

LETTER TO SHAREHOLDERS

May 2020

Dear Fellow Shareholders,

Our thoughts go out to all those affected by COVID-19. We especially want to express our gratitude and admiration to all the front-line healthcare workers who are putting themselves at risk as they treat and comfort patients.

Citius Pharmaceuticals, Inc. (“Company”) has made significant progress since our last communication to shareholders, and we have significant news to share with you about recent developments that relate directly to the pandemic affecting us all. We recently acquired an option from Novellus, Inc. to license a potential therapy to treat Acute Respiratory Distress Syndrome (ARDS), which is a major complication of the COVID-19 coronavirus and has led to the majority of COVID-19 patient deaths.

While the COVID-19 pandemic has affected the progress of virtually all clinical trials, including our own, the Company continues to make progress, albeit at a slower pace. The Mino-Lok pivotal Phase 3 trial is now expected to complete enrollment in the first half of 2021 and, prior to full enrollment, we also expect to conduct an interim analysis for efficacy and safety in the second half of 2020. For Mino-Wrap, we have been consulting with FDA and anticipate having a pre-IND (PIND) meeting by the end of 2020. For Halo-Lido, we plan to initiate a Phase 2b trial in the second half of 2020.

Citius Drug Pipeline

Program	Market (Worldwide)	Preclinical	Phase I	Phase II	Phase III
Mino-Lok® Treat CVC Infections	> \$1.5B	Next milestone: Interim Efficacy Analysis - results in 2H 2020			
CITI-002 (Halo-Lido) Rx Therapy for Hemorrhoids	> \$2B	Next milestone: Phase 2B Initiated (expected 2H 2020)			
CITI-101 (Mino-Wrap) Prevent Infections Associated with Breast Implants	~ \$400M	Pre-IND meeting w/FDA by YE2020			
Option CITI-401 NoveCite Cells Treat ARDS	Multi-billion	Pre-IND meeting w/FDA 2Q20			

Stem-Cell Therapy for ARDS due to COVID-19 — Exclusive Option to License Novel Therapy from Novellus, Inc.

In the span of just a few months, the COVID-19 pandemic has had a tremendous impact on the world — including the deaths of hundreds of thousands of people — and has led to social distancing policies for millions of people and an unprecedented global economic slowdown in terms of speed and breadth. Considerable and concerted worldwide efforts are now focused on developing a vaccine and other therapies to address the COVID-19 crisis. In early April, we announced that we signed an exclusive six-month option with Novellus, Inc., a privately held preclinical stage biotechnology company focused on creating new engineered cellular therapies and diagnostics, to in-license a stem-cell therapy for ARDS with an initial targeted application in ARDS associated with COVID-19.

ARDS is the most common cause of respiratory failure and mortality in COVID-19 patients with no currently approved drug therapy available. Mechanical ventilation, which is essentially oxygen forced into the lungs, is typically used in the worst cases of COVID-19, but ARDS is believed to account for 80% of the deaths in ventilated patients suffering from COVID-19. ARDS is characterized by widespread inflammation in the lungs and affects approximately 250,000 people each year in the U.S. Unfortunately, the pandemic has caused the prevalence of ARDS to sharply increase beyond this base case. ARDS has a 30-50% mortality rate and has symptoms of shortness of breath, rapid breathing and heart rate, chest pain (especially while inhaling), and bluish skin coloration.

Novellus' cellular process relies on its exclusive non-immunogenic synthetic messenger ribonucleic acid (mRNA) reprogramming process to create a master cell bank of induced pluripotent stem cells (iPSCs). The iPSCs create mesenchymal stem cells (MSCs) that, due to their multi-potent nature and their ability to secrete multiple paracrine factors, such as anti-inflammatory cytokines, can potentially treat the major abnormalities that underlie ARDS. While the immunomodulatory properties of MSCs have been well characterized, clinical results in ARDS are only now being investigated. The cellular processing technology used by Novellus provides a virtually unlimited supply of MSCs (called NC-MSCs) that are allogeneic (i.e., "off-the-shelf"). To put it in simpler terms, these NC-MSCs are derived from a new and improved source, are quick to produce, can scale easily, can be transported and delivered easily, and are especially potent. Furthermore, MSCs, in general, have a favorable safety profile from their history of use in other indications.

Of course, working with Novellus, we still need to pursue the traditional regulatory path and conduct clinical trials to confirm that these seemingly superior NC-MSCs are effective in humans in order to obtain FDA approval for this ARDS therapy, but we certainly are encouraged by the preclinical data we have seen thus far. Previous research suggests the rationale for using MSCs in ARDS is that they can offer potent anti-inflammatory properties that can counter the cytokine storm in the lungs and can enhance the clearance of fluid from the lungs. They may also exhibit antimicrobial properties and restore endothelial and epithelial barrier integrity in the lungs.

In late April, we announced a pre-IND (Investigational New Drug) submission to the FDA under its new Coronavirus Treatment Acceleration Program (CTAP) for this novel stem-cell therapy for ARDS in COVID-19 patients. We hope to initiate a clinical trial in patients by the end of 2020. The FDA's emergency CTAP program was designed to accelerate the development of COVID-19 treatments via faster communications and regulatory review protocols. Thus, we can benefit from a faster track at the FDA throughout the traditional regulatory process because the FDA is prioritizing such development activity given the current pandemic.

