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) September 4, 2019

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))

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).

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	Nasdaq

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 September 4, 2019, we issued a press release to report a change to the primary endpoint in our current Phase 3 pivotal trial for Mino-Lok.

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

Exhibit No.	Description
99.1	Press release dated September 4, 2019.

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: September 4, 2019

/s/ Myron Holubiak
Myron Holubiak
President and Chief Executive Officer

Exhibit 99.1

CITIUS ANNOUNCES CHANGE TO PRIMARY ENDPOINT IN MINO-LOK® PHASE 3 STUDY

NEW ENDPOINT IMPROVES ABILITY TO CONDUCT STUDY MORE EXPEDITIOUSLY WITH SIGNIFICANTLY FEWER PATIENTS

Clinical Trial Cost Savings Estimated to Approach $10 million

CRANFORD, N.J. – September 4, 2019 -- Citius Pharmaceuticals, Inc. ("Citius") (“Company”) (CTXR), a specialty pharmaceutical company focused on adjunctive cancer care and critical care drug products, today reported that the FDA responded to the Company’s proposal to refine the endpoints in the current Phase 3 pivotal trial for Mino-Lok.

The current Phase 3 trial being conducted compares Mino-Lok therapy (MLT) to antibiotic lock therapy (ALT) to not only disinfect colonized catheters causing bacteremias, but also to keep the treated catheters functioning and infection free for 8 weeks post therapy.

The new proposed primary endpoint is planned to demonstrate a significant difference in the time to catheter failure when comparing MLT to ALT. This is clinically important because eliminating the source of infection enables antibiotic treatment of the bacteremia to work more effectively and expeditiously. Additionally, if a catheter can be maintained for the time that it is needed, the patient does not need to be subjected to the procedures for removing and replacing the catheter that are associated with some serious adverse events.

The FDA noted that *time to catheter failure is an acceptable primary efficacy endpoint.* They also instructed the Company to identify and consider the various types of reasons for catheter failure, and to show the clinical significance of this endpoint.

“Citius is very pleased about the change in efficacy endpoints,” said Mr. Myron Holubiak, President and CEO of Citius Pharmaceuticals. “We believe this focus will allow us to demonstrate the real benefit of Mino-Lok therapy (MLT) which is that MLT works more efficiently and expeditiously to break up biofilm and eliminate the bacteria causing the bacteremia than current antibiotic lock therapies (ALTs). We now have a clearer way forward to prove the superior efficacy of Mino-Lok to ALTs, and we believe we can do this faster with fewer patients than originally planned. At this time Citius believes that the change to the primary endpoint will result in fewer than 150 total subjects in Phase 3 trial. These changes would enable Citius to realize clinical trial cost savings approaching $10 million.”

The Company has recently submitted a response to the FDA with the new sample size estimate which the agency is reviewing.

About Citius Pharmaceuticals, Inc.
Citius is a specialty pharmaceutical company dedicated to the development and commercialization of critical care products, with a focus on anti-infectives, cancer care and unique prescription products that use innovative, patented or proprietary formulations of previously-approved active pharmaceutical ingredients. We seek to achieve leading market positions by providing therapeutic products that address unmet medical needs; by using previously approved drugs with substantial safety and efficacy data, we seek to reduce the risks associated with pharmaceutical product development and regulatory requirements. Citius develops products that have intellectual property protection and competitive advantages to existing therapeutic approaches. For more information, please visit www.citiuspharma.com.

About Mino-Lok®

Mino-Lok® is an antibiotic lock solution used to treat patients with catheter-related blood stream infections (CRBSIs). CRBSIs are very serious life-threatening infections, especially in cancer patients receiving therapy through central venous catheters (CVCs), and in hemodialysis patients where venous access presents a challenge. The current Phase 3 trial is being conducted in 36 sites. There are currently no approved therapies to salvage infected central venous catheters (CVCs).

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," "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 the design of our ongoing Phase 3 trial for Mino-Lok, including the change to the primary endpoint for that trial and our ability to show clinical significance of that endpoint; risks associated with conducting our Phase 3 trial for Mino-Lok, including completing patient enrollment, patient retention and the reasons for catheter failure in the trial; risks associated with sourcing components of our product candidates; our dependence on third-party suppliers; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; the estimated markets for our product candidates and the acceptance thereof by any market; risks relating to the results of research and development activities; risks associated with developing Mino-Wrap, including that preclinical results may not be predictive of clinical results and our ability to file an IND; uncertainties relating to preclinical and clinical testing; the early stage of products under development; risks related to our growth strategy; our ability to identify, acquire, close and integrate product candidates and companies successfully and on a timely basis; our ability to attract, integrate, and retain key personnel; our need for substantial additional funds; 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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