



Citius Pharmaceuticals, Inc.
(NASDAQ: CTXR)

Corporate Overview
APRIL 2022



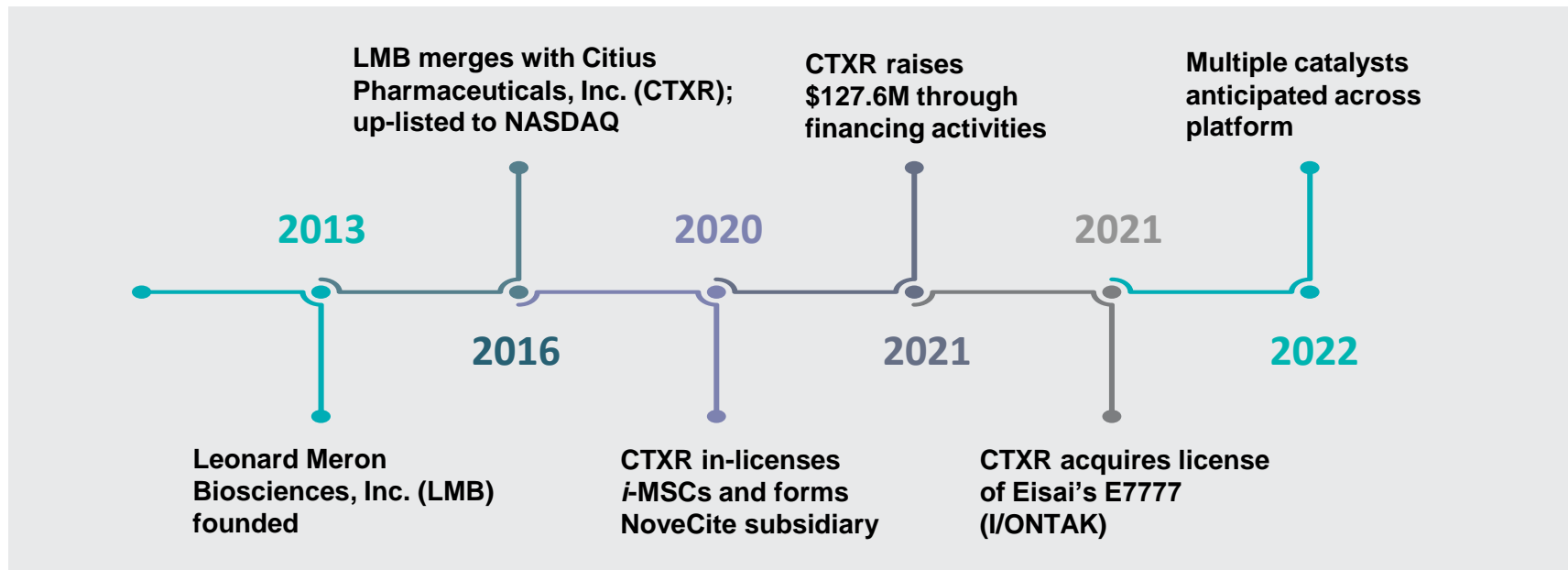
FORWARD-LOOKING STATEMENTS

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CITIUS: BUILDING A BIOTECH PLATFORM

Citius is a **late-stage biopharmaceutical** company dedicated to the development and commercialization of first-in-class critical care products



HALO-LIDO
Rx therapy for hemorrhoids



MINO-LOK
Salvage CVCs



MINO-WRAP
Prevent infections associated with breast implants post-mastectomy



NC *i*-MSC
Treat ARDS with *i*-MSCs



I/ONTAK
Treat CTCL, PTCL, I/O

2013

2020

2021

INVESTMENT HIGHLIGHTS



**DIVERSIFIED
PIPELINE WITH
MULTIPLE EXPECTED
CATALYSTS IN 2022**



**LARGE
ADDRESSABLE
MARKETS**



**SEASONED
MANAGEMENT &
ADVISORS**



**STRONG FINANCIAL
PLATFORM**

- **Five Active Programs**

- PHASE 3**

- I/ONTAK: purified reformulation of IL-2 diphtheria toxin fusion protein for CTCL
 - Mino-Lok®: potential to be **first and only** FDA-approved product to salvage infected CVCs causing CRBSI/CLABSI
 - Halo-Lido Rx: potential to be **first and only** FDA-approved Rx therapy for hemorrhoids
 - 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






