

## Citius Corporate Update

November 2019

### Dear Investors:

Citius Pharmaceuticals, Inc. (“Company”) has had a very productive and encouraging quarter.

On September 27, 2019, we closed a \$7 million capital raise with H.C. Wainwright (“HCW”) to position our Company better for growth and advance our ongoing research. We have worked with HCW in the past, and, to date, management has invested nearly \$27 million in the Company. This significant investment, when compared to many other biotech microcap companies, is a testimony to the commitment we have made to the success of the company and the unwavering belief we share in the potential and value of the assets we are developing.

To date, management has invested nearly \$27 million in the Company.

We are currently advancing three proprietary product candidates into large markets that are underserved by the current standards of care:

- **Mino-Lok®**, which is in FDA Phase III trials, is our lead product and is an antibiotic lock solution for use to treat cancer patients or hemodialysis patients with catheter-related bloodstream infections (“CRBSIs”). In a previous Phase IIb trial, Mino-Lok demonstrated a 100% efficacy rate in salvaging colonized central venous catheters (“CVCs”) and had no significant adverse events (“SAE”) vs. an 18% SAE rate when infected CVCs were removed and replaced.
- **Mino-Wrap™** (or CITI-101), which is pre-clinical, is a bio-absorbable film impregnated with minocycline and rifampin used to prevent post-surgical infections and reduce microbial colonization of breast tissue expanders used in breast reconstruction following mastectomies.
- **Halo-Lido** (or CITI-002), which is in FDA Phase II trials, is being developed for symptomatic relief of hemorrhoids and combines the high-potency steroid halobetasol with lidocaine.

### ***Mino-Lok® (FDA Phase III) — Very Positive Progress, Reached the Interim Analysis, Change in End Point, Substantial Savings in Clinical Trial Costs***

Following a series of discussions with the FDA regarding the Mino-Lok trial, we recently announced a change in the pivotal study’s primary endpoint to the agreed-upon “time to catheter failure.” This change in study design substantially reduced the required sample size of the trial from 700 subjects to approximately 144 evaluable subjects to achieve the pre-specified 92 catheter failure events needed to conclude the trial.

It is believed that the median time to catheter failure for the antibiotic lock therapy (“ALT”) arm, or the control arm in the trial, is estimated to be 21 days, based on our evaluation of the applicable published studies. The median time to catheter failure for the Mino-Lok therapy (“MLT”) arm is expected to be greater than 38 days. Allowing these subjects to keep the catheter for 21 days or longer is clinically meaningful, as it eliminates the need for patients to undergo often painful removal and replacement procedures of CVCs. Replacement procedures of CVCs are inherently costly and risky, given the typically high-risk patient population being treated. Importantly, patients would have continuous venous access for therapy for their underlying disease, and this would represent a major step forward in the treatment of CRBSIs.

In addition to the significant reduction in patients now required to complete the trial, the new trial protocol also incorporates two interim analyses, a futility analysis and a superiority analysis. We recently announced that we reached the first interim analysis of the trial, the futility analysis. The trial data is being gathered, analyzed, and sent to our drug

monitoring committee (“DMC”), composed of three independent experts and an unblinded statistician, for the standard futility analysis. The outcome of the futility analysis is expected by the end of 2019.

**Management is confident that Mino-Lok has \$750+ million/year potential in the U.S. market and at least that in the rest of the world, bringing worldwide market potential to \$1.5+ billion/year.**

As we await the futility analysis report, we also anticipate closing in on the superior efficacy analysis and expect to reach the required number of catheter failure events for this analysis in early 2020. The superior efficacy analysis is designed to determine if there is sufficient statistical evidence to justify concluding the trial early due to overwhelming efficacy of Mino-Lok once 69 catheter failure events (75% of the 92 catheter failure events designed into the trial) have occurred in the trial. If the trial is not concluded early due to the superiority analysis, the trial is expected to conclude by the third quarter of 2020.

Regarding Mino-Lok, it is important to note that these changes to the trial’s protocol could save the Company approximately \$10 million in clinical trial expenses because far fewer patients than originally anticipated would need to be enrolled. Moreover, the trial should take considerably less time due to the lower enrollment requirements, and there is a chance of the trial being concluded even earlier now that there is a superiority analysis added to the protocol. While it took some time to get to this point, we are very excited about the regulatory path Mino-Lok is now on.

Management is confident that Mino-Lok has \$750+ million/year potential in the U.S. market and at least that in the rest of the world, bringing worldwide market potential to \$1.5+ billion/year. We feel there is tremendous value in the Company’s assets and commercial outlook, as witnessed by our repeated investments in each financing round and our total investment of nearly \$27 million to date.

***Mino-Wrap™ — Post-Mastectomy Infection Prevention, Unmet Need, Jurisdictional Status Determined, Preparations for Pre-IND Meeting***

The Company has expanded its relationship with MD Anderson Cancer Center by entering into a worldwide license for Mino-Wrap. Mino-Wrap is a bio-absorbable, antimicrobial solid film wrap that would be wrapped around a tissue expander and placed in the surgical pocket following a mastectomy to provide prophylaxis against infection for an extended period of time. Once installed, it slowly liquefies in place (*in situ*) for a specified period of time, providing extended protection against infection from the most likely pathogens.

A tissue expander 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. After a few months, the tissue expander is removed, and the patient receives either microvascular flap reconstruction or the insertion of a permanent breast implant.

