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) August 26, 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 August 26, 2020, Citius Pharmaceuticals, Inc. issued a press release announcing that it has expanded the intellectual property associated with its global license agreement with the MD Anderson Cancer Center (MDACC), as the United States Patent and Trademark Office (USPTO) has issued a patent and patent application publication both in continuation of the patent associated with the license agreement. 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 August 26, 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: August 26, 2020

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

Exhibit 99.1

Citius Pharmaceuticals Announces Improved Design and Expansion of Intellectual Property for Mino-Wrap

Expansion of patents granted to The University of Texas System on behalf of M. D. Anderson Cancer Center

CRANFORD, N.J., Aug. 26, 2020 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("Citius" or the "Company") (Nasdaq: CTXR), a specialty pharmaceutical company focused on developing and commercializing critical care drug products, announced that it has expanded the intellectual property associated with its global license agreement with the MD Anderson Cancer Center ("MDACC"). Through this license agreement, Citius is developing Mino-Wrap, which is a novel approach to reducing post-mastectomy infections associated with the use of a tissue expander ("TE").

The United States Patent and Trademark Office (USPTO) has issued patent 10,434,221 B2 and patent application publication US 2019/0388591 A1, both continuations of the initial patent for "Antimicrobial Wraps for Medical Implants".

The intellectual property expansion was granted to The Board of Regents of The University of Texas System on behalf of The University of Texas M. D. Anderson Cancer Center and enhances the design and use of Mino-Wrap.

"The frequency of post-mastectomy breast reconstruction, following breast cancer treatment, has been increasing on an annual basis. There are over 100,000 patients in the U.S. undergoing breast reconstruction procedures following mastectomies and approximately 80% of the time, a TE is used to prepare the surgical site for breast implants either immediately after mastectomy or in a separate procedure afterwards. The published rate of infection for TEs used in breast reconstructive surgery is between 2.5 % and 24%, with an estimated mean at around 12% to 14%. These data points are concerning and not well understood. Through our agreement with MDACC, we believe Mino-Wrap has the potential to provide a significant reduction in the incidence of infection, sparing the patient the pain and discomfort of extended hospitalization and further aggressive and lengthy courses of antibiotics in an attempt to salvage the TEs. In many cases the TE is removed leading to a delay in lifesaving chemo-radiation therapy, which can be a devastating consequence for the patient. " said Myron Holubiak, President and CEO of Citius Pharmaceuticals. "We are especially pleased that the claims for Mino-Wrap intellectual property are being expanded and broadened as we develop the optimal design and application."

The Company is also currently developing Mino-Lok®, an antibiotic lock treatment for catheter-related bloodstream infections (CRBSIs), in collaboration with MDACC. Mino-Lok is in phase 3 development.

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-Wrap
Mino-Wrap is a novel approach to reducing post-operative infections associated with surgical implants. Mino-Wrap is a liquefying gel-based wrap containing minocycline and rifampin for reducing tissue expander (TE) infections following breast reconstructive surgeries. It is a laminate film comprised of porcine gelatin plasticized with glycerol. Mino-Wrap also contains the antibiotics minocycline and rifampin to reduce bacterial bioburden on implantable devices preventing colonization over a sustained period of time. In the setting of breast reconstruction, Mino-Wrap is designed to provide more durable antimicrobial protection of the implant-tissue interface than peri-operative irrigation with antibiotic solutions (the current standard of care). Both porcine gelatin (and collagen) as well as the combination of minocycline and rifampin have long histories of successful medical use in implantable devices in multiple anatomical settings.

About Tissue Expanders and Infection Risk
A common breast reconstruction technique is tissue expansion, which involves expansion of the breast skin and muscle using a temporary tissue expander. A tissue expander is an empty breast implant that is filled with normal saline over 6 to 8 weeks until it reaches the breast size that is desired. In this type of reconstruction, the surgeon will either make a pocket under a large muscle in the chest and place a tissue expander in that space or place the expander above the large muscle. About 4 to 8 weeks after the tissue expansion is finished, a second surgery is required to remove the tissue expander and insert the permanent breast implant. The patient receives either microvascular flap reconstruction, or the insertion of a permanent breast implant. Infection is one of the most common complications of tissue expanders and implants during breast reconstruction, with an infection rate ranging from 2.5 to 24 percent.

About MD Anderson Cancer Center
The University of Texas MD Anderson Cancer Center in Houston ranks as one of the world's most respected centers focused on cancer patient care, research, education and prevention. The institution's sole mission is to end cancer for patients and their families around the world. MD Anderson is one of only 45 comprehensive cancer centers designated by the National Cancer Institute (NCI). MD Anderson is ranked No.1 for cancer care in U.S. News & World Report's "Best Hospital's" survey. It has ranked as one of the nation's top two hospitals since the survey began in 1990, and has ranked first for 11 of the past 14 years. MD Anderson receives a cancer center support grant from the NCI of the National Institutes of Health (P30 CA016672).

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). CLABSIs/CRBSIs are very serious, especially in cancer patients receiving therapy through central venous catheters (CVCs) and in hemodialysis patients, for whom venous access presents a challenge. There are currently no approved therapies for salvaging infected 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: patent and intellectual property matters, market and other conditions; our ability to attract, integrate, and retain key personnel; our need for substantial additional funds; the risk of successfully negotiating within the option period a license agreement with Novellus, Inc. for our planned Novecite therapy for ARDS; risks associated with conducting clinical trials and drug development; the estimated markets for our product candidates and the acceptance thereof by any market; risks related to our growth strategy; 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 identify, acquire, close and integrate product candidates and companies successfully and on a timely basis; our dependence on third-party suppliers; government regulation; 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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