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

- **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**

- **Cash runway into 2023 (\$65.4M cash as of 12/31/21)**
- **\$26.5M invested by management / founders**

DIVERSIFIED PIPELINE WITH FIVE ACTIVE PROGRAMS

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					Complete Ph 3 2022
HALO-LIDO (CITI-002)	Rx THERAPY FOR HEMORRHOIDS	> \$2B					Complete Ph 2b 2022
MINO-WRAP (CITI-101)	PREVENT INFECTIONS ASSOCIATED WITH BREAST IMPLANTS	> \$400M					
NC i-MSC™ (CITI-401)	TREAT ARDS	Multi-billion					

* Anti-IL-2 receptor

As of 4/2022, best estimate subject to impact of COVID-19 pandemic on operations

MANAGEMENT TEAM WITH PROVEN TRACK RECORD



LEONARD MAZUR
CHAIRMAN & CEO*



MYRON HOLUBIAK
VICE CHAIRMAN & CO-FOUNDER*



JAIME BARTUSHAK
EVP, CFO & CBO*



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EVP, CHIEF MEDICAL OFFICER



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EVP, OPERATIONS



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EVP, CMC



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SVP, BUSINESS STRATEGY



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ILANIT ALLEN
VP, INVESTOR RELATIONS





SCIENTIFIC ADVISORY BOARD OF LEADING KOLS

INFECTIOUS DISEASE / CANCER ADVISORS

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John Laffey MD, MA, FCAI, FJFICMI

National University of Ireland (NUI Galway)

I/ONTAK (E7777)

PHASE 3

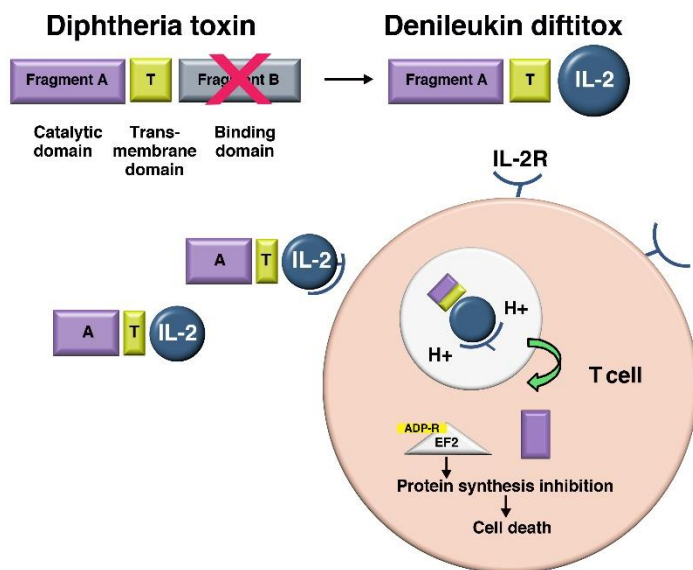
A NOVEL IMMUNOTHERAPY WITH A DUAL MOA

I/ONTAK is an engineered IL-2-diphtheria toxin fusion protein with a unique dual mechanism of action

- purified and more bioactive formulation of previously marketed ONTAK®
- targets both malignant T-cells and immunosuppressive Tregs

