

**Citius Pharmaceuticals, Inc. (Nasdaq: CTXR)** is a specialty pharmaceutical company dedicated to the development and commercialization of drug products that address important unmet medical needs. The Company concentrates on adjunctive cancer therapies, critical care medicine, and anti-infectives. The Company is focused on obtaining intellectual property protection for a significant post-approval period and also seeks to identify regulatory opportunities for market exclusivity. Citius recently signed an exclusive worldwide licensing agreement with privately-held Novellus, Inc. for unique stem cell therapy for Acute Respiratory Distress Syndrome (ARDS) associated with COVID-19. Citius is advancing three product candidates: 1) Mino-Lok® is in Phase III trials and is enrolling patients, 2) Halo-Lido (CITI-002) is being prepared for a Phase IIb trial, and 3) Mino-Wrap™ (CITI-101) is in pre-clinical stage. The markets for these products are large, underserved, and provide unique opportunities for the Company. Mino-Lok and Mino-Wrap are the results of collaborations with MD Anderson Cancer Center. Founders and Company officers have cumulatively invested \$26.5 million into the Company.

### Product Development Pipeline

Program	Estimated Market (Worldwide)	Preclinical	Phase I	Phase II	Phase III
<b>Mino-Lok®</b> Treat CVC Infections	> \$1.5B	Interim Safety/Efficacy Analysis (Sep); Last Pat. Visit est. Q2'21			
<b>CITI-002 (Halo-Lido)</b> Rx Therapy for Hemorrhoids	> \$2B	Next milestone: IND (exp Q2 2021); Ph 2B Initiated (exp Q3)			
<b>CITI-101 (Mino-Wrap)</b> Prevent Infections Associated with Breast Implants	> \$400M	IND est. Q4'21			
<b>CITI-401 (i-MSC)</b> Treat ARDS	Multi-billion	IND est. Q1-2 '22			

\* Best estimate, subject to impact of COVID-19 pandemic on clinical trial conduct and operations.

### Anticipated Milestones

Milestone	When
CITI-101 Pre-IND Meeting	2H '20
CITI-101 IND Filing	Q4 '21
CITI-002 IND Filing	Q3 '21
CITI-002 Phase IIb Trial Start	Q3 '21
M-L Phase III Interim Efficacy	Q2 '21
M-L Phase III Trial Completed	Q3 '21
CITI-401 IND Filing	Q1-2 '22
M-L NDA Submission	Q4 '21

### Investment Catalysts

**Market Opportunity – ARDS associated with COVID-19:** ARDS is a type of respiratory failure characterized by rapid onset of widespread inflammation in the lungs. ARDS is a rapidly progressive disease that occurs in critically ill patients – most notably now in those diagnosed with COVID-19. ARDS affects approximately 250,000 people in the U.S. annually, exclusive of the current COVID-19 pandemic, and has a 30% to 50% mortality rate. It has been reported that 31% of hospitalized COVID-19 patients develop ARDS. Among those who survive ARDS, a decreased quality of life is relatively common. ARDS is the most common cause of respiratory failure and mortality in COVID-19 patients and lacks any currently approved therapy. Several earlier generation adult-derived stem-cell therapies are currently in clinical trials and have established the regulatory pathway forward. Our next generation “induced” mesenchymal stem-cell (i-MSC) therapy is derived from an induced pluripotent stem cell (iPSC) bank. Previous research shows that MSCs produce potent anti-inflammatory and immunomodulatory properties that help counter the cytokine storm that brings about ARDS. MSCs also restore endothelial and epithelial barrier integrity, enhance the clearing of fluid from the lungs, and may exhibit antimicrobial properties.

**Market Opportunity – Critical Care/Infectious Disease:** The market potential for an effective antibiotic lock therapy (“ALT”) is estimated at \$750 million per year in the U.S. and is projected to reach \$1.84 billion globally in 2028. Currently, removing and replacing infected central venous catheters (“CVCs”) is the standard of care for most catheter-related bloodstream infections (“CRBSIs”). CVCs are life-saving vascular access ports in patients requiring long-term intravenous therapy. Of the approximately 7 million CVCs used annually in the US, up to 500,000 become infected and lead to CRBSIs. Infected CVCs must be removed, and most need to be replaced. However, these procedures are costly and discomforting, and 15-20% of them are associated with significant morbidity. There are currently no approved therapies to salvage infected CVCs. Mino-Lok penetrates biofilm, eradicates bacteria, and salvages infected, indwelling vascular catheters while providing anti-clotting properties. Mino-Lok has the potential to change the standard of care for the management of these serious infections.

