May 13, 2021

Citius Pharmaceuticals, Inc. Reports Second Fiscal Quarter 2021 Financial Results and Provides General Business Update

Raised gross proceeds of $96.5 million from financing activities during the quarter providing financial runway into 2023

$103.7 million in cash and cash equivalents as of March 31, 2021 to support clinical development and business growth

Advanced four pipeline programs, including the Mino-Lok® Phase 3 superiority trial despite challenges recruiting subjects due to COVID-19

CRANFORD, N.J., May 13, 2021 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("Citius" or the "Company") (Nasdaq: CTXR) today reported financial results for the second fiscal quarter of 2021 and provided a general business update.

"The Citius team is focused on advancing a growing pipeline of first-in-class treatment options that have the potential to transform the current standards of care for patients around the world. We believe our near-term milestones, including an upcoming meeting with the Drug Monitoring Committee (DMC) for our lead product candidate, Mino-Lok®, will continue to drive momentum. Although COVID-19 slowed enrollment in the Mino-Lok® Phase 3 pivotal superiority trial, we remain on track to meet our milestones for the upcoming DMC meeting, which will clarify our clinical path forward. Our expectation, currently, is that we will file an NDA for Mino-Lok® in 2022, at which time Mino-Lok®'s Fast Track designation would make it eligible for expedited review," stated Myron Holubiak, President and Chief Executive Officer of Citius Pharmaceuticals.

"In parallel, we continue to advance our other clinical and pre-clinical programs. The U.S. Food and Drug Administration (FDA) guided us in developing a patient reported outcome (PRO) tool as the primary endpoint to assess clinical outcomes and efficacy for Halo-Lido. We have now submitted the PRO for FDA review and are awaiting feedback. Importantly, we remain focused on supporting our pre-clinical programs: a novel stem cell therapy to treat Acute Respiratory Distress Syndrome (ARDS) in COVID-19 patients, and Mino-Wrap, an anti-microbial film to prevent infection associated with post-mastectomy breast implants in cancer patients. Preparations are currently underway for *in vitro* studies for Mino-Wrap. Additionally, based on guidance from the FDA on our proprietary stem cell program, we are engaged in preclinical work, including the creation of an accession cell bank, development of a cGMP manufacturing process, and a proof-of-concept and dosing study in a large animal model. As we advance this program, we are mindful that this would be an important

treatment option for patients suffering from ARDS, for which there are currently no FDA-approved therapies," added Mr. Holubiak.

"I am also pleased to report that we successfully raised $96.5 million during the quarter, strengthening our balance sheet and providing us with significant runway into 2023. This will allow us to support our multiple development programs and invest in the long-term growth of our business. We are committed to developing novel first-in-class products that provide clear benefits compared to current standards of care for patients, physicians and caregivers. This is an exciting time at Citius and we appreciate the continued support of our shareholders in our mission," concluded Mr. Holubiak.

Second Fiscal Quarter 2021 and Recent Business Highlights

- Raised approximately $96.5 million from financing activities during the first quarter of 2021;
- Reported $103.7 million in cash and cash equivalents as of March 31, 2021;
- Advanced Mino-Lok® Phase 3 clinical superiority trial despite COVID-19-related study enrollment challenges; upcoming DMC meeting expected to clarify clinical path forward;
- Progressed NoveCite *i*-MSC preclinical development; on track to establish accession cell bank and continue large animal proof-of-concept study;
- Submitted Halo-Lido patient-reported outcome (PRO) tool to FDA for review and are awaiting feedback; and,
- Advanced preclinical pharmacology and toxicology studies and chemistry, manufacturing and controls (CMC) development for Mino-Wrap.