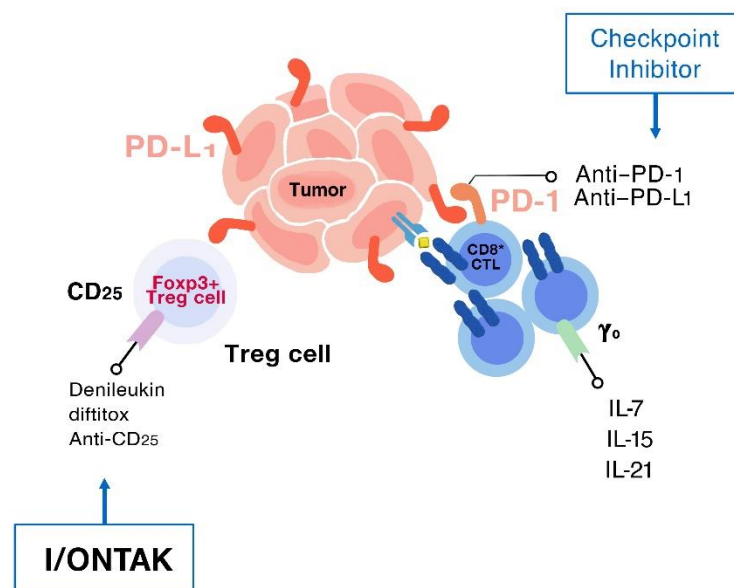
Malignant T-cells

I/ONTAK binds with IL-2 receptor to kill tumor cells directly



Immunosuppressive Tregs

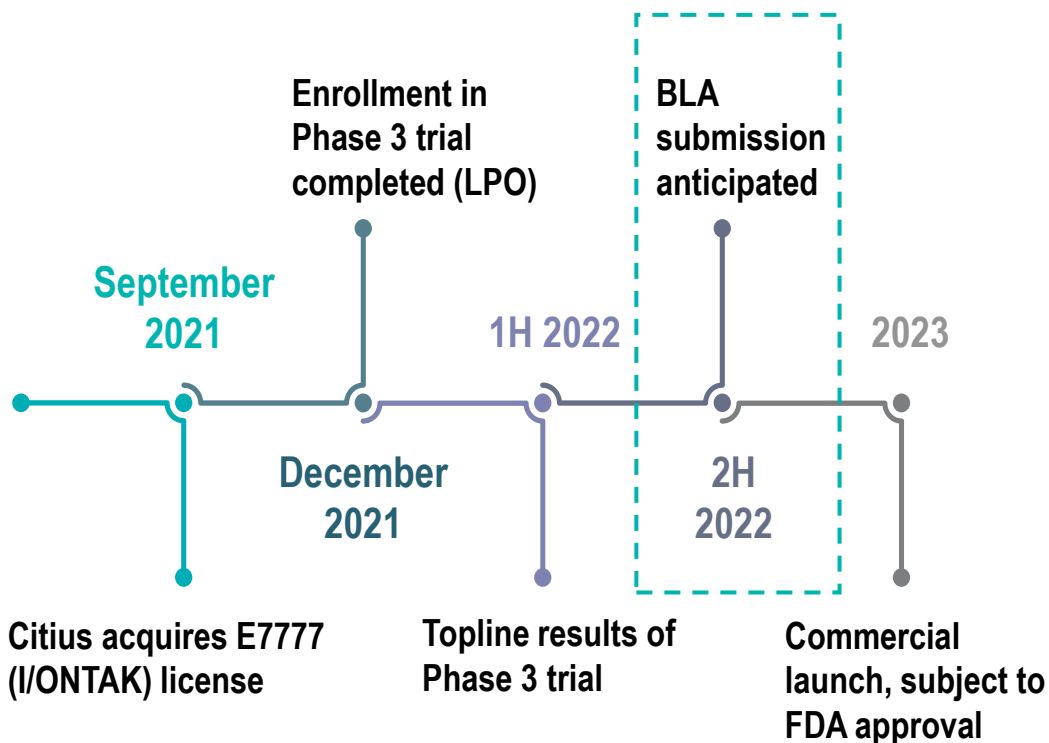
I/ONTAK unleashes potent immune response against tumors by transiently eliminating Treg cells



I/ONTAK: PHASE 3 CANCER AGENT NEARING FDA SUBMISSION

Reformulated oncology asset with an attractive near-term revenue opportunity

- Improved formulation of previously-approved drug (ONTAK) for treatment of cutaneous T-cell lymphoma (CTCL)
- Orphan indication: market est. \$300M
- Upside potential in PTCL and immuno-oncology (I/O)
- Pivotal Phase 3 trial completed
- Anticipated BLA submission 2H 2022



WHAT IS CUTANEOUS T-CELL LYMPHOMA (CTCL)?



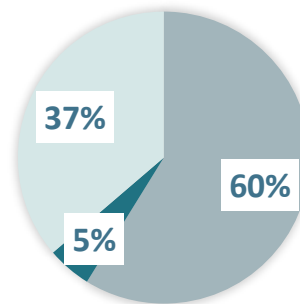
Considered to be incurable, CTCL is a general term for T-cell lymphoma that involve the skin, but may also involve the blood, lymph nodes, and internal organs



