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. The Company focuses on adjunctive cancer therapies, critical care medicine, and anti-infectives. Citius designs and develops products for new and expanded indications primarily utilizing the U.S. Food and Drug Administration's (FDA's) 505(b)(2) pathway for new drug approvals. 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.

Product Development Pipeline

Anticipated Milestones

Milestone	When
M-L Phase III Interim Data	Q4 '19
CITI-002 Toxicity Data	Q1 '20
M-L Phase III Interim Superiority	Q2 '20
CITI-101 Pre-IND Meeting	Q2 '20
CITI-002 Phase IIb Trial Initiation	Q3 '20
M-L Data Lock	Q2 '21
M-L NDA Submission	Q4 '21

Investment Catalysts

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 approximately $1.5 billion worldwide. Currently, removing and replacing colonized 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, up to 500,000 become infected and lead to CRBSIs. Infected CVCs must be removed, and most need to be replaced. These procedures are costly and discomforting, and 15-20% of them are associated with significant morbidity. Although ALTs are sometimes attempted when venous access is unavailable, there are not adequate data available to evaluate their efficacy. Additionally, it has been shown that antibiotics alone are unable to penetrate the biofilm formed by bacteria to protect the colonies. There are currently no approved therapies to salvage infected CVCs. Mino-Lok is an antibiotic lock solution used to treat patients with CRBSIs in combination with an appropriate systemic antibiotic(s) to preserve central venous access and to avoid the complications and morbidities associated with catheter removal and reinsertion. 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 frequency of post-mastectomy breast reconstruction following breast cancer treatment has been increasing annually. 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. A TE is a silicone implant that serves as a temporary device that is placed within a surgical pocket in the mastectomy space and inflated with saline over a period of time to prepare the area for a permanent breast implant. There is significant natural flora in and around breast tissues. Following the disruption of dermal barriers to microbial penetration during surgical mastectomy, microbes can gain access to the surgical pocket. Chronic inflammation in the surgical pocket is also a potential problem with breast reconstructions and can lead to fibrosis and other morbidities or eventually even anaplastic large cell lymphoma. Ultimately, the presence of virulent microbial biofilms can be a prelude 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. Based on discussions with the Citius Scientific Advisory Board, the Company believes the infection rate is between 12 and 14%. There is a high association of positive microbial cultures with TE-associated infections. TE infections frequently require removal of the TE and treatment with culture-directed antibiotics, possibly resulting in further complications for the patient.

Market Opportunity – Gastrointestinal: 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 25 million units of topical combination prescription products for hemorrhoids are sold in the U.S. Hemorrhoids are a common gastrointestinal disorder characterized by pain, swelling, itching, tenderness, and bleeding. Although hemorrhoids are not life-threatening, individual patients often suffer painful symptoms that can limit social activities and have a negative impact on the quality of life. Citius believes the market for hemorrhoid treatment is large and underserved and that an effective prescription-strength product would be unique and highly welcomed by both healthcare professionals and consumers.

Market Snapshot—NASDAQ: CTXR

Price: $0.60 (03/09/20) **Float:** 15.04M free trading shares **52-Wk. Range:** $0.40-$1.59 **Shares Outstanding:** 38M

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

Company Highlights

- Achieved 50% patient enrollment in Phase 3 Mino-Lok® pivotal trial in Feb '20
- Issued a corporate update on the progress of the Company's product candidates Mino-Lok®, Mino-Wrap™, and Halo-Lido in Nov '19
- Reached the interim analysis for the pivotal Phase III study on Mino-Lok in Oct '19
- Announced closing of $7.0 million underwritten offering priced at-the-market in Sept '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
- Over $26.8 million invested privately by the founders and insiders; $21 million by the public
- Reported that Mino-Lok is highly efficacious in rapidly eradicating Candida auris
- 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
- Announced a $5.3 million offering priced at-the-market in April '19
- Announced $10.0 million underwritten offering priced at-the-market in Aug '18
- Announced $2.0 million registered direct offering in March '18
- Provided a status report on the Mino-Lok Phase III trial
- Reported Phase IIb development plan for the hemorrhoid program
- Published expert roundtable discussion on treatment consideration for catheter-related bacteremias
- 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. Mino-Wrap is designed to provide inflammatory tissue protection and prevent infection and biofilm formation in tissue expanders and breast implants post-mastectomy
- Met with FDA CDRH to determine best regulatory pathway for Mino-Wrap in June '19
- Highly experienced and successful management team investing significantly in the Company

Product Candidates

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 QIDP designation providing fast track status, priority review, and additional market exclusivity. 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. In September 2019, the Company announced the FDA agreement to modify the primary endpoint of the Phase III study to "time-to-catheter-failure," effectively reducing the number of patients and time to conduct and complete the trial. This protocol change could result in clinical trial cost savings approaching $10 million.

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 early 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.

Development & Commercialization Strategy

The Company's goal is to build a successful pharmaceutical company through developing and commercializing innovative, efficacious, and cost-effective products that address compelling market opportunities. Citius maintains a partnership with MD Anderson Cancer Center for the development of its adjunctive cancer and infectious disease products. Citius seeks to leverage the FDA's 505(b)(2) pathway for new drug approvals and bring products to market faster and with less risk as compared to other FDA new drug approval pathways. Objectives include:

- Develop drug therapies and devices that make a meaningful contribution to healthcare;
- Focus on the most relevant and advanced technologies to provide our new product candidates with superior product characteristics and intellectual property protection;
- Introduce products that are cost-effective and even cost-saving;
- Identify indications that are typically treated by a relatively small number of specialist physicians and can therefore be efficiently addressed;
- Manage our business in a financially disciplined and cost-conscious manner

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.

Gary F. Talarico, EVP Operations: Mr. Talarico is highly experienced and successful in developing and leading commercial activities for a number of pharmaceutical companies. He has directed all of the commercial disciplines including marketing, sales, operations, training, trade and managed markets, and KOL development.

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.