**Market Opportunity – Post-Mastectomy Device Infections:** The market opportunity for preventing post-mastectomy infections in the U.S. is estimated at \$400 million per year. In 2017, the American Society of Plastic Surgeons reported that over 105,000 women in the U.S. underwent a post-mastectomy breast reconstructive procedure. A common breast reconstruction technique is tissue expansion, which involves the expansion of the breast skin and muscle using a temporarily implanted tissue expander (“TE”). Approximately 80% of the time, a TE is used to prepare the surgical site for permanent breast implants either immediately after mastectomy or in a separate procedure afterward. Following a mastectomy, microbes can gain access to the surgical pocket, and chronic inflammation in the surgical pocket is also a potential problem with breast reconstructions that can lead to fibrosis and other morbidities or eventually even anaplastic large cell lymphoma. Ultimately, the presence of virulent microbial biofilms can lead to TE-associated infections. There is a reported rate of TE-related infections of between 2.5% and 24%, depending on the extent of surgery, duration of postoperative drainage, and many other factors.

**Market Opportunity – Prescription Hemorrhoid Product:** We believe the \$2 billion worldwide market for hemorrhoid treatment is underserved and that an effective prescription-strength product would be unique and highly welcomed by both healthcare professionals and consumers. In the U.S., hemorrhoids affect nearly 5% of the population, with approximately 10 million patients annually reporting symptoms of hemorrhoidal disease. Approximately one-third of these patients visit a physician for evaluation and treatment of their hemorrhoids. Between 50% and 90% of the general population will experience hemorrhoidal disease at least once in their life. According to IMS, over 20 million units of topical combination prescription products for hemorrhoids are sold in the U.S.

### Market Snapshot—NASDAQ: CTXR

**Price:** \$1.93 (3/18/21)

**Float:** 67.62M free trading shares

**52-Wk. Range:** \$0.44-\$2.90

**Shares Outstanding:** 125.78M

Price quote from NASDAQ & public float calculated using SEC shelf filing rules.

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## Company Highlights

- Announced closing of \$76.5 million registered direct offering priced at-the-market in February '21
- Announced closing of \$20.0 million private placement priced at-the-market in January '21
- Received FDA response and guidance to Pre-IND consultation submission for Mino-Wrap in December '20
- Announced data from a study of induced mesenchymal stem cell ("*i*-MSC") therapy in an in vivo model of acute respiratory distress syndrome ("ARDS") – Pre-clinical studies of *i*-MSC therapy in the study show improvement in critical parameters, such as improved oxygenation, less systemic shock, and reduced lung injury, compared to the control group, in December '20
- Announced results of study that Mino-Lok eradicates *S. aureus* biofilm more effectively and expeditiously than components in November '20
- Citius Pharmaceuticals signed an exclusive worldwide licensing agreement with Novellus Therapeutics for unique *i*-MSC-therapy for acute inflammatory respiratory conditions including COVID-19 related Acute Respiratory Distress Syndrome (ARDS) in October 2020
- September 2020 - DMC makes recommendation to continue trial with no modifications and requests an ad hoc meeting in near future
- Announced closing of \$9.6 million bought deal offering and full exercise of underwriter's option to purchase additional shares in August '20
- Received FDA response on pre-investigational new drug (PIND) application for its induced mesenchymal stem cells (*i*-MSCs) to treat Acute Respiratory Distress Syndrome (ARDS) in patients with COVID-19 in June '20
- Received positive FDA feedback on its submitted plan to study catheter compatibility for Mino-Lok® therapy in June '20
- Expanded Access program for investigational Phase 3 Mino-Lok® in May '20
- Announced closing of \$7.5 million registered direct offering priced at-the-market under Nasdaq rules in May '20
- Submitted a pre-IND to FDA under the Coronavirus Treatment Acceleration Program (CTAP) for a novel stem cell therapy for Acute Respiratory Distress Syndrome (ARDS) in COVID-19 in April '20
- Signed exclusive option with Novellus to license novel stem-cell therapy for Acute Respiratory Distress Syndrome (ARDS) associated with COVID-19 in April '20
- Acquired a worldwide license for Mino-Wrap (CITI-101) from MD Anderson Cancer Center
- Highly experienced and successful management team that, along with the founders, has invested \$26.5 million into the Company

## Product Candidates

**NoveCite Cells – *i*-MSCs:** Citius signed an exclusive worldwide licensing agreement with Novellus, Inc., a privately-held biotechnology company creating new engineered cellular therapies, for a novel stem-cell therapy that would initially target Acute Respiratory Distress Syndrome (ARDS) associated with COVID-19. ARDS is the most common cause of respiratory failure and mortality in COVID-19 patients. The Novellus cellular manufacturing process (using mRNA reprogramming) is unique and creates a mesenchymal stem cell bank that is derived from induced pluripotent stem cells instead of harvesting cells from adult tissue. *i*-MSCs can be produced rapidly, can be expanded quickly to much greater levels than adult-donor derived MSCs, and may overcome the limitations of adult-derived MSCs, providing enhanced growth potential and overexpressing immunomodulatory proteins. We recently submitted a pre-IND plan to the FDA under the new Coronavirus Treatment Acceleration Program (CTAP) for the treatment of ARDS in COVID-19 patients and desire to file an IND by Q4' of 2021.