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

PATIENT POPULATION WITH
PERSISTENT OR RECURRENT
CTCL THAT REQUIRE
SYSTEMIC THERAPY¹

10k

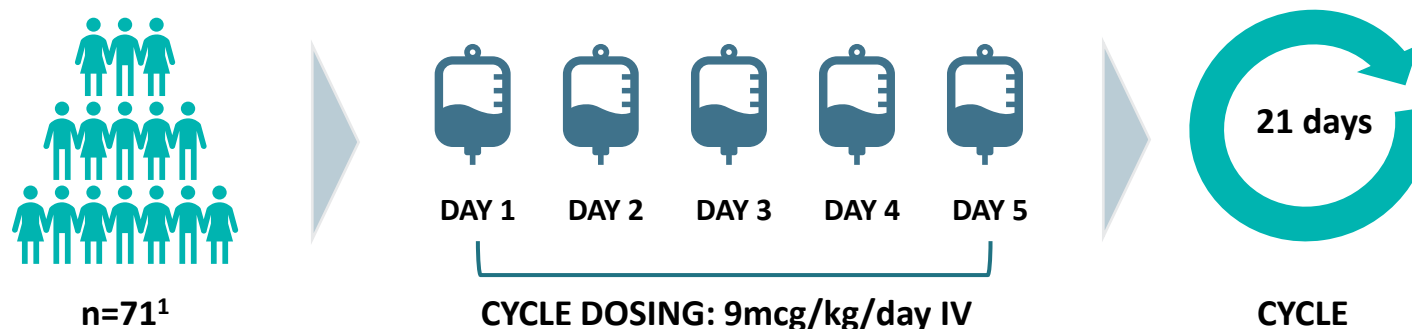


Tumor Stage

1. Company estimate

I/ONTAK PIVOTAL PHASE 3 TRIAL: COMPLETED

Single Arm trial completed December 2021

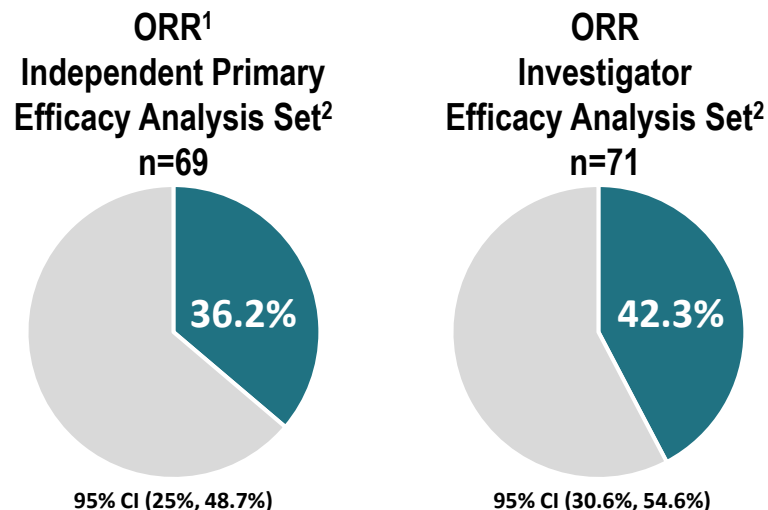


- The FDA provided written comments in December 2021 indicating that their efficacy evaluation will be based on study results showing the lower limit of a 95% confidence interval to exceed a clinically relevant response rate (determined during BLA review)
 - may be supported with data from the prior ONTAK study that led to its initial approval.
 - adequate magnitude of duration of response and an acceptable risk/benefit ratio to be considered

1. 71 subjects with Stage I-III persistent or recurrent CTCL from the Lead-In and Main Studies were assessed for efficacy.

TOPLINE RESULTS: I/ONTAK PHASE 3 TRIAL

Topline results of I/ONTAK®: consistent with the prior formulation



1. Objective Response is Complete Response and Partial Response, according to the ISCL/EORTC Global Response Score (Olsen 2011).
 2. Primary Efficacy Analysis Set includes 69 Stage I-III CTCL subjects from the Lead-In Study and the Main Study who received a dose of 9 ug/kg/day of study drug. Two subjects included in the Investigator Efficacy Analysis Set were considered by the Independent Review Committee to have Stage IV CTCL and excluded from the Primary Efficacy Analysis Set. This dataset matches the patient population used for the ONTAK indication.

