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) February 4, 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 February 4, 2020, Citius Pharmaceuticals, Inc., or the Company, issued a press release to report that it achieved 50% patient enrollment in the Company's ongoing Phase 3 clinical trial for Mino-Lok® in patients with central line-associated bloodstream infections or catheter-related bloodstream infections.

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release dated February 4, 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: February 4, 2020

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

Exhibit 99.1

Citius Achieves 50% Patient Enrollment in Phase 3 Mino-Lok® Pivotal Trial

Next major milestone in Mino-Lok trial is the 75% interim analysis for superior efficacy and is expected in first half of 2020

CRANFORD, N.J. February 4, 2020 -- Citius Pharmaceuticals, Inc. ("Citius" or the "Company") (NASDAQ: CTXR), a specialty pharmaceutical company focused on adjunctive cancer care and critical-care drug products, today announced that the Company's lead program, Mino-Lok vs. standard-of-care ("SOC") antibiotic locks, has randomized its 72nd patient, thereby passing the halfway point for enrollment in this Phase 3 trial. The Company previously announced the results of a futility analysis when it passed the threshold of 40% of patients completing end of therapy. That analysis showed a positive outcome, as it met the prespecified interim futility analysis criteria. The next major milestone in the Mino-Lok trial, expected to be achieved in the first half of 2020, will be the 75% interim analysis for superior efficacy. The endpoints for this analysis require that the time to catheter failure be at least 38 days for Mino-Lok vs. 21 days for SOC antibiotic locks.

"We are extremely happy that our trial is proceeding according to plan. The independent drug monitoring committee ("DMC") will next evaluate the clinical data at the 75% level of enrollment to see if Mino-Lok demonstrates superior efficacy versus SOC antibiotic locks," said Myron Holubiak, Chief Executive Officer of Citius. "We believe that the Mino-Lok clinical trial will be a major contribution to the study of catheter-related bloodstream infections (CRBSI) and the utility of antibiotic locks. Effective alternatives are needed to the practice of removing and replacing infected central venous lines."

About Mino-Lok®
Each year, up to approximately 500,000 central venous catheters of the 7 million used in the U.S. become infected and lead to CRBSIs, increasing both patient morbidity risk and costs to the medical system. It has been shown that antibiotics alone are unable to penetrate the biofilm caused by bacteria, and there are currently no approved therapies for salvaging infected central venous catheters. Mino-Lok is an antibiotic lock solution that is being developed to treat patients with CRBSIs in combination with an appropriate systemic antibiotic(s) to preserve central venous access and to avoid the complications and morbidities associated with catheter removal and reinsertion. Mino-Lok penetrates biofilm, eradicates bacteria and salvages infected, indwelling vascular catheters while providing anticlotting properties. Mino-Lok has the potential to change the standard of care for the management of these serious infections. The market potential for an effective antibiotic lock therapy is estimated to be $750+ million per year in the U.S. and approximately $1.5 billion worldwide.

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 over existing therapeutic approaches. 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," "should," and "may," along with 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 III trial for Mino-Lok, including our ability to complete patient enrollment; risks relating to our need for substantial additional funds; possible changes in 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 the risk that preclinical results may not be predictive of clinical results or of our ability to file an IND; uncertainties relating to preclinical and clinical testing; uncertainties associated with the early stage of products under development; risks related to our growth strategy; risks related to our ability to obtain, perform under, and maintain financing and strategic agreements and relationships; uncertainties relating to our ability to identify, acquire, close and integrate product candidates and companies successfully and on a timely basis; uncertainties relating to our ability to attract, integrate and retain key personnel; possible changes in government regulation; risks associated with patent and intellectual property matters; and risks relating to 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 in events, conditions or circumstances on which any such statement is based, except as required by law.

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