UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) October 25, 2020

Citius Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction of incorporation)

333-206903	27-3425913
(Commission File Number)	(IRS Employer Identification No.)
11 Commerce Drive, 1st Floor, Cranford, NJ	07016
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code (908) 967-6677

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.001 par value	CTXR	The Nasdaq Capital Market
Warrants to purchase common stock	CTXRW	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

On October 25, 2020, we provided a letter to our shareholders to update them on our development program. A copy of the letter is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Letter to Shareholders October 2020.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CITIUS PHARMACEUTICALS, INC.

Date: October 26, 2020

/s/ Myron Holubiak

Myron Holubiak
President and Chief Executive Officer

Exhibit 99.1

CITIUS PHARMA

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ascott@citiuspharma.com

LETTER TO SHAREHOLDERS

October 2020

Dear Fellow Shareholders,

Citius Pharmaceuticals, Inc. ("Company") has made considerable progress in 2020 with recent developments designed to contribute to increased value for our shareholders. Additionally, there are many upcoming milestones that could be catalysts for further acceleration to corporate advancement.

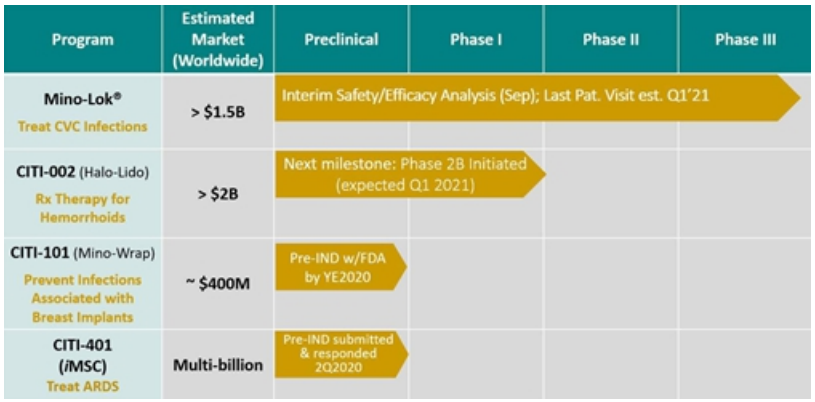
Our **Mino-Lok** product, which is a project with MD Anderson Cancer Center that is in Phase 3, is in our opinion well positioned for entry into a $1.5 billion market and has the potential to save the lives of many critical care patients. Our second project with MD Anderson Cancer Center is the development of **Mino-Wrap**, which is a novel approach to dramatically reduce the rate of infection in post-mastectomy patients who elect to undergo reconstructive breast surgery. We believe that this serious condition affects about 100,000 women in the U.S. and many more in the rest of the world.

Our **Halo-Lido** product has an addressable market of more than $2 billion. Based on National Institutes of Health reports, hemorrhoids affect approximately 12.5 million adults in the U.S. (approximately 5% of the adult U.S. population). Halo-Lido could be the first prescription medication approved by FDA for hemorrhoids and is moving toward its Phase 2b trial.

We recently executed our option from Novellus Therapeutics Limited and licensed a very significant cellular therapy to treat acute respiratory distress syndrome (ARDS). ARDS is devastating in its own right but it is also a major complication of the SARS-CoV-2 viral infection (COVID-19) and has led to the majority of COVID-19 patient deaths. Combined, all these positive events demonstrate the value creation we are building for shareholders.

While the COVID-19 pandemic has affected the patient recruitment in almost all clinical trials, including our own, the Company continues to make progress. Recently we had our second interim analysis and report from the independent Drug Monitoring Committee (DMC) for the Mino-Lok pivotal Phase 3 trial. We will soon reach the 75% point (event-based end point) in the trial, when the DMC and the Company could decide to stop the trial and file the NDA (New Drug Application). For Mino-Wrap, we have submitted a pre-investigational new drug (PIND) consultation request, have been issued an IND (Investigational New Drug) number, and expect a written response and guidance from the FDA in November 2020. For Halo-Lido, we have completed our patient survey to develop a patient reported outcome (PRO) instrument and plan to initiate a Phase 2b trial in the first quarter of 2021.

Citius Drug Pipeline



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Stem-Cell Therapy for ARDS Due to COVID-19 — We Licensed a Promising Novel Therapy from Novellus Therapeutics Limited

On October 7, we announced that we signed an exclusive worldwide licensing agreement with Novellus Therapeutics Limited, to in-license second-generation cellular therapy for acute inflammatory respiratory conditions including COVID-related acute respiratory distress syndrome (ARDS).

This technology is based on a unique and patented approach of engineering mesenchymal stem cells (MSCs) from an induced pluripotent stem cell (iPSC) bank. We call these cells **induced** mesenchymal stem cells (***i***MSCs). The starting point in this semi-synthetic process is a patented, non-immunogenic, mRNA gene programming and editing procedure to create mutation-free, extensively characterized iPSCs that provide an unlimited source of pristine MSCs. Currently, donor-derived MSCs are sourced from human bone marrow, adipose tissue, placenta, umbilical tissue, etc. and have significant challenges; e.g., variable donor and tissue sources, limited supply, low potency, and inefficient and expensive manufacturing processes. Our *i*MSCs overcome these challenges because they:

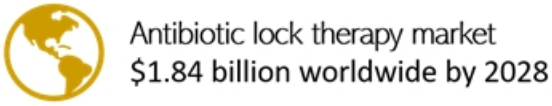
- Are more potent and secrete exponentially higher levels of immunomodulatory proteins;
- Have practically unlimited supply for high doses and repeat doses;
- Are from a single donor and clonal, so they are economically produced at scale with consistent quality and potency, as well as being footprint-free (compared to viral reprogramming methods); and,
- Have significantly higher expansion capability.