- Overall rates of adverse events (AEs) and were consistent with previously approved ONTAK studies
- No new safety signals identified
- Proceeding with BLA submission

	Independent (IRC) Stage I-III Primary Efficacy Analysis Set (n=69)	Investigator Stage I-III Efficacy Analysis Set (n=71)
Duration of Response		
Subjects with Objective Response (n)	25	30
Median observed DOR (months)	6.5	5.7
Range (Min, Max)	(3.0+, 23.5+)	(0.7+, 26.1+)
Time to Response		
Median (months)	1.41	1.41
Clinical Benefit Rate, n (%) (CR + PR + Durable Stable Disease)	34 (49.3)	38 (53.5)
95% CI	(37.0, 61.6)	(41.3, 65.5)

WELL-POSITIONED AMONG EXISTING TARGETED THERAPIES

With no single SOC, I/ONTAK expected to be an important option as the only IL-2R targeted therapy

I/ONTAK

(E7777)

(denileukin diftitox)

targets IL-2 receptor

expressed on malignant cells and transiently eliminates regulatory T-cells (Tregs)



CD30 antigen directed¹



CCR4 targeted²



Bristol Myers Squibb™

HDAC inhibitor³



MERCK

HDAC inhibitor³

LIMITATIONS OF EXISTING TARGETED THERAPIES

Often discontinued due to toxicity / AEs

Limited duration of response / Development of resistance

“non-curative”

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

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

eliminates biosimilar
competition

Patents Pending

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



MINO-LOK[®]

PHASE 3

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**

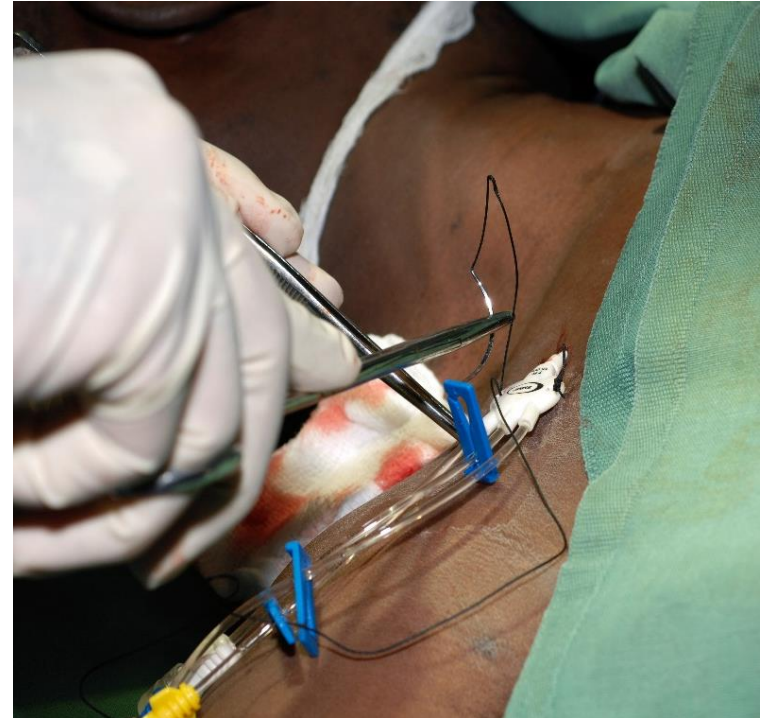
* Shah H., Bosch W., Hellinger W. C., Thompson K. M. (2013). Intravascular catheter-related bloodstream infection. Neurohospitalist 3, 144–151. doi: 10.1177/1941874413476043.

** Antoňáková 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.

CURRENT STANDARD OF CARE IS A POOR OPTION

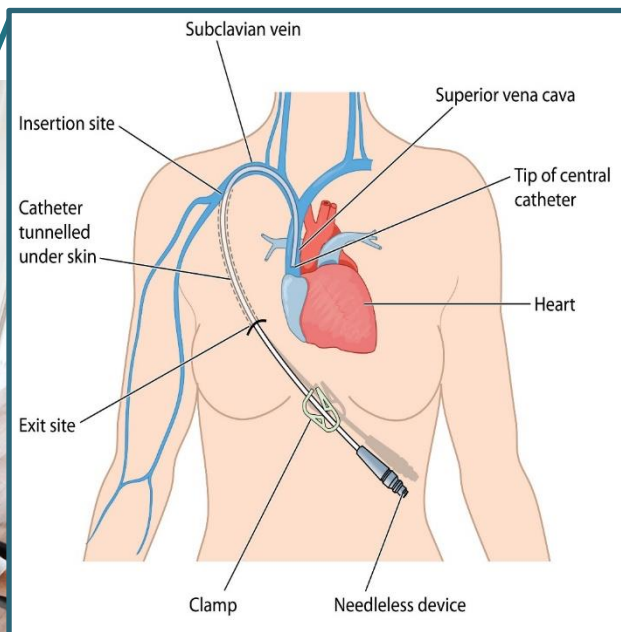
Removing & replacing infected CVCs has multiple limitations