The reported rate of tissue expander-related infections is between 2.5% and 24%, depending on the extent of surgery, duration of post-operative drainage, and many other factors. Our own research suggests that the post-mastectomy infection rate is approximately 14% even when following the standard prophylaxis protocol. 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 lifesaving chemo-radiation therapy, which can be a devastating consequence for the patient.

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.

**The Company has expanded its relationship with MD Anderson Cancer Center by entering into a worldwide license for Mino-Wrap™.**

Conclusions from the pre-clinical work with Mino-Wrap are as follows:

- Mino-Wrap remains intact for at least one week after being submerged in a collagenase saline solution at 37°C.
- Mino-Wrap is safe and not cytotoxic toward human fibroblasts.
- The active ingredients in Mino-Wrap remain active after gamma radiation sterilization.
- The antibacterial components in Mino-Wrap are active against the most common bacterial clinical isolates responsible for tissue expander infections for at least 10 days.

Essentially, we believe that Mino-Wrap has the characteristics necessary for an advance in the protection of human implants from subsequent infection.

In late June 2019, the FDA determined that Mino-Wrap is considered a drug, not a medical device, due to its perceived antibacterial benefits, and will be reviewed by the FDA's Center for Drug Evaluation and Research ("CDER") division. The Company has begun to prepare for a pre-IND meeting with the FDA, which we expect to occur in early 2020.

### ***Halo-Lido — Reformulated, Vasoconstrictor Assay Completed***

The Company initiated a program to develop a topical formulation containing a corticosteroid and topical anesthetic to treat symptoms of hemorrhoids. We initially selected a combination of hydrocortisone acetate, a low-potency steroid, and lidocaine hydrochloride, a well-characterized topical anesthetic, as our lead formulation. The Company collected valuable data from the Phase II study to modify and further develop the program. Specifically, we concluded that, compared to hydrocortisone, a higher potency steroid would contribute higher efficacy in combination with lidocaine hydrochloride.

We subsequently selected halobetasol propionate, a highly potent steroid, and have reformulated combinations of lidocaine hydrochloride and halobetasol propionate. Several clinical formulations were successfully manufactured at a 20-kg scale under Good Manufacturing Practice ("GMP") conditions. Additionally, the specifications and analytical procedures used to release the product and assess stability have been developed and validated.

After testing various formulations *in vitro*, we selected two formulations for an *in vivo* study in healthy volunteers to assess their vasoconstrictive properties and compare them to commercially available formulations. Dosing has been completed, and there were no serious adverse events reported in any tested formulation. We will use the results from this study to select one formulation and expect to initiate an acute toxicology study by year-end before initiating a planned expanded Phase II study in 2020.

### ***Other Corporate Activities — Industry Events and Investor Outreach***

In early October, the Company held an in-person Scientific Advisory Board ("SAB") meeting where we were fortunate to gain strategic insight from our SAB members, who are leaders in the field of infectious disease. Their guidance will be pivotal as we continue to advance our Mino-Lok Phase III trial along with plans for the development of Mino-Wrap.

In early October, we also held an investigator meeting where an update on the Mino-Lok® trial was provided to a set of principal investigators and their staff. The consensus of the attendees confirms the Company's belief that Mino-Lok therapy has the potential to change the standard of care and would be a welcome addition for the adjunctive treatment of CRBSIs.

We continue an aggressive investor outreach campaign. In the fourth quarter of 2019, we attended or plan on attending the H.C. Wainwright, Dawson James, BioFlorida, and LD Microcap conferences. Additionally, we often meet with microcap and/or healthcare investors at roadshows and luncheons in a number of cities, including New York, Boston, Philadelphia, and West Palm Beach.

## ***NASDAQ Listing***

We recently disclosed that the Company no longer complies with the \$1.00 minimum bid price requirement for continued listing on the Nasdaq Capital Market. Importantly, this noncompliance has no immediate effect on the listing or trading of the Company's common stock. We have until April 27, 2020 to regain compliance with the minimum bid price requirement and intend to consider all available alternatives that would allow for continued listing of the common stock on the Nasdaq Capital Market.

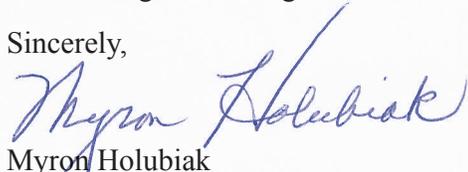
## ***Moving Forward into Fiscal Year 2020***

Looking ahead, we view our corporate road map with a renewed sense of confidence. In the coming months, our primary focus will be on Mino-Lok and finalizing the futility analysis from the pivotal trial, reaching the second interim analysis (testing for the superiority) in the trial, and successfully concluding the trial. These are key milestones for the Company, and we are quite eager to reach them.

Management has conviction in our strategy and assets and has expressed such with our repeated financial commitment to invest tens of millions of dollars alongside our investors. We are extremely excited about our Mino-Lok pivotal trial, especially now that we are reaching important clinical milestone events. We believe that we clearly see the light at the end of the tunnel.

On behalf of the Citius Pharmaceuticals team, we thank you for your continued support and look forward to developing breakthrough technologies that will significantly enhance and improve the lives of patients.

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: risks associated with conducting our Phase 3 trial for Mino-Lok®, including completing patient enrollment, opening study sites, and achieving the required number of catheter failure events; risks associated with developing Mino-Wrap™, 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; our need for substantial additional funds; 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; uncertainties relating to preclinical and clinical testing; 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.