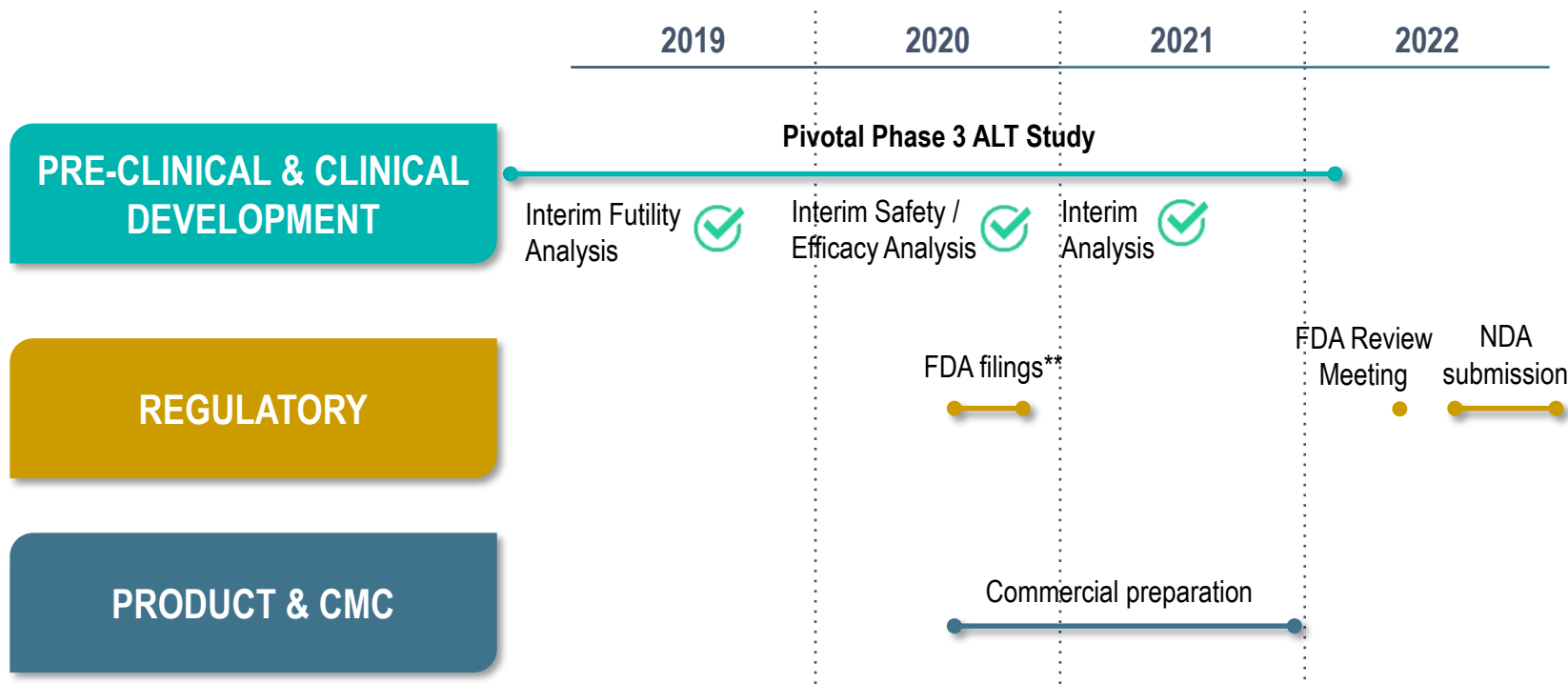
Primary Endpoint: Comparison of “Time to Catheter Failure” TOC = 6 weeks (42 days)

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® DEVELOPMENT PLAN*

Completing Phase 3 pivotal superiority trial



*As of 90/2021, 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	• US: 7,601,731 • EP: 04754538.9 • CA: 2,528,522	2009	2024
Issam Raad, M.D. Joel Rosenblatt, Ph.D. et al	Formulation/Enhanced Stability	• US: 10,086,114 • Pub.No.: US 2017/051373 A1 • Global IP: UTFC.P1283WO	2018	2036
Issam Raad, M.D. et al	Method of Use	• US: 9,078,441 • EP: 1644024 • CA: 2528522	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

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[®] 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