- 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

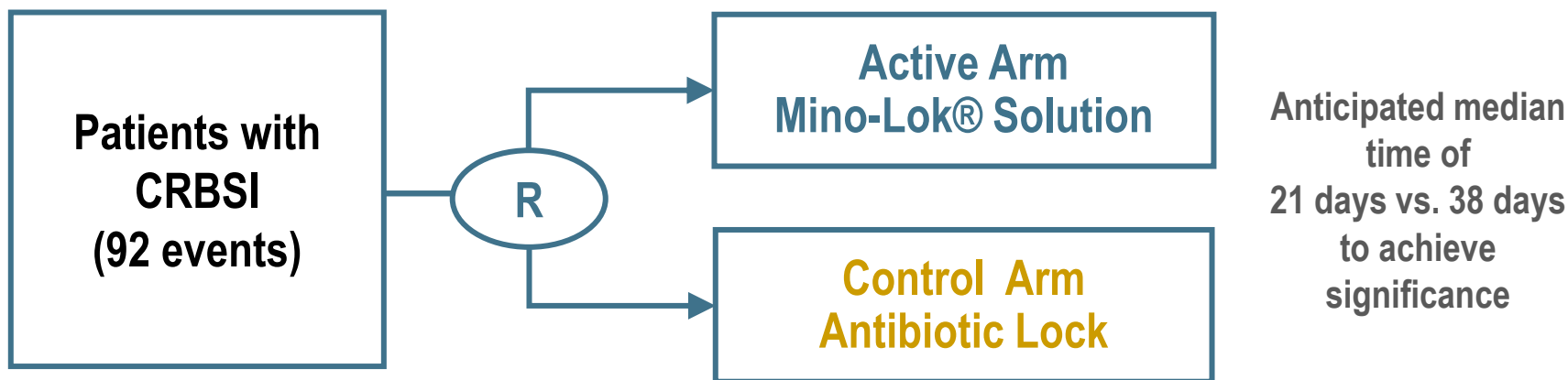
Mino-Lok® demonstrated a strong safety and efficacy signal

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: DMC recommended proceeding with trial without modification following all 3 reviews



IP & REGULATORY PROTECTIONS

Mino-Lok® is supported by a robust intellectual property portfolio with protection through 2036

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

HALO-LIDO

Halobetasol/Lidocaine

Prescription Strength Topical for Symptomatic Hemorrhoid Treatment

HALO-LIDO AT-A-GLANCE

Would be the first FDA-approved prescription product to treat hemorrhoids in the US

- 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
- A cream formulation containing novel excipient selected for Phase 2b study
- IND filing accepted by FDA Q1 2022
- Phase 2b study expected to begin 1H 2022
 - 5 cohorts of 60 subjects each
 - Primary endpoint: reduction in hemorrhoidal symptoms
 - Subjects to self-report using proprietary ePRO mobile app

10+ MILLION

Patients report symptoms of hemorrhoidal disease and 1/3 seek physician treatment¹

1. Source: <https://www.mayoclinic.org/medical-professionals/digestive-diseases/news/hemorrhoidal-disease-diagnosis-and-management/mac-20430067>



SUMMARY

FINANCIAL SUMMARY*

Bandwidth to Execute

- \$65.4M cash & equivalents as of 12/31/21
- \$5.5M R&D expense Q1 2022
- Runway into 2023
- \$26.5M invested by insiders

As of 12/31/21 unless otherwise noted.

