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) October 6, 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 1.01. Entry into a Material Definitive Agreement.

On October 6, 2020, we, through our subsidiary NoveCite, Inc., recently established by us specifically for this purpose, entered into a license agreement with Novellus Therapeutics Limited ("Licensor"), whereby NoveCite acquired an exclusive, worldwide license, with the right to sublicense, to develop and commercialize a stem cell therapy based on the Licensor's patented technology for the treatment of acute pneumonitis of any etiology in which inflammation is a major agent in humans. The patented technology consists of mesenchymal stem cells ("MSCs") derived from an induced pluripotent stem cell line that is made by Licensor using the mRNA cell reprogramming methods in the patents covering the licensed technology.

Upon execution of the license agreement, we paid an upfront payment of $5,000,000 and issued to Licensor shares of Novecite's common stock representing 25% of Novecite's currently outstanding equity. We own the other 75% of NoveCite's currently outstanding equity. Pursuant to the terms of the stock subscription agreement between Novellus and NoveCite, if NoveCite issues additional equity, subject to certain exceptions, prior to its initial public offering or a change of control (as defined in the license agreement), NoveCite must maintain Novellus's ownership at 25% by issuing to Novellus additional shares.

NoveCite is obligated to pay Licensor up to an aggregate of $51,000,000 in milestone payments upon the achievement of various regulatory and developmental milestones. NoveCite also must pay on a fiscal quarter basis a royalty equal to low double-digit percentages of net sales, commencing upon the first commercial sale of a licensed product. This royalty is subject to downward adjustment on a product-by-product and country-by-country basis to an upper-single digit percentage of net sales in any country in the event of the expiration of the last valid patent claim or if no valid patent claim exists in that country. The royalty will end on the earlier of (i) date on which a biosimilar product is first marketed, sold, or distributed by Licensor or any third party in the applicable country or (ii) the 10 year anniversary of the date of expiration of the last-to-expire valid patent claim in that country. In the case of a country where no licensed patent ever exists, the royalty will end on the later of (i) the date of expiry of such licensed product's regulatory exclusivity and (ii) the 10 year anniversary of the date of the first commercial sale of the licensed product in the applicable country. In addition, NoveCite will pay to Licensor an amount equal to a mid-twenties percentage of any sublicensee fees it receives.

Under the terms of the license agreement, in the event that Licensor receives any revenue for a sale, license, option, or similar transaction involving the original cell line included in the licensed technology, then Licensor shall remit to NoveCite, on a fiscal quarter basis, 50% of such revenue received in such fiscal quarter.

During the term of the license agreement, NoveCite is required to use commercially reasonable efforts to make commercially available at least one product in at least two markets: the United States and either the United Kingdom, France, Germany, China or Japan. Additionally, NoveCite shall (i) on or before the five year anniversary of the date of the license agreement, file an IND for a licensed product in the field of acute pneumonitis treatment and (ii) receive regulatory approval for a licensed product in the field of acute pneumonitis treatment in the United States or in a major market country on or before the ten year anniversary of the date of the license agreement.

Pursuant to the terms of the license agreement, NoveCite has been granted a right of first negotiation to exclusively license the rights to any new products developed or acquired by Licensor that may be used within the field of acute pneumonitis treatment. After receiving notice from the Licensor of the new product opportunity, NoveCite has 30 days to notify Licensor of its desire to negotiate a license agreement for the new product. If such notice is given by NoveCite, the parties shall then have a period of 150 days from the date of Licensor's notice to NoveCite to negotiate, exclusively and in good faith, the terms and conditions for the new product license agreement.

The term of the license agreement commences on the date of execution and will continue on a country-by-country and licensed product-by-licensed product basis until the expiration of the last-to-expire royalty term for any and all licensed products unless earlier terminated in accordance with its terms. Either party may terminate the license agreement upon written notice if the other party is in material default or breach of the agreement, subject to cure within the designated time periods. Either party also may terminate the license agreement if the other party files for bankruptcy or takes related actions or is unable to pay its debts as they become due, subject to cure within the designated time period. Additionally, Licensor will have the right to terminate the agreement if NoveCite directly or indirectly challenges the patentability, enforceability or validity of any licensed patent. NoveCite may terminate the license agreement at any time without cause upon 90 days prior written notice.