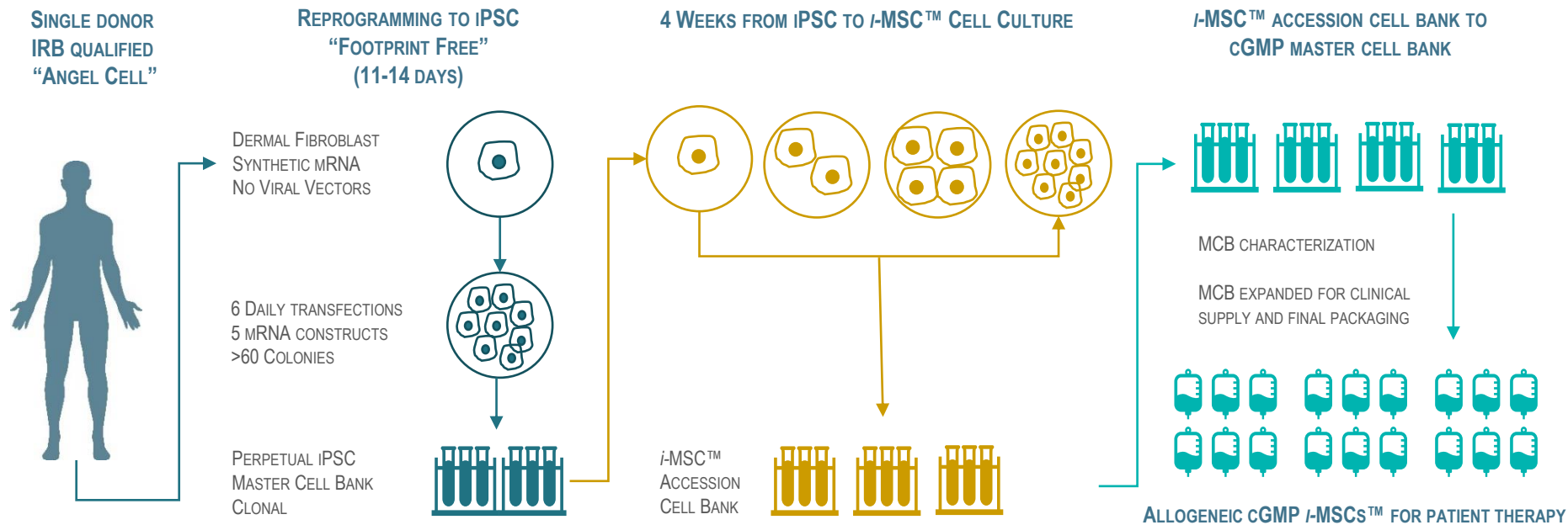
RESTORED TELOMERES

- 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

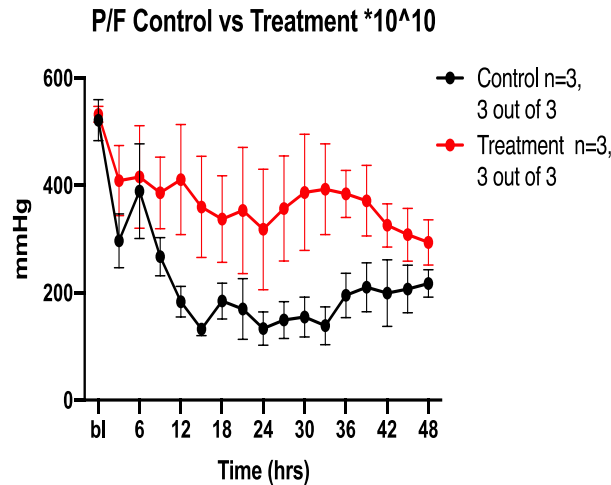
cGMP compliant scalable manufacturing for preclinical and clinical studies

i-MSCs™ packaged in cryopreserved mini-bags

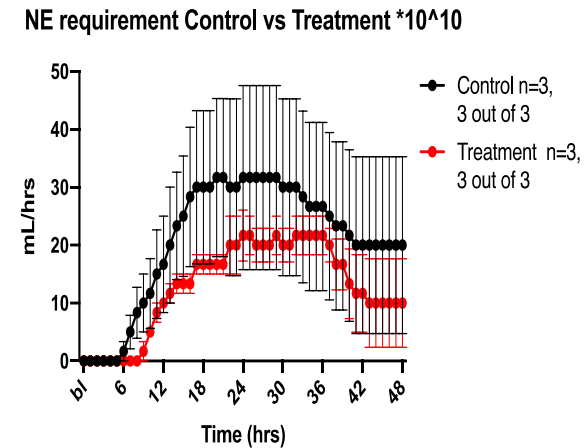
INTERIM RESULTS OF *i*-MSC™ STUDY IN SHEEP MODEL OF ARDS

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

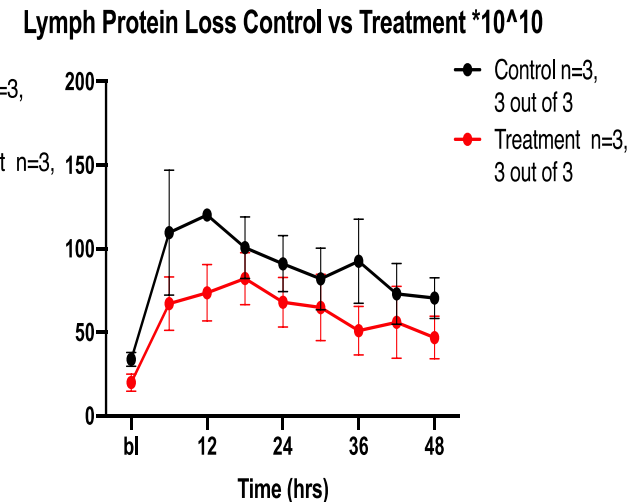
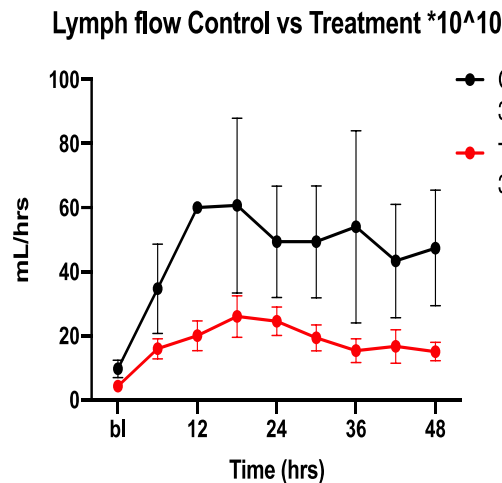
Improved Oxygenation



