

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) November 30, 2020

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

Nevada
(State or other jurisdiction of incorporation)

333-206903
(Commission File Number)

27-3425913
(IRS Employer Identification No.)

11 Commerce Drive, 1st Floor, Cranford, NJ
(Address of principal executive offices)

07016
(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 November 30, 2020, Citius Pharmaceuticals, Inc. issued a press release announcing the results of a Boston Analytical study that demonstrated that Mino-Lok eradicates *S. aureus* biofilm more effectively and expeditiously than its components. 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

<u>Exhibit No.</u>	<u>Description</u>
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99.1	Press release dated November 30, 2020.
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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: November 30 2020

/s/ Myron Holubiak

Myron Holubiak

President and Chief Executive Officer

Citius Announces Results of Study that Mino-Lok Eradicates *S. aureus* Biofilm More Effectively and Exponentially than Components

- **Mino-Lok superior to EDTA and Ethanol in eradicating most worrisome pathogen**
- **Two strains of resistant *Staphylococcus aureus* tested**
- **Study reinforces previous studies that all three components needed for some biofilm forming pathogens**

CRANFORD, NJ – November 30, 2020 – Citius Pharmaceuticals, Inc. (“Citius” or the “Company”) (Nasdaq: CTXR), a specialty pharmaceutical company focused on developing and commercializing critical care drug products, today announced the completion of a Boston Analytical study “Silicone Disk Method for *In Vitro* Assessment of Antimicrobial Activity Against Resistant Staphylococcal Biofilms by Minocycline-EDTA-Ethanol and EDTA-Ethanol Lock Solutions.” This study demonstrated that all three components of Mino-Lok (30 mg/mL EDTA, 19.5% ethanol and 1 mg/mL minocycline) were superior to EDTA/ethanol (30 mg/mL EDTA and 19.5% ethanol). There were two strains of *Staphylococcus aureus* used for the inocula and two samples of each strain were tested as four reference groups. The test solutions were examined following incubation for the following three time points: 60 minutes; 90 minutes; and 120 minutes. The Colony Forming Units (CFU)/Disk value was assessed from 10 disks at each time-point for each group. The results indicate that when the exposure time is 60 minutes, the number of CFU/Disk under the MLT group is significantly smaller than the number of CFU/Disk under the EDTA/ethanol group in one strain and very close to significance (p-value = 0.0598) in the second strain. For all exposure times, the number of CFU/Disk was always lower in the MLT treated disks compared to the EDTA/ethanol treated disks.

The researchers concluded that “... taken together, the results suggest that MLT can eradicate the biofilm quicker than EDTA/ethanol.”

“*Staph aureus* is one of the most worrisome pathogens in catheter related bloodstream infections (CRBSI). This pathogen receives special consideration even in the IDSA guidelines for treating CRBSI. We are very pleased to show that Mino-Lok appears to be more effective, and work more expeditiously, than even ethanol,” commented Myron Holubiak, Chief Executive Officer of Citius. “It has been demonstrated in earlier studies and reports that all three components of Mino-Lok are necessary to eradicate MRSA and *Candida parapsilosis*. More recently we showed that MLT was effective *in vitro* against 10 strains of *Candida Auris*. All of these pathogens are of great concern in cancer patients with central lines. As we approach the final stages of our pivotal trial, we are very excited to be able to report new findings about Mino-Lok. Our pivotal trial is designed to show the superiority of Mino-Lok to standard antibiotic locks in time-to-catheter-failure. If all these studies prove to be successful, we believe ready to use Mino-Lok will be superior to local pharmacy mixed antibiotic locks in both efficacy and dosing schedules.”

Mino-Lok has the potential to change the standard of care, which currently calls for a procedure to remove and replace the infected catheter. Each year, up to 500,000 CVCs of the 7 million used become infected and lead to CLABSIs, 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. According to DelveInsight, the market size of CLABSIs and closely associated catheter-related bloodstream infections (CRBSIs) in the global market is expected to reach \$1.84 billion in 2028, up from \$1.24 billion in 2017.

About Citius Pharmaceuticals, Inc.

Citius is a late-stage specialty pharmaceutical company dedicated to the development and commercialization of critical care products, with a focus on anti-infectives and cancer care. For more information, please visit www.citiuspharma.com.

About Mino-Lok[®]

Mino-Lok[®] is an antibiotic lock solution being developed as an adjunctive therapy in patients with central line-associated bloodstream infections (CLABSIs) or catheter-related bloodstream infections (CRBSIs). There are currently no approved therapies for salvaging infected CVCs. Mino-Lok is used 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 is currently in a Phase 3 clinical trial.

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 developing our product candidates, including that preclinical results may not be predictive of clinical results and our ability to file an IND for such candidates; risks associated with conducting trials for our product candidates, including our Phase III trial for Mino-Lok; risks relating to the results of research and development activities; our need for substantial additional funds; the estimated markets for our product candidates, and the acceptance thereof by any market; uncertainties relating to preclinical and clinical testing; the early stage of products under development; risks related to our growth strategy; our ability to obtain, perform under, and maintain financing and strategic agreements and relationships; 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; 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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