Licensor will be responsible for preparing, filing, prosecuting and maintaining all patent applications and patents included in the licensed patents in the territory. Provided however, that if Licensor decides that it is not interested in maintaining a particular licensed patent or in preparing, filing, or prosecuting a licensed patent, it will promptly advise NoveCite in writing and NoveCite will have the right, but not the obligation, to assume such responsibilities in the territory at NoveCite's sole cost and expense.

During the term of the license agreement, Licensor is prohibited from commercializing or exploiting (directly or indirectly) any product that includes mesenchymal stem cells for any purpose in acute pneumonitis treatment (subject to certain sponsored research exceptions), or exploiting (directly or indirectly) or enabling a third party to exploit, for any purpose in acute pneumonitis treatment or otherwise, the original licensed cell banks line or any GMP-grade cell banks of a cell line derived therefrom and that can be used as starting material for the manufacture of products derived from the licensed technology. During the term of the license agreement, each party is prohibited from soliciting any employee of the other party, subject to certain exceptions.

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 Annual Report on Form 10-K for the year ended September 30, 2020.

A copy of the press release, dated October 7, 2020, announcing the entry into the 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 October 7, 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: October 9, 2020

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

Exhibit 99.1

Citius Pharmaceuticals Signs an Exclusive Worldwide Licensing Agreement with Novellus Therapeutics for Unique*i*MSC-Therapy for Acute Inflammatory Respiratory Conditions including COVID-19 Related Acute Respiratory Distress Syndrome (ARDS)

- *NoveCite, a newly formed subsidiary of Citius Pharmaceuticals, Inc., plans to develop, manufacture and commercialize a unique induced mesenchymal stem cells (NC-iMSCs)*
- *Novellus, a Cambridge, Mass-based cell engineering company, has developed patented, non-immunogenic mRNA-based **induced** mesenchymal stem cell (**i**MSC) platform*
- *NC-iMSCs demonstrate higher potency, uniformity and consistency - significant advantages over donor derived MSCs*

CRANFORD, NJ – October 7, 2020 – Citius Pharmaceuticals, Inc. ("Citius" or the "Company") (Nasdaq: CTXR), a specialty pharmaceutical company developing and commercializing critical care drug products, announced that it has signed an exclusive agreement with Novellus Therapeutics Limited ("Novellus") to license iPSC-derived mesenchymal stem cells (iMSCs), and has created a new subsidiary, NoveCite, that will be focused on developing cellular therapies.

NoveCite has a worldwide exclusive license from Novellus, an engineered cellular medicines company, to develop and commercialize NoveCite mesenchymal stem cells ("NC-*i*MSCs") to treat acute respiratory conditions with a near term focus on Acute Respiratory Distress Syndrome ("ARDS") associated with COVID-19. Several cell therapy companies using donor-derived MSC therapies in treating ARDS have demonstrated that MSCs reduce inflammation, enhance clearance of pathogens and stimulate tissue repair in the lungs. Almost all these positive results are from early clinical trials or under the emergency authorization program.

NC-*i*MSCs are the next generation mesenchymal stem cell therapy. They are believed to be differentiated and superior to donor-derived MSCs. Human donor-derived MSCs are sourced from human bone marrow, adipose tissue, placenta, umbilical tissue, etc. and have significant challenges (e.g., variable donor and tissue sources, limited supply, low potency, inefficient and expensive manufacturing). iMSCs overcome these challenges because they:

- Are more potent and secrete exponentially higher levels of immunomodulatory proteins;
- Have practically unlimited supply for high doses and repeat doses;
- Are from a single donor and clonal so they are economically produced at scale with consistent quality and potency, as well as being footprint free (compared to viral reprogramming methods); and,
- Have significantly higher expansion capability.

Globally, there are 3 million cases of ARDS every year out of which approximately 200,000 cases are in the United States. The COVID-19 pandemic has added significantly to the number of ARDS cases. Once the COVID patients advance to ARDS, they are put on mechanical ventilators. Death rate among patients on ventilators can be as high as 50% depending on associated co-morbidities. There are no approved treatments for ARDS, and the current standard of care only attempts to provide symptomatic relief.