Corporate Highlights:

Mino-Lok®

Citius is developing Mino-Lok, an antibiotic lock solution to treat patients with catheter-related blood stream infections that was licensed from The University of Texas MD Anderson Cancer Center. We believe Mino-Lok® provides a superior alternative to removing and replacing a central venous catheter (CVC), leading to a reduction in serious adverse events and cost savings to the healthcare system. A multicenter Phase 3 pivotal superiority trial is currently underway. During the quarter, several participating clinical trial sites were closed as a result of the COVID-19 pandemic, slowing enrollment. However, we remain on track for an upcoming DMC meeting. Pending DMC review and guidance, Citius expects to file an NDA in 2022.

If approved, Mino-Lok® would be the first and only FDA-approved treatment that salvages central venous catheters that cause central line-related blood stream infections.

Halo-Lido

Halo-Lido (CITI-102) is a topical formulation of halobetasol and lidocaine to provide anti-inflammatory and anesthetic symptomatic relief to people with hemorrhoids. The FDA guided Citius to develop a novel patient-reported outcome (PRO) instrument to assess clinical outcomes and efficacy of Halo-Lido. The PRO is currently being reviewed by the FDA. Pending feedback from the FDA, we expect to file an IND and initiate the Phase 2b trial.

If approved, Halo-Lido would be the first and only FDA-approved prescription-strength product for the treatment of hemorrhoids for the more than 10 million individuals suffering each year.

NoveCite i-MSCs

In September 2020, Citius formed NoveCite, Inc. to develop a novel stem-cell therapy that would initially target Acute Respiratory Distress Syndrome (ARDS) associated with COVID-19. ARDS is the most common cause of respiratory failure and mortality in COVID-19 patients. The manufacturing process for development of NoveCite's proprietary mesenchymal stem cells (NC *i*-MSCs) is currently underway. Reported interim results of an ongoing proof-of-concept large animal study are encouraging. Once completed, we expect to initiate pilot and toxicology studies shortly thereafter. We anticipate filing an IND in 2022.

Currently, there is no FDA-approved drug therapy for ARDS.

Mino-Wrap

Mino-Wrap (CITI-101), also licensed from MD Anderson, is a liquefying gel-based wrap containing minocycline and rifampin designed to provide inflammatory tissue protection and prevent infection and biofilm formation in tissue expanders and breast implants post-mastectomy. Citius is developing this novel approach to reducing post-operative infections associated with surgical implants. Following guidance from the FDA, we are conducting *in vitro* experiments and product characterization studies for Mino-Wrap. Animal studies are underway.

Second Fiscal Quarter 2021 Financial Results:

Liquidity

As of March 31, 2021, the Company had $103.7 million in cash and cash equivalents. During the three months ended March 31, 2021, the Company raised approximately $96.5 million in gross proceeds from the issuance of common stock and warrants. In January, 2021, the Company closed a private placement for common stock and warrants totaling gross proceeds of approximately $20 million. In February, 2021, the Company raised net proceeds of approximately $4.5 million from the exercise of warrants, and closed a registered direct offering of its common stock and warrants for gross proceeds of approximately $76.5 million. We estimate that we will have sufficient funds for our operations through March 2023.

Research and Development (R&D) Expenses

R&D expenses were $1.6 million and $7.7 million for the three and six months ended March 31, 2021, respectively, compared to $2.0 million and $4.7 million for the comparable periods in 2020. The decrease in research and development expenses for the quarter ended March 31, 2021 compared to the prior year quarter reflects decreases in R&D expense for our Mino-Lok®, Halo-Lido and Mino-Wrap product candidates, offset by an increase in R&D expense for our recently in-licensed proposed novel stem cell therapy for Acute Respiratory Distress Syndrome (ARDS). During the three months ended March 31, 2020, we recorded a milestone expense of $0.6 million associated with the Mino-Lok® Phase 3 trial.

The increase in research and development for the six months ended March 31, 2021 compared to the prior year period reflects a decrease in manufacturing research and development for registration batches of Mino-Lok® produced in the six months ended December 31, 2020, and a decrease in R&D expenses for our other pipeline candidates, offset by an increase of $5.4 million in R&D expense related to our recently in-licensed proposed novel stem cell therapy for ARDS.