CURRENT CAPITALIZATION	SHARES	% OF FULLY DILUTED
BASIC SHARES OUTSTANDING	146,029,630	74.8%
WARRANTS	40,136,844	20.6%
OPTIONS	9,020,171	4.6%
FULLY DILUTED SHARES OUTSTANDING	195,186,645	100%

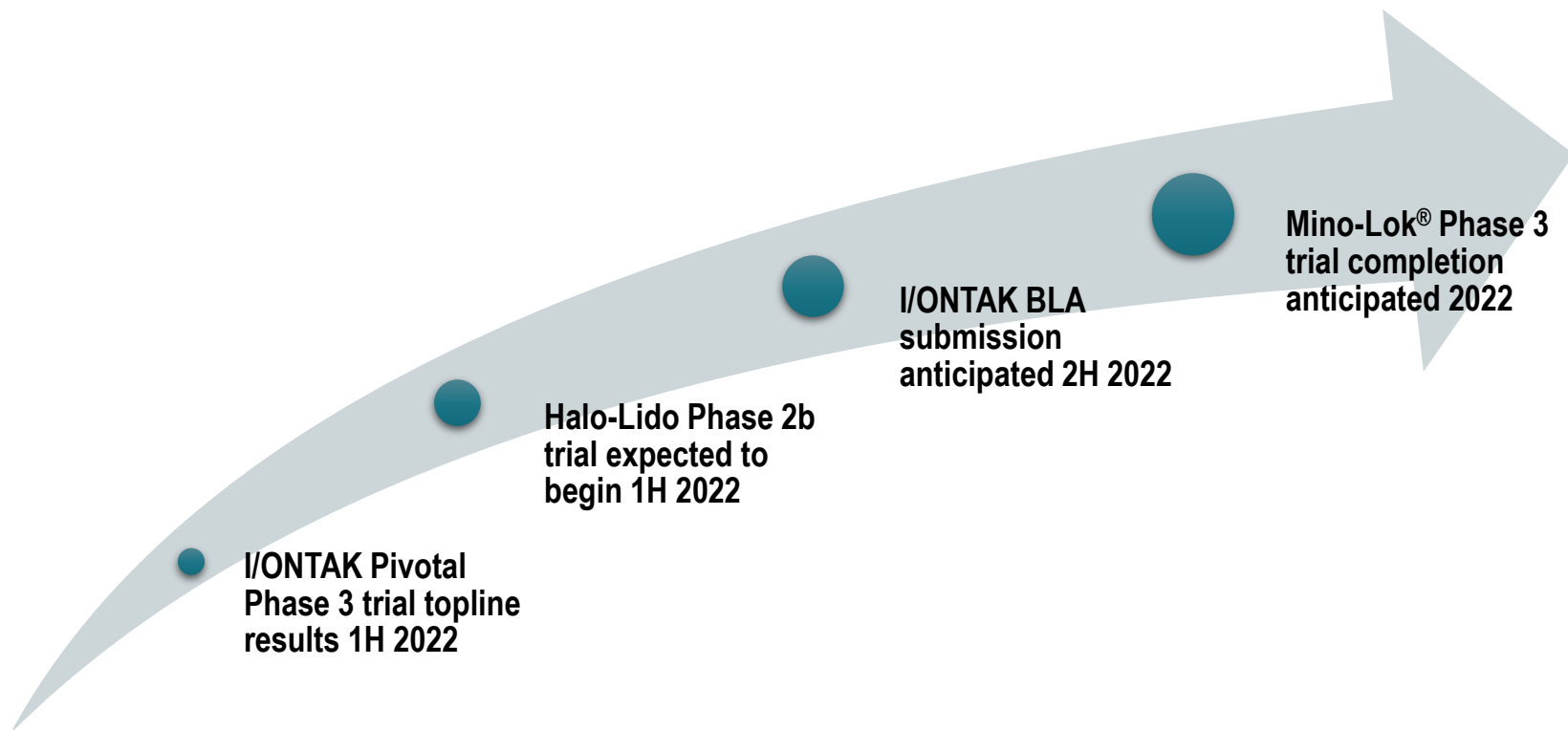
PRINCIPAL INSIDER SHAREHOLDERS ⁽¹⁾

LEONARD MAZUR	11.8%
MYRON HOLUBIAK	2.6%

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

BIOTECH PLATFORM POISED FOR GROWTH IN 2022

Multiple value-driving catalysts expected in 2022



HALO-LIDO
Rx therapy for hemorrhoids



MINO-LOK
Salvage CVCs



MINO-WRAP
Prevent Infections associated with breast Implants post-mastectomy



NC i-MSc
Treat ARDS with i-MSCs



I/ONTAK
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The background of the slide features a glowing blue DNA double helix structure, composed of numerous small dots connected by lines, set against a dark blue background with faint, swirling golden lines. The Citius Pharma logo is positioned in the upper left corner.

CITIUS

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