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) January 2, 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).

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 1.01. Entry into a Material Definitive Agreement.

On January 2, 2019, we entered into a patent and technology license agreement with the Board of Regents of the University of Texas System on behalf of the University of Texas M. D. Anderson Cancer Center ("Licensor"), whereby we in-licensed exclusive worldwide rights to patent technology for any and all uses relating to breast implants. With this technology, we intend to develop Mino-Wrap, a liquefying gel-based wrap containing minocycline and rifampin for the reduction of infections associated with breast implants following breast reconstructive surgeries. Under the agreement, we are required to use commercially reasonable efforts to commercialize Mino-Wrap under several regulatory scenarios and achieve milestones that are associated with these regulatory options leading to an approval from the U.S. Food and Drug Administration.

Within 30 days of execution of the license agreement, we will pay Licensor an upfront payment of $125,000. We are obligated to pay annual maintenance fees that increase annually until reaching a designated amount, which we must pay until the first sale of product. We also must pay up to an aggregate of $2.1 million in milestone payments, depending on the achievement of various regulatory and commercial milestones. Under the terms of the license agreement, we also must pay a royalty equal to mid- to upper single digit percentages of net sales, depending on the level of sales in that year, and subject to downward adjustment to lower- to mid-single digit percentages in the event there is no valid patent for the product in the United States at the time of sale. After the first sale of product, we will owe an annual minimum royalty payment that will increase annually for the duration of the term. We will be responsible for all patent expenses incurred by Licensor for the term of the agreement although Licensor is responsible for filing, prosecution and maintenance of all patents.

The term of the license agreement will end on the later of: (i) the expiration of all licensed patents, or (ii) the fifteenth anniversary of the agreement. Licensor may terminate the license agreement at any time after four years in any country if we have not commercialized or are not actively attempting to commercialize a product in such country. The license agreement will terminate in the event we breach any of our payment or reporting obligations under Article IV of the agreement, or Licensor breaches any of its obligations under the agreement. Licensor will have the right to terminate the agreement if we bring or participate in an action to challenge Licensor's ownership of any of the licensed patent rights. We may terminate the license agreement upon 180 days' notice. The license agreement may also be terminated upon our and the Licensor's mutual consent.

The above description of the license agreement is qualified in its entirety by reference to the full and complete terms contained in the license agreement, which will be filed as an exhibit to our Quarterly Report on Form 10-Q for the quarter ended December 31, 2018.

A copy of the press release announcing the entry into the license agreement is attached hereto as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

d) Exhibits

Exhibit No.	Description
99.1	Press release dated January 8, 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: January 8, 2019

/s/ Myron Holubiak

Myron Holubiak
President and Chief Executive Officer

Exhibit 99.1

CITIUS LICENSES MINO-WRAP FROM MD ANDERSON CANCER CENTER

- **New technology designed to reduce infections after implantation of devices**
- **First target is breast tissue expanders**
- **Intended for minimizing serious complications of post-operative infections associated with implants**
- **Expands relationship with the world's top rated cancer center**

CRANFORD, N.J. – January 8, 2019 -- Citius Pharmaceuticals, Inc. ("Citius") ("Company") (NASDAQ: CTXR), a specialty pharmaceutical company focused on adjunctive cancer care and critical care drug products, today reported that a definitive license agreement has been reached with MD Anderson Cancer Center ("MDACC") to develop and commercialize a novel approach to reducing post-operative infections associated with surgical implants. The initial product called "Mino-Wrap", or CITI 101, is a liquefying gel-based wrap containing minocycline and rifampin for reducing tissue expander (TE) infections following breast reconstructive surgeries.

There are approximately 100,000 patients in the U.S. undergoing breast reconstruction procedures following mastectomies. Approximate 80% of the time, a tissue expander (TE) is used to prepare the surgical site for breast implants either immediately after mastectomy or in a separate procedure afterwards. A TE is a silicone implant that serves as a temporary device that is placed within a surgical pocket in the mastectomy space and inflated with saline over a period of time to prepare the area for a permanent breast implant. There is a reported rate of TE-related infections of between 2.5% and 24%, depending on the extent of surgery, duration of post-operative drainage and many other factors. TE infections frequently require removal of the TE, treatment with culture-directed antibiotics, and could result in further complications for the patient.

Scientists and physicians at MDACC have developed a bioabsorbable, antimicrobial solid film wrap that would be placed in the surgical pocket to prevent infections over a sustained period of time providing protection over longer durations than irrigation with antibiotic solutions. Studies have been performed to assess the duration of antimicrobial efficacy and potential cytotoxic adverse effects that could impact healing in the surgical pocket. Complete inhibition of bacterial biofilm formation was shown against all Gram-positive and Gram-negative organisms. This limited study indicates Mino-Wrap was efficacious at preventing bacterial growth on silicone surfaces. The antimicrobial efficacy persisted for the full 10 days during which challenges were performed; this time period corresponds to the length of time drains are usually used and represents the time of greatest risk for infection. The challenges consisted of attempted inoculations of MRSA, MRSE and *Pseudomonas aeruginosa,* among the most difficult-to-treat organisms in these infections.

"We are extremely pleased that Citius was able to secure the worldwide license for CITI 101, and to continue collaborating with MDACC, one of world's most respected cancer centers, in developing innovative products that address critical medical needs. Mino-Wrap is another example of utilizing existing active pharmaceutical ingredients and applying these to new indications. We have been exploring the unique properties of minocycline in both Mino-Wrap and Mino-Lok® which is currently in phase 3 trials. We will be working with the FDA to determine what regulatory pathway is appropriate to evaluate CITI 101 through its development stages," said Mr. Myron Holubiak, President and CEO of Citius Pharmaceuticals. "We hope to be able to communicate further positive developments on this promising project in the near future."

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 MD Anderson Cancer Center

The University of Texas MD Anderson Cancer Center in Houston ranks as one of the world's most respected facilities for 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) and is ranked No.1 for cancer care in U.S. News & World Report's most recent "Best Hospital's" survey. The center 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).

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. After a few months, the expander is removed and the patient receives either microvascular flap reconstruction, or the insertion of a permanent breast implant. This type of breast reconstruction requires two separate operations. A breast tissue expander is an inflatable breast implant designed to stretch the skin and muscle to make room for a future, more permanent implant. Through a tiny valve mechanism located inside the expander, saline is periodically injected to gradually fill the expander over several weeks or months. The process usually begins three to four weeks after mastectomy. After the skin over the breast area has stretched enough, the expander is removed in a second operation and either flap reconstruction or a permanent implant is inserted.

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.

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 Mino-Wrap, including that preclinical results may not be predictive of clinical results; risks associated with conducting our Phase 3 trial for Mino-Lok, including completing patient enrollment and opening study sites; 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; 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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