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Citius Pharmaceuticals, Inc.

New Unit Offering Raises $9.2 Million

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Introduction and Summary

Citius Pharmaceuticals is a specialty pharmaceutical company that recently raised $10.0 million in a unit offering (stock and warrants), half of which was purchased by its CEO, Myron Holubiak and Chairman, Leonard Mazur. Net proceeds of $9.2 million will be used to fund the development of (1) ***Mino-Lok***, an antibiotic lock solution to treat and salvage infected central venous catheters ("CVCs") in patients with catheter-related bloodstream infections ("CRBSIs") and ***Hydro-Lido***, a topical formation of hydrocortisone and lidocaine intended for the treatment of hemorrhoids. Mino-Lok was granted "Fast-Track" status by the U.S. Food and Drug Administration ("FDA") in October 2017.

Citius currently has no revenues and expended $8 million in cash in 2017 and $8.8 million in the first half of 2018 (much of which was associated with the start of a Phase 3 trial for Mino-Lok). Assuming eventual FDA approval, it will likely be at least a couple of years before Mino-Lok begins to contribute meaningfully to Citius's revenues and profits. Thus, the company will require additional equity capital in order to complete its product development program, which will dilute the equity interests of current shareholders.

While the company is positioning Mino-Lok as an effective alternative to removal and replacement of CVCs, Mino-Lok's sales and market share potential may also depend upon its effectiveness versus existing preventive antibiotic lock treatments. Two other companies are developing products designed to prevent laboratory confirmed "central line" (i.e. long fine catheter) bloodstream infections ("CLABSIs"), which could eventually be extended to CVCs.

Using simplified assumptions, i.e. that Citius captures a 25% share of its estimated market potential, achieves a 21.5% operating margin, further dilutes the interests of existing shareholders by 90% and eventually obtains a P/E multiple of 20, I estimate that its stock could rise to $5.19 in 2022, which translates into a compounded annualized return of 33% on the August 20 closing share price of $1.51.

Discussion and Analysis

Citius Pharmaceuticals is a specialty pharmaceutical company focused on the development and commercialization of anti-infective drugs (used in adjunct cancer care) and other unique prescription products. It seeks candidates that have a lower development risk than is typically associated with new chemical compounds, including combinations of previously approved drugs that have the potential for high safety and efficacy profiles.

The company was founded in Massachusetts in 2007 and came public in 2014 through a reverse merger with a Nevada corporation. In 2016, Citius acquired Leonard-Meron Biosciences (LMB), which held the rights to Mino-Lok (though a patent and technology license agreement with Novel Anti-Infective Therapeutics, Inc.). Myron Holubiak, the founder, CEO and President of LMB is now Citius's President and CEO.

Mino-Lok is a patented solution of minocycline, disodium ethylenediaminetetraascetic acid (edetate) and ethyl alcohol designed to work together to treat and salvage infected CVCs in patients with CRBSIs. *Minocycline* is a broad-spectrum, tetracycline antibiotic, used to treat severe acne, urinary tract and other infections. *Edetate* is a chemical used medically to treat mercury and lead poisoning and remove iron from the body. It also serves as an anticoagulant in blood analysis and a slime disbursement agent.

In Citius's application, 0.8 to 2.0 milliliters of the Mino-Lok solution are injected the lumen of the catheter, which is then locked to prevent the solution from flowing into the vein. It remains there for two hours. Catheters with multiple lumens are simultaneously or sequentially locked depending upon whether the patient requires simultaneous infusion therapy. After the two-hour lock period, the solution is aspirated, and the catheter is flushed with a saline solution. The Mino-Lok treatment consist of five locks (two hours per day for five days) followed by two additional locks in the subsequent two weeks. A clinical study at the MD Anderson Cancer Center found that no minocycline or edetate was detected in the blood sera of the patients that used Mino-Lok at the proposed concentration levels.

From April 2013 to July 2014, 30 patients with CVC-related CRBSIs received Mino-Lok therapy in a Phase 2b study. Their median age was 56 years (ranging from 21-73 years). All patients received a culture-directed, first-line intravenous antibiotic before receiving the Mino-Lok therapy. Mino-Lok eradicated the microbial infections in all 30 patients without any serious adverse events ("SAEs"). By comparison