

First & Only Therapies Faster to Market Upside Potential



FACT SHEET

SEPTEMBER 2022

CORPORATE OVERVIEW

Citius Pharmaceuticals, Inc. (Citius) is a late-stage biopharmaceutical company focused on the development and commercialization of first-in-class critical care products, with a diversified pipeline of five active programs. Three of its pipeline candidates would be the first and only prescription treatments in their indications if approved by the FDA. The Company has two late-stage product candidates, Mino-Lok®, an antibiotic lock solution to salvage infected central venous catheters (CVCs) of patients with catheter-related bloodstream infections (CRBSIs), which is currently enrolling patients in a Phase 3 Pivotal superiority trial, and I/ONTAK (E7777), a novel IL-2R immunotherapy for an initial indication in cutaneous T-cell lymphoma (CTCL), which has completed its Phase 3 trial and is on track for submission of a biologics license application (BLA) with the U.S. Food and Drug Administration (FDA) in the second half of 2022. Mino-Lok® was granted Fast Track designation by the FDA. I/ONTAK has received orphan drug designation by the FDA for the treatment of CTCL and peripheral T-cell lymphoma (PTCL). Citius has announced its intention to spinoff I/ONTAK into standalone oncology-focused publicly traded company. During the second quarter of 2022, Citius initiated a Phase 2b trial of Halo-Lido, potentially the first and only FDA-approved prescription treatment for hemorrhoids; patient enrollment in the trial is expected to be completed by the end of 2022. Citius has two additional pipeline assets in pre-clinical development: a novel proprietary mesenchymal stem cell (i-MSC) treatment for acute respiratory conditions, and Mino-Wrap, for the prevention of infection in tissue expanders and breast implants post mastectomy.

Achieved and Anticipated 2022 catalysts

- I/ONTAK topline results reported 1H 2022
- Halo-Lido Phase 2b trial initiated 1H 2022
- I/ONTAK BLA submission 2H 2022
- Mino-Lok Phase 3 trial enrollment completion by end of 2022
- Halo-Lido Phase 2b trial enrollment completion by end of 2022

NASDAQ: CTXR

Share Price	\$1.22 (9/6/22)
52-Wk.Range	\$0.83-\$2.25
Avg. Vol.	932K
Shares O/S	146.1M
Market Cap	\$178.2M

INVESTMENT HIGHLIGHTS

Advancing Diversified Pipeline with Five Active Programs

- E7777 'I/ONTAK' (Phase 3): purified reformulation of IL-2 diphtheria toxin fusion protein immunotoxin for CTCL
- Mino-Lok® (Phase 3): potential to be the **first and only** FDA-approved product to salvage infected central venous catheters (CVCs)
- Halo-Lido: potential to be the **first and only** FDA-approved prescription therapy for hemorrhoids
- Mino-Wrap: potential to be the **first and only** FDA-approved product to prevent infections associated with post mastectomy breast implants
- NC i-MSC: novel stem cell therapy for acute respiratory distress syndrome (ARDS), for which there is no FDA-approved drug therapy available

Multi-billion Global Market Opportunities

- CTCL market est. >\$300M with larger potential in peripheral T-cell lymphoma (PTCL) and immuno-oncology (I/O)
- Attractive diversified multibillion-dollar opportunities in adjunctive cancer care, infectious and gastrointestinal diseases
- CRBSI and central line-associated bloodstream infection (CLABSI) market total estimated at \$1.8B worldwide
- Prescription hemorrhoid market est. >\$2B US
- ARDS market large with no approved therapies
- Tissue expander infection prevention market est. \$400M worldwide

Seasoned Leadership

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

Strong Financial Platform

- Cash runway into 2023 (\$48.0M cash as of 6/30/22)
- Management fully committed with \$26.5 million invested by founders

LEADERSHIP

Leonard Mazur, CHAIRMAN & CEO

Myron Holubiak, EXECUTIVE VICE CHAIRMAN

Jamie Bartushak, EVP, CFO & CHIEF BUSINESS OFFICER

Dr. Myron Czuczman, EVP & CHIEF MEDICAL OFFICER

Gary Talarico, EVP, OPERATIONS

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Kevin Carey, VP, PROGRAM MANAGEMENT

Dr. Preeti Singh, VP, CLINICAL DEV. & MEDICAL AFFAIRS

Ilanit Allen, VP, INVESTOR RELATIONS

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

I/ONTAK (E7777)

I/ONTAK (E7777) is a novel oncology asset with an attractive near-term revenue opportunity in the treatment of cutaneous T-cell lymphoma (CTCL). I/ONTAK, a purified version of denileukin diftitox, is a reformulation of previously FDA-approved oncology treatment ONTAK® which was marketed in the U.S. from 1999 to 2014. Manufacturing improvements resulted in a new formulation, which maintains the same amino acid sequence but features improved purity and bioactivity. The new formulation received regulatory approval in Japan for the treatment of CTCL and PTCL in 2021. In 2011 and 2013, the FDA granted orphan drug designation (ODD) to I/ONTAK for the treatment of PTCL and CTCL, respectively, making it potentially eligible for seven years of market exclusivity post-approval for each indication. The Pivotal trial of I/ONTAK has been completed and topline data shows consistency with the original formulation; a pre-biologics license application (BLA) meeting was held for I/ONTAK in July 2022 and the BLA for its first indication in CTCL remains on track for submission in the second half of 2022.

MINO-LOK®

In late-stage development, Mino-Lok® is potentially the first and only antibiotic lock solution under investigation to salvage infected central venous catheters (CVCs) causing catheter-related bloodstream infections. Citius believes Mino-Lok® provides a superior alternative to removing and replacing a CVC, leading to a reduction in serious adverse events and cost savings to the healthcare system. A multi-center Phase 3 pivotal superiority trial is currently underway. Citius licensed the worldwide rights to Mino-Lok® from The University of Texas MD Anderson Cancer Center.

HALO-LIDO

Halo-Lido (CITI-002) is a topical formulation of halobetasol and lidocaine designed to provide anti-inflammatory and anesthetic symptomatic relief to people with hemorrhoids. There are no FDA-approved prescription products on the market to treat hemorrhoids, and Citius's formulation could become the first FDA-approved prescription product to treat hemorrhoids in the United States. Citius initiated a Phase 2b study of Halo-Lido in the first half of 2022.

NC i-MSCs (Stem Cells)

Preclinical activities are underway for Citius's unique, proprietary stem cell therapy for an initial indication in the treatment of Acute Respiratory Distress Syndrome (ARDS). Compared with donor-derived cells that require a continuous supply of new donors, Citius believes its induced mesenchymal stem cells (i-MSCs), derived from a single clonal induced pluripotent stem cell (iPSC), offer multiple advantages including consistent and scalable manufacturing and a potentially limitless supply. Positive interim results from a proof-of-concept study demonstrate a marked improvement in i-MSC-treated animals over control animals in key clinical parameters. Currently, there is no FDA-approved drug therapy available for ARDS.

Mino-Wrap

Mino-Wrap (CITI-101) is a novel therapeutic designed to significantly reduce the rate of infection in post-mastectomy breast cancer patients that elect to undergo reconstructive breast surgery. This liquefying gel-based wrap provides inflammatory tissue protection and prevents infection in tissue expanders and breast implants post mastectomy. Mino-Wrap, licensed from MD Anderson Cancer Center, has the potential to be the first and only FDA-approved product for this indication.

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