Mino-Lok® (FDA Phase III) — Interim Data Analysis and Enrollment Update

Mino-Lok® is our lead product and is an antibiotic lock solution for use in treating catheter-related bloodstream infections (CRBSIs). In mid-December 2019, we announced a positive outcome for the pre-specified interim futility analysis for our ongoing pivotal Phase 3 trial of Mino-Lok vs. standard-of-care antibiotic locks. This analysis was performed once enrollment in the trial reached 40% in late September 2019. The trial’s Data Monitoring Committee (DMC), an independent panel of experts who monitor the safety and efficacy of the trial’s progress, recommended the trial proceed as planned. In February 2020, we announced the trial had reached 50% enrollment. The next trial milestone will be an interim analysis of safety and superior efficacy. We expect to collect the relevant data by the end of June and hold our next DMC meeting in the third quarter. If the trial were to meet the interim superiority threshold, it could be halted earlier than anticipated. However, we expect that the trial will continue as planned until it is fully enrolled, which we anticipate to be in the first half of 2021.

The antibiotic lock therapy market is a \$750 million annual opportunity in the U.S. and is expected to reach \$1.84 billion worldwide by 2028. We look forward to playing a significant role in eliminating the approximately 500,000 “extra” procedures performed each year just to remove and replace infected central venous catheters (CVCs) that lead to CRBSIs. These invasive procedures are discomforting to the patient and are costly for the hospital system, and 15-20% of them are associated with significant morbidity for the patient. We believe Mino-Lok is a better solution for both patients and hospitals and are excited about future trial results. Furthermore, we know of no other competitive products being developed to treat and salvage indwelling, infected CVCs, and we maintain worldwide rights and would have more than 10 years of exclusivity at the time of anticipated launch, which is estimated to be in 2022.



Antibiotic lock therapy market
\$1.84 billion worldwide by 2028

Mino-Wrap™ — Post-Mastectomy Infection Prevention, a \$400 Million Market Opportunity

Mino-Wrap is a bio-absorbable, antimicrobial solid film wrap that is wrapped around a tissue expander and placed in the surgical pocket following a mastectomy to prevent post-surgical infections by reducing microbial colonization of the device. Once installed, Mino-Wrap slowly liquefies *in situ* for a specified period of time, providing extended protection against infection.

The reported rate of tissue expander-related infections is between 2.5% and 24%, depending on the extent of surgery, duration of postoperative drainage, and many other factors. Once the tissue expander becomes infected, the patient is hospitalized, and the tissue expander may need to be removed. These serious infections may lead to a delay in life-saving chemo-radiation therapy, which can be a devastating consequence for the patient, and can also lead to a delay in permanent breast implantation.

Mino-Wrap is designed to allow the temporary tissue expander to be inflated without any restrictions and to prevent infection and biofilm formation surrounding the tissue expander over a longer duration than that from the current treatment regimen. Mino-Wrap could also be used with breast implants during reconstruction following removal of the tissue expander.

We currently expect to have a PIND meeting with the FDA before the end of the year and begin a Phase 2 clinical study in 2021. The market opportunity for Mino-Wrap in preventing infections following breast implant surgeries following mastectomies is estimated to be \$400 million.

Halo-Lido — Aiming to be the first FDA-approved prescription product to treat hemorrhoids in the U.S.

Halo-Lido is being developed for symptomatic relief of hemorrhoids and combines the high-potency steroid halobetasol with lidocaine. Based on results of previous clinical work and a Vasoconstriction Assay (VCA), we selected a cream formulation combining the potent steroid Halobetasol Propionate and Lidocaine HCl to move forward in clinical development. The manufacturing scale-up is complete and the formulation has met chemical, physical, and stability criteria. This formulation will be used in a Phase 2b study expected to start in the second half of 2020.

Over 10 million patients in the U.S. admit to symptoms of hemorrhoidal disease and one-third of them seek physician treatment, yet there are no FDA-approved prescription products available. Over-the-counter hemorrhoid product sales are approximately 20 million units annually. Our formulation, if approved, would be the first prescription product to treat hemorrhoids approved by the FDA in the U.S.

Other Corporate Activities — Investor Outreach

We believe our products in development and the market opportunities we are pursuing are quite compelling and are always looking for ways to share our story with investors. Since December 2019, we have presented at the 12th Annual LD Micro Main Event, Noble Capital Markets' 16th Annual Investor Conference, and the 2020 LD Micro Virtual Conference, while also delivering a virtual presentation at the Spring Investor Summit. Additionally, we regularly update our corporate presentation and make that available to investors on our website and in regulatory filings with the Securities and Exchange Commission.

Looking Forward

The remainder of 2020 should be an exciting time for all Citius shareholders given the numerous milestones ahead across our full pipeline of products:

- For Mino-Lok, results from the interim efficacy analysis are expected to be available in the second half of 2020. We also expect the trial to be completed during the first half of 2021. The antibiotic lock solution market is estimated to be a \$750 million opportunity in the U.S. and is expected to grow to \$1.84 billion worldwide by 2028
- We have a six-month option to license the novel stem-cell therapy (NC-MSD) for ARDS associated with COVID-19 from Novellus. Working with Novellus, we have already filed a pre-IND submission under the FDA's emergency CTAP program. The human toll COVID-19 has caused calls for new therapies to be developed, and we think Novellus's stem-cell technology is quite compelling
- We expect to have a PIND meeting with the FDA for Mino-Wrap by the end of 2020 and hope to initiate a Phase 2 trial by the end of 2021. We estimate the U.S. market to prevent infections associated with breast implant procedures to be a \$400 million market opportunity
- For Halo-Lido, we plan to start a Phase 2b study for symptomatic relief of hemorrhoids in the second half of 2020. Halo-Lido has the potential to be the first FDA-approved prescription product on the \$2 billion hemorrhoidal market

On behalf of the Citius Pharmaceuticals team, thank you for your interest in our Company. We look forward to sharing future important corporate developments and our clinical progress with you. In this current healthcare crisis, we hope you and your family stay healthy and safe.

Sincerely,



Myron Holubiak

Chief Executive Officer, President, and Director



Leonard Mazur

Chairman of the Board

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.