ARDS patients experience widespread inflammation in the lungs and symptoms of shortness of breath, rapid breathing and heart rate, chest pain (especially while inhaling), and bluish skin coloration. As you may know, ARDS is the most common cause of respiratory failure and mortality in COVID-19 patients, with a 30-50% mortality rate. The pandemic has increased the ARDS population well beyond the baseline of 200,000 patients. There is no currently approved drug therapy available, and mechanical ventilation and supportive care measures are typically used in the most difficult cases of COVID-related ARDS.

We are currently conducting a proof-of-concept large-animal ARDS study with promising results thus far. We have submitted a PIND to the FDA and have received their guidance and feedback to our development plans.

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

Mino-Lok®, our lead product, is an antibiotic lock solution for use in treating catheter-related bloodstream infections (CRBSIs). We recently held an independent Data Monitoring Committee (DMC) meeting to review data and evaluate the progress of the trial. The DMC reported to the Company that there were no safety concerns, and all the endpoints were being met to continue with the trial. Following the ad-hoc meeting, the DMC recommended that another interim analysis was warranted, and encouraged us to determine if the trial will meet the interim superiority threshold at 69 events, and therefore be able to be halted earlier than anticipated. It is difficult to predict the further impact of the pandemic on the recruitment of patients in the trial; however, we expect that the trial will make significant progress through the first half of 2021.



The antibiotic lock therapy is greater than a $750 million annual market in the U.S. and is expected to reach $1.84 billion worldwide by 2028. We also believe Mino-Lok may help eliminate as many as 500,000 procedures each year to remove and replace infected central venous catheters (CVCs), reducing patient discomfort and saving large amounts of money throughout the healthcare system. We are not aware of any competitive products in development to treat and salvage indwelling, infected CVCs. Our company has worldwide rights to this technology and will have more than 10 years of exclusivity at the time of anticipated launch, which is estimated to be in 2022.

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

Mino-Wrap is a bio-absorbable, antimicrobial semi-solid gel that is wrapped around a tissue expander and placed in the surgical pocket following a mastectomy to prevent post-surgical infections. 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 post-operative 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. The market for Mino-Wrap in preventing infections following breast implant surgeries following mastectomies is estimated to be $400 million.

We've submitted a pre-investigational new drug (PIND) consultation request with the FDA. They assigned an IND number, which is a positive sign. The next step is for us to receive written comments from the FDA in November 2020, in which they will respond to our questions and provide direction about the clinical development program that we submitted.

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.

Halo-Lido — Aiming to Be the First FDA-Approved Prescription Product to Treat Hemorrhoids in the U.S.

Halo-Lido is targeted to the symptomatic relief of hemorrhoidal symptoms and combines the high-potency steroid halobetasol with lidocaine. Based on results of previous clinical work, we selected a gel 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 first quarter of 2021.

Most importantly, we have just completed a rigorous study of the severity and impact of symptoms of Grade 2 and 3 hemorrhoids in order to create a patient reported outcome (PRO) instrument. We are preparing for our Phase 2b trial to test our new formulation and validate the PRO. This innovative trial will use hand-held devices specifically programmed to record patient diaries in electronic form, which should improve the quality of the data and the speed with which they are processed.

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, equivalent to an annual $2 billion market. Our formulation, if approved, would be the first prescription product to treat hemorrhoids approved by the FDA in the U.S.

While there are some commonly used prescription products, none have been reviewed or approved by the FDA because they entered the market prior to 1962, and are considered Drug Efficacy Study Implementation (DESI) products and are allowed on the market without modern review. We anticipate that these DESI products may have to be withdrawn when an evidence-based trial is conducted and should FDA approval be granted.

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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, we expect that the trial will continue as planned until it is fully enrolled, which we expect to be in the first half of 2021, given the continuing impact of the COVID-19 pandemic on clinical trials. 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 licensed an exciting new cellular therapy and hope to become a leader in next-generation stem cells for the treatment of COVID-related ARDS and other acute respiratory indications.

- For Mino-Wrap, we are making progress as planned and the next step is for us to have a call with the FDA in November to discuss our preclinical submission as we hope to initiate a Phase 2 trial by the end of 2021.

- For Halo-Lido, we have just completed the development of a proprietary PRO, which will be used to measure the improvement in symptomatology for Grade 2 and 3 hemorrhoids. We are getting ready for our Phase 2b trial and expect to initiate this Phase 2b trial in the first quarter of 2021. Halo-Lido would be the first FDA-approved prescription product for symptomatic relief of hemorrhoids.

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: 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™ and our planned ARDS therapy, 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.

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