Less Systemic Shock

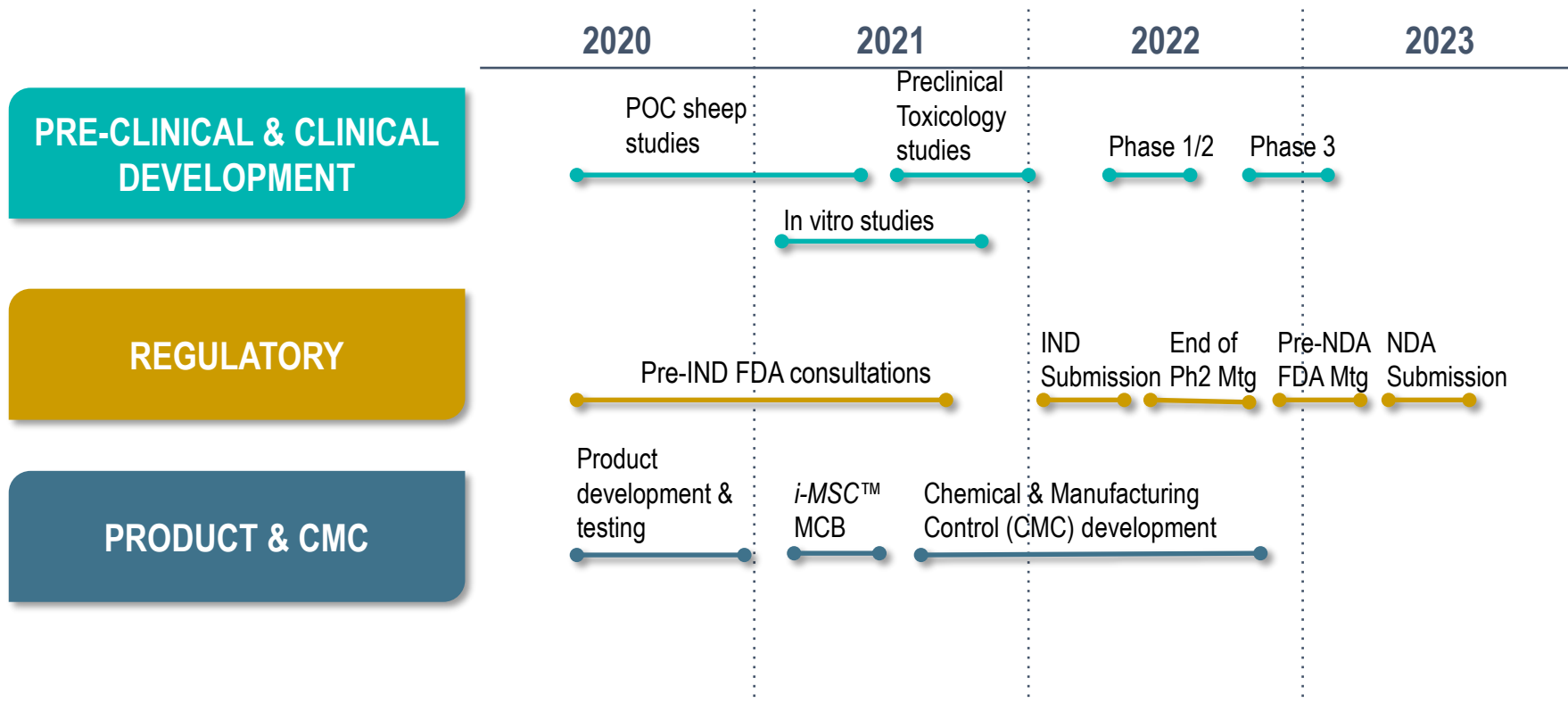


Reduced Lung Vascular Injury



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 9/2021, 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)

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 ⁽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.

POISED FOR GROWTH

Attractive diversified pipeline in oncology, adjunctive cancer care, infectious disease and gastrointestinal disease



HALO-LIDO

Rx therapy for hemorrhoids



MINO-LOK

Treat CVC infections



I/ONTAK (E7777)

Treat CTCL/PTCL, I/O



NC i-MSC

Treat ARDS



MINO-WRAP

Prevent Infections associated with breast Implants post-mastectomy

The background of the slide features a complex, glowing blue and yellow network of lines and dots, resembling a molecular structure or a data network. A prominent yellow DNA double helix is visible on the right side. The Citius Pharma logo is positioned in the upper left corner.

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