NASDAQ: CTXR

CITIUS PHARMA

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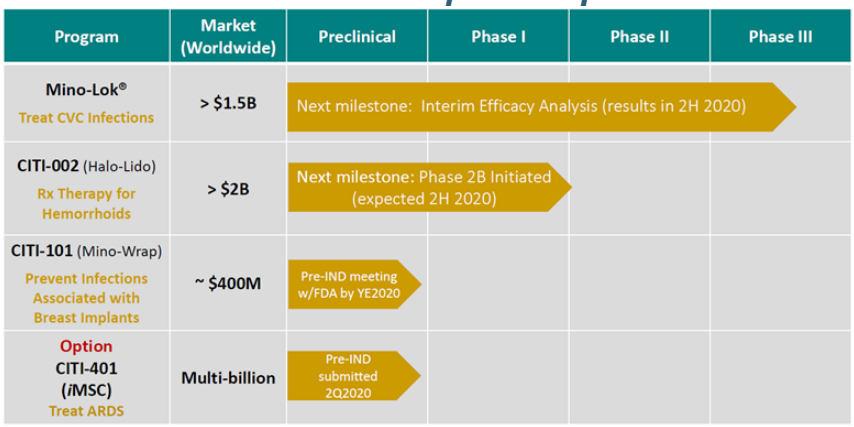
Citius Pharmaceuticals, Inc. (Nasdaq: CTXR) is a specialty pharmaceutical company dedicated to the development and commercialization of drug products that address important unmet medical needs. Citius recently acquired an exclusive option with privately-held Novellus, Inc. to license a novel stem-cell therapy for Acute Respiratory Distress Syndrome (ARDS) associated with COVID-19. 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 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



Anticipated Milestones

Milestone	When
CITI-101 Pre-IND Meeting	2H '20
CITI-002 IND Filing	Q3 '20
CITI-002 Phase IIb Trial Start	Q4 '20
M-L Phase III Interim Efficacy	2H '20
M-L Phase III Trial Completed	Q4 '20
CITI-401 IND Filing	Q1 '21
M-L NDA Submission	Q3-4 '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. The FDA's new Corona Treatment Acceleration Program (CTAP) provides for an ultra-fast track regulatory pathway for the development of therapies treating COVID-19. 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 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 approximately $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 – Gastrointestinal: Citius believes 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: $0.93 (8/31/20) **Float:** 26.8M free trading shares **52-Wk. Range:** $0.40-$1.97 **Shares Outstanding:** 55.4M

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

Company Highlights

- 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
- Announced publication in **Antimicrobial Agents and Chemotherapy** journal of positive preclinical results for Mino-Lok® in rapidly eradicating Candida auris
- Achieved 50% patient enrollment in Phase 3 Mino-Lok® pivotal trial in Feb '20
- Reached the interim analysis for the pivotal Phase III study on Mino-Lok in Oct '19 and subsequently announced positive outcome of interim futility analysis in Dec '19
- Announced a change in primary endpoint in Phase III trial to "time-to-catheter-failure" reducing the time to conduct the trial with significant savings in clinical trial costs in Sept '19
- In a meta-analysis of two separate studies conducted in four institutions in four different countries, it was shown that Mino-Lok was 98% effective (49/50) in salvaging catheters that caused bacteremia
- Received "Fast Track" designation by FDA for Mino-Lok investigational trial
- 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 holds a six-month option with Novellus, a privately-held biotechnology company creating new engineered cellular therapies, to license 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-derived MSCs, and may overcome the limitations of adult-derived MSCs, providing enhanced growth potential and overexpressing immunomodulatory proteins. *i*MSCs have the potential to reduce the number of ventilator days (in a 28-day period) as compared to the standard of care. Working with Novellus, 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 the end of 2020

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. The Company is currently preparing for a pre-IND meeting with CDER, which is expected to occur in the second half of 2020.

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 Q3 2020 and initiate the phase 2b trial in Q4 2020.

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.