We expect that research and development expenses will increase in fiscal 2021 as we continue to focus on our Phase 3 trial for Mino-Lok®, progress the Halo-Lido product candidate and continue our research and development efforts related to ARDS and Mino-Wrap.

General and Administrative (G&A) Expenses

G&A expenses were $2.3 million and $4.0 million for the three and six months ended March 31, 2021, respectively, compared to $2.3 million and $3.8 million for the comparable periods in 2020. General and administrative expenses consist primarily of compensation costs, professional fees related to our capital raising activities, corporate development services, and investor relations.

Stock-based Compensation Expense

For the three months ended March 31, 2021, stock-based compensation expense was $0.3 million as compared to $0.2 million for the three months ended March 31, 2020. For the six months ended March 31, 2021, stock-based compensation expense was $0.6 million as compared to $0.4 million for the six months ended March 31, 2020. The increase reflects expenses related to new grants made by Citius and the recently adopted NoveCite stock option plan.

Net loss

Net loss was $4.1 million and $12.3 million for the three and six months ended March 31, 2021, respectively, compared to a net loss of $4.4 million and $8.7 million for the comparable periods in 2020. The decrease in net loss during the three months ended March 31, 2021 compared to the prior year period is primarily due to the decrease in research and development expenses. The increase in net loss during the six months ended March 31, 2021 compared to the prior year period reflects the increase in our research and development activities related to ARDS.

About Citius Pharmaceuticals, Inc.

Citius is a late-stage biopharmaceutical company dedicated to the development and commercialization of first-in-class critical care products, with a focus on anti-infectives in adjunct cancer care, unique prescription products, and stem cell therapy. The Company's lead product candidate, Mino-Lok®, an antibiotic lock solution for the treatment of patients with catheter-related bloodstream infections (CRBSIs), is currently enrolling patients in a Phase 3 pivotal superiority trial. Mino-Lok® was granted Fast Track designation by the U.S. Food and Drug Administration (FDA). Through its subsidiary, NoveCite, Inc., Citius is developing a novel proprietary mesenchymal stem cell treatment derived from induced pluripotent stem cells (iPSCs) for acute respiratory conditions, with a near-term focus on

Acute Respiratory Distress Syndrome (ARDS) associated with COVID-19. 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," "plan," "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 our product candidates; 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; the ability of our product candidates to impact the quality of life of our target patient populations; our need for substantial additional funds; market and other conditions; risks related to our growth strategy; patent and intellectual property matters; 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; our ability to procure cGMP commercial-scale supply; government regulation; competition; as well as other risks described in our SEC filings. These risks have been and may be further impacted by Covid-19. Accordingly, these forward-looking statements do not constitute guarantees of future performance, and you are cautioned not to place undue reliance on these forward-looking statements. Risks regarding our business are described in detail in our Securities and Exchange Commission ("SEC") filings which are available on the SEC's website at www.sec.gov, including in our Annual Report on Form 10-K for the year ended September 30, 2020, filed with the SEC on December 16, 2020 and updated by our subsequent filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof, and 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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-- Financial Tables Follow --

CITIUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	March 31, 2021	September 30, 2020
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 103,697,162	$ 13,859,748
Prepaid expenses	1,277,029	122,237
Total Current Assets	104,974,191	13,981,985
Property and equipment, net	1,272	1,577
Operating lease right-of-use asset, net	906,092	986,204
Other Assets:		
Deposits	38,062	57,093
In-process research and development	19,400,000	19,400,000
Goodwill	9,346,796	9,346,796
Total Other Assets	28,784,858	28,803,889
Total Assets	$ 134,666,413	$ 43,773,655
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,132,877	$ 1,856,235
Accrued expenses	240,610	164,040
Accrued compensation	1,172,375	1,654,919
Accrued interest	97,877	89,970
Notes payable – related parties	172,970	172,970
Operating lease liability	167,937	158,999
Total Current Liabilities	2,984,646	4,097,133
Note payable – paycheck protection program	164,583	164,583
Deferred tax liability	4,985,800	4,985,800
Operating lease liability – non current	769,218	855,471
Total Liabilities	8,904,247	10,102,987
Commitments and Contingencies		
Stockholders' Equity:		
Preferred stock – $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock – $0.001 par value; 200,000,000 shares authorized; 134,701,219 and 55,576,996 shares issued and outstanding at March 31, 2021 and September 30, 2020, respectively	134,701	55,577
Additional paid-in capital	210,289,813	104,208,958
Accumulated deficit	(85,262,728)	(70,593,867)
Total Citius Pharmaceuticals, Inc. Stockholders' Equity	125,161,786	33,670,668
Non-controlling interest	600,380	—
Total Equity	125,762,166	33,670,668
Total Liabilities and Equity	$ 134,666,413	$ 43,773,655

CITIUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE THREE AND SIX MONTHS ENDED MARCH 31, 2021 AND 2020
(Unaudited)

	Three Months Ended		Six Months Ended	
	March 31, 2021	March 31, 2020	March 31, 2021	March 31, 2020
Revenues	$ —	$ —	$ —	$ —

Operating Expenses				
Research and development	1,551,341	2,015,940	7,742,520	4,680,486
General and administrative	2,293,517	2,258,322	3,982,181	3,821,317
Stock-based compensation – general and administrative	342,962	158,833	619,544	379,217
Total Operating Expenses	4,187,820	4,433,095	12,344,245	8,881,020
Operating Loss	(4,187,820)	(4,433,095)	(12,344,245)	(8,881,020)
Other Income (Expense)				
Other income	—	—	—	110,207
Interest income	69,327	12,106	82,811	31,445
Interest expense	(3,939)	(3,980)	(7,907)	(7,971)
Total Other Income, Net	65,388	8,126	74,904	133,681
Net Loss	$ (4,122,432)	$ (4,424,969)	$ (12,269,341)	$ (8,747,339)
Net Loss Per Share - Basic and Diluted	$ (0.04)	$ (0.13)	$ (0.16)	$ (0.28)
Weighted Average Common Shares Outstanding				
Basic and diluted	95,997,427	34,318,761	75,565,121	31,744,379

CITIUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE SIX MONTHS ENDED MARCH 31, 2021 AND 2020
(Unaudited)

	2021	2020
Cash Flows From Operating Activities:		
Net loss	$ (12,269,341)	$ (8,747,339)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	619,544	379,217
Issuance of common stock for services	68,000	406,020
Amortization of operating lease right-of-use asset	80,112	81,847
Depreciation	305	354
Changes in operating assets and liabilities:		
Prepaid expenses	(1,154,792)	(5,553)
Deposits	19,031	—
Accounts payable	(723,358)	(1,189,182)
Accrued expenses	76,570	(96,234)
Accrued compensation	(482,544)	(368,812)
Accrued interest	7,907	7,971
Operating lease liability	(77,315)	(50,158)
Net Cash Used In Operating Activities	(13,835,881)	(9,581,869)
Cash Flows From Financing Activities:		
Proceeds from sale of NoveCite, Inc. common stock	500	—
Net proceeds from private placement	18,450,410	—
Net proceeds from registered direct offering	70,979,842	—
Net proceeds from common stock warrant exercises	14,242,543	6,027,137
Net Cash Provided By Financing Activities	103,673,295	6,027,137
Net Change in Cash and Cash Equivalents	89,837,414	(3,554,732)
Cash and Cash Equivalents - Beginning of Period	13,859,748	7,893,804
Cash and Cash Equivalents - End of Period	$ 103,697,162	$ 4,339,072
Supplemental Disclosures Of Cash Flow Information and Non-cash Activities:		
Operating lease right-of-use asset and liability recorded upon adoption of ASC 842	$ —	$ 1,137,724

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