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) July 1, 2021

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 July 1, 2021, Citius Pharmaceuticals, Inc. issued a press release announcing a positive recommendation by the independent Data Monitoring Committee to continue the Mino-Lok® Phase 3 trial as planned. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is filed herewith:

Exhibit No.	Description
99.1	Press Release dated July 1, 2021.

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: July 1, 2021

By: /s/ Myron Holubiak

Name: Myron Holubiak
Title: President and Chief Executive Officer

Citius Pharmaceuticals, Inc. Announces Positive Recommendation by Independent Data Monitoring Committee to Continue the Mino-Lok® Phase 3 Trial as Planned

- DMC interim safety and efficacy review of Mino-Lok® Phase 3 Trial concluded with favorable recommendation to continue the trial as planned, with the protocol-defined sample size and power to achieve the primary endpoint –

- Citius to proceed in conducting largest controlled clinical trial to salvage infected catheters with no modifications requested by the DMC and no safety concerns identified -

CRANFORD, N.J., July 1, 2021 -- Citius Pharmaceuticals, Inc. ("Citius" or the "Company") (Nasdaq: CTXR), a biopharmaceutical company dedicated to the development and commercialization of first-in-class critical care products with a focus on anti-infective products in adjunct cancer care, unique prescription products and stem cell therapy, today announced that following a unblinded data review of safety and efficacy, the independent Data Monitoring Committee (DMC) for the Mino-Lok® Phase 3 Pivotal Superiority Trial has recommended proceeding with the trial as planned. The DMC did not identify any safety concerns and no modifications were recommended to the protocol-defined sample size or power to achieve the primary endpoint.

“We greatly appreciate the thoughtful analysis and guidance provided by the Data Monitoring Committee following their review of the interim trial data. Consistent with our expectations, we are pleased with the DMC recommendation to continue this trial without modification. This marks the third recommendation by the DMC supporting the continuation of the Mino-Lok® trial. With each DMC review, the hurdles to meet our protocol-defined criteria for safety and superior efficacy increase. Consequently, this favorable outcome indicates that based on our pre-defined parameters, it would be possible to achieve our primary endpoint by continuing the trial as planned, and is an encouraging signal when combined with the results of our prior studies,” stated Myron Holubiak, President and Chief Executive Officer of Citius.

“Patients suffering from catheter-related infections are at the forefront of our efforts to advance Mino-Lok®. We believe we are conducting the largest controlled trial to salvage catheters, and that this trial will provide important information about the future role of antibiotic locks in treating patients with catheter related infections. Our primary aim is to provide critically ill patients and their caregivers with a safe and effective treatment option that addresses the complications, discomfort and high cost of removing and replacing infected catheters. With Covid-19 restrictions easing, we believe we are now better positioned to accelerate our efforts to complete the trial. To that end, we will continue to engage with the U.S. Food and Drug Administration (FDA) and look forward to their guidance as we advance this program,” added Mr. Holubiak.

As defined in the DMC charter, the primary role of the independent DMC is to safeguard the interests of study participants, assess the safety of the treatment, and monitor the overall conduct of the study. In order to ensure the protection of patients enrolled in the trial and to assure the timely and efficient completion of the study, each DMC recommendation is bound by strict parameters outlined in the DMC charter. A recommendation to continue the trial as planned indicates that the data reviewed by the DMC, at this juncture, is within the statistical boundaries determined by Citius in order to complete the trial with the protocol-defined sample size and power to achieve the primary endpoint.

The Mino-Lok® Phase 3 pivotal superiority trial is a multi-center, randomized, open-label, blinded study to determine the efficacy and safety of Mino-Lok® (MLT), a novel antibiotic lock therapy that combines minocycline with edetate disodium. The primary endpoint for this study is the time (in days following randomization) to a catheter failure event between randomization and TOC (Week 6) in the Intent-to-Treat (ITT) Population.

Approximately 144 subjects diagnosed with CRBSI/CLABSI and who meet all necessary criteria for the study are to be randomized in a 1:1 ratio to receive either Mino-Lok® therapy or standard of care antibiotic lock therapy.

Subjects in the Mino-Lok® arm receive one MLT dose daily with a dwell time of two to four hours for a total of seven doses. For subjects in the Control arm, the investigator determines the antibiotic used in the lock, dose, dwell time, and number of days of administration based on institutional standards or Infectious Diseases Society of America (IDSA) guidelines.

About Mino-Lok®

Citius is developing Mino-Lok®, an antibiotic lock solution to treat patients with catheter-related blood stream infections that was licensed from The University of Texas MD Anderson Cancer Center. Citius believes Mino-Lok® provides a superior alternative to removing and replacing a central venous catheter (CVC), leading to a reduction in serious adverse events and cost savings to the healthcare system. If approved, Mino-Lok® would be the first and only FDA-approved treatment that salvages central venous catheters that cause central line-related blood stream infections.

About Citius Pharmaceuticals, Inc.

Citius is a late-stage biopharmaceutical company dedicated to the development and commercialization of first-in-class critical care products, with a focus on anti-infectives in adjunct cancer care, unique prescription products, and stem cell therapy. The Company’s lead product candidate, Mino-Lok®, an antibiotic lock solution for the treatment of patients with catheter-related bloodstream infections (CRBSIs), is currently enrolling patients in a Phase 3 pivotal superiority trial. Mino-Lok® was granted Fast Track designation by the U.S. Food and Drug Administration (FDA). Through its subsidiary, NoveCite, Inc., Citius is developing a novel proprietary mesenchymal stem cell treatment derived from induced pluripotent stem cells (iPSCs) for acute respiratory conditions, with a near-term focus on acute respiratory distress syndrome (ARDS) associated with COVID-19. For more information, please visit www.citiuspharma.com.

Safe Harbor

This press release 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," "plan," "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: our ability to successfully undertake and complete clinical trials and the results from those trials for our product candidates, including Mino-Lok®; risks relating to the results of research and development activities; uncertainties relating to preclinical and clinical testing; the early stage of products under development; the estimated markets for our product candidates and the acceptance thereof by any

market; the ability of our product candidates to impact the quality of life of our target patient populations; our need for substantial additional funds; market and other conditions; risks related to our growth strategy; patent and intellectual property matters; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; our dependence on third-party suppliers; our ability to procure cGMP commercial-scale supply; government regulation; competition; as well as other risks described in our SEC filings. These risks have been and may be further impacted by Covid-19. Accordingly, these forward-looking statements do not constitute guarantees of future performance, and you are cautioned not to place undue reliance on these forward-looking statements. Risks regarding our business are described in detail in our Securities and Exchange Commission ("SEC") filings which are available on the SEC's website at www.sec.gov, including in our Annual Report on Form 10-K for the year ended September 30, 2020, filed with the SEC on December 16, 2020 and updated by our subsequent filings with the SEC. These forward-looking statements speak only as of the date hereof, and 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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