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) December 9, 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 December 9, 2020, Citius Pharmaceuticals, Inc. issued a press release announcingits receipt of a written response and guidance from the U.S. Food and Drug Administration to the company's Pre-Investigational New Drug consultation request for its Mino-Wrap briefing package. 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 December 9, 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: December 9, 2020

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

Citius Pharmaceuticals Receives FDA Response and Guidance to Pre-IND Consultation Submission for Mino-Wrap

-- Mino-Wrap's novel approach to reducing post-mastectomy infections associated with the use of a tissue expander is on track in its preclinical stage

-- Some next steps for Mino-Wrap development include designing and executing a large animal study and the clinical plan

CRANFORD, N.J., December 9, 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 its receipt of a written response and guidance from the U.S. Food and Drug Administration (FDA) Division of Anti-Infective Products to the Company's Pre-Investigational New Drug (Pre-IND) consultation request for its Mino-Wrap briefing package. Through its global license agreement with the The University of Texas MD Anderson Cancer Center, Citius is developing Mino-Wrap, a novel approach to reducing post-mastectomy infections associated with the use of a tissue expander. The briefing package contained information regarding pre-clinical data and a clinical development plan, along with questions for the FDA regarding safety and efficacy data that would be required to advance Mino-Wrap into clinical trials.

The FDA granted a Written Response Only meeting regarding guidance and direction on the Mino-Wrap development plan. The agency indicated that bio absorption simulation studies may provide information to support the development of Mino-Wrap and made suggestions on what should be provided relative to non-clinical support. The FDA provided guidance on the design of the drug elution studies and agreed that a large animal pharmacology study would be appropriate. They also agreed that a 28-day toxicology study appears appropriate and that microbiology support through existing data is acceptable.

"The FDA provided us with valuable guidance and confirmed a number of our initial plans on the development of Mino-Wrap," said Myron Holubiak, President and CEO of Citius Pharmaceuticals. "We are very pleased to have guidance support from the agency because this is such an under-recognized problem, and current preventative measures have not yielded very acceptable results. We think we have an important innovation for the prevention of post-operative infections associated with breast reconstructive surgery after mastectomies."

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 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.

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: our ability to successfully undertake and complete clinical trials and the results from those trials for Mino-Wrap; our need for substantial additional funds; 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; risks related to our growth strategy; patent and intellectual property matters, market and other conditions; our ability to attract, integrate, and retain key personnel; 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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