**Mino-Lok®:** Mino-Lok is a late-stage development product in Phase III trials. Citius has partnered with MD Anderson Cancer Center ("MDACC"), a world-leading cancer center to develop Mino-Lok. Mino-Lok has received Qualified Infectious Disease Product (QIDP) designation providing fast track status, priority review, and additional market exclusivity. We believe 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.

**CITI 101 – Mino-Wrap:** Mino-Wrap, or CITI 101, is a liquefying gel-based wrap containing minocycline and rifampin designed to provide inflammatory tissue protection and prevent infection and biofilm formation in tissue expanders and breast implants post-mastectomy. In January 2019, Citius signed a definitive license agreement with MDACC to develop and commercialize a novel approach to reducing post-operative infections associated with surgical implants estimated to be 12-14%. Mino-Wrap will be reviewed by the FDA's Center for Drug Evaluation and Research ("CDER") division.

**CITI-002 – Halo-Lido:** Citius is developing a topical formulation of halobetasol, a corticosteroid, and lidocaine to provide anti-inflammatory and anesthetic symptomatic relief to people with hemorrhoids. Corticosteroids and lidocaine have each been separately approved by the FDA for other indications and are commercially available and marketed by other companies. Citius is advancing its combination therapy for hemorrhoids as being synergistic to its individual components and is pursuing a patent for the new halobetasol-lidocaine formulation. If this formulation is approved by the FDA, Citius would have the only FDA-approved prescription-strength product on the market proven to be safe and effective for the treatment of hemorrhoids. Halobetasol is not used in combination in currently marketed hemorrhoid products but is included as an FDA-approved topical product to treat a variety of dermatological disorders. We expect to file an IND in Q2 2021 and initiate the phase 2b trial in Q3 2021.

## Management Team

**Myron Holubiak, President & CEO:** Mr. Holubiak has extensive experience in managing both large and emerging pharmaceutical companies. Most recently, he was the Founder, Director, and CEO of Leonard Meron Biosciences, Inc. which merged with Citius. He is the former President of Roche Laboratories, Inc., USA, a major research-based pharmaceutical company. During his tenure as President of Roche, Holubiak transformed Roche Labs into a major biotechnology company.

**Leonard Mazur, Chairman:** Mr. Mazur is a highly accomplished industry executive with notable accomplishments in founding, building, and creating value and returns for investors. Mr. Mazur is a founder/co-founder of the following companies: Genesis, Triax, Akrimax, and Rouses Point. He previously served as Executive VP at Medicis Pharmaceutical Corporation and VP of Sales & Marketing at ICN Pharmaceuticals, Inc. and Knoll Pharma.

**Jaime Bartushak, CFO:** Mr. Bartushak is an experienced finance professional for early-stage pharmaceutical companies and has over 20 years of corporate finance, business development, and strategic planning experience.

**Myron Czuczman, M.D., CMO and EVP:** Dr. Czuczman is the newest member to the Citius team, before that he was the Therapeutic Area Head, Vice President, Clinical Research and Development Global Lymphoma/CLL Program at Celgene Corporation. At Celgene, he was responsible for worldwide clinical development in Lymphoma/CLL and for the development of all compounds from Proof-of-Principle through registration globally. Dr. Czuczman has published greater than 180 peer-reviewed journal articles.

**Alan Lader, PhD, VP Clinical Operations:** Dr. Lader, has over 25 years of experience in medical research. Dr. Lader earned his Master's degree from the Hartford Graduate Center of Rensselaer Polytechnic Institute. He went on to receive his Ph.D. in Biomedical Science and Physiology from the University of South Carolina School of Medicine, then returned for post-doctoral training at Harvard Medical School and Massachusetts General Hospital. Following his post-doctoral training, Dr. Lader was an Instructor in Medicine at Harvard Medical School and Brigham and Women's Hospital.

Safe Harbor: This communication may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements are made based on our expectations and beliefs concerning future events impacting Citius. You can identify these statements by the fact that they use words such as "will," "anticipate," "estimate," "expect," "should," and "may," and other words and terms of similar meaning or use of future dates. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition, and stock price. Factors that could cause actual results to differ materially from those currently anticipated are: the risk of successfully negotiating a license agreement with Novellus within the option period; our need for substantial additional funds; the ability to access the FDA's CTAP program for our planned ARDS treatment; risks associated with conducting our Phase 3 trial for Mino-Lok®, including completing patient enrollment; risks associated with developing Mino-Wrap™ and our planned treatment for ARDS, including that preclinical results may not be predictive of clinical results and our ability to file an IND; the estimated markets for our product candidates and the acceptance thereof by any market; uncertainties relating to preclinical and clinical testing; risks related to our growth strategy; our ability to identify, acquire, close, and integrate product candidates and companies successfully and on a timely basis; risks relating to the results of research and development activities; the early stage of products under development; our ability to obtain, perform under, and maintain financing and strategic agreements and relationships; our ability to attract, integrate, and retain key personnel; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions, or circumstances on which any such statement is based, except as required by law.