“NoveCite iMSCs have the potential to be a breakthrough in the field of cellular therapy for acute respiratory conditions because of the high potency seen in Novellus’ pre-clinical studies, and because iMSCs are iPSC-derived, and therefore overcome the manufacturing challenges associated with donor derived cells,” said Myron Holubiak, Chief Executive Officer of Citius.

“We are excited to be part of this effort because of the promise to save lives and reduce long term sequelae in patients with devastating respiratory diseases such as ARDS caused by COVID-19,” said Dr. Matthew Angel, Chief Science Officer of Novellus. “Our iMSC technology has multimodal immunomodulatory mechanisms of action that make it potentially promising therapy to treat acute respiratory diseases.”

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 Novellus, Therapeutics, Limited

Novellus is a pre-clinical stage biotechnology company developing engineered cellular medicines using its patented non-immunogenic mRNA high specificity gene editing, mutation-free & footprint-free cell reprogramming and serum insensitive mRNA lipid delivery technologies. Novellus is privately held and is headquartered in Cambridge, MA. For more information, please visit www.novellus-inc.com.

About NoveCite iMSC (NC-iMSC)

NoveCite’s mesenchymal stem cell therapy product is derived from a human induced pluripotent stem cell (iPSC) line generated using a proprietary mRNA-based (non-viral) reprogramming process. The NC-iMSCs produced from this clonal technique are differentiated from human donor-derived MSCs (bone marrow, placenta, umbilical cord, adipose tissue, or dental pulp) by providing genetic homogeneity. In *in-vitro* studies, NC-iMSCs exhibit superior potency and high cell viability. NC-iMSCs secrete immunomodulatory proteins that may reduce or prevent pulmonary symptoms associated with acute respiratory distress syndrome (ARDS) in patients with COVID-19. NC-iMSC is an allogeneic (unrelated donor) mesenchymal stem-cell product manufactured by expanding material from a master cell bank.

First generation (human donor-derived) MSCs are isolated from donated tissue followed by “culture expansion”. Since only a relatively small number of cells are isolated from each donation, first generation MSCs are increased by growing the cells in culture. Unfortunately, these type of MSCs start to lose potency, and ultimately become senescent. Each donation produces a limited number of MSCs, so a continuous supply of new donors is needed to produce commercial scale. The number and quality of MSCs that can be isolated from different donors can vary substantially.

About Acute Respiratory Distress Syndrome (ARDS)

ARDS is an inflammatory process leading to build-up of fluid in the lungs and respiratory failure. It can occur due to infection, trauma and inhalation of noxious substances. ARDS accounts for approximately 10% of all ICU admissions and almost 25% of patients requiring mechanical ventilation. Survivors of ARDS are often left with severe long-term illness and disability. ARDS is a frequent complication of patients with COVID-19. ARDS is sometimes initially diagnosed as pneumonia or pulmonary edema (fluid in the lungs from heart disease). Symptoms of ARDS include shortness of breath, rapid breathing and heart rate, chest pain (particularly while inhaling), and bluish skin coloration. Among those who survive ARDS, a decreased quality of life is relatively common.

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: the risks associated with developing the NoveCite technology as a treatment for ARDS; risks associated with developing any of our product candidates, including any licensed from Novellus, Inc., including that preclinical results may not be predictive of clinical results and our ability to file an IND for such candidates; our need for substantial additional funds; the estimated markets for our product candidates, including those for ARDS, and the acceptance thereof by any market; risks relating to the results of research and development activities; uncertainties relating to preclinical and clinical testing; the early stage of products under development, including the NoveCite technology; our ability to obtain, perform under and maintain licensing, financing and strategic agreements and relationships; our ability to attract, integrate, and retain key personnel; risks related to our growth strategy; our ability to identify, acquire, close and integrate product candidates and companies successfully and on a timely basis; 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.

Contact:
Andrew Scott
Vice President, Corporate Development
(O) 908-967-6677 x105
(M) 646-522-8410
ascott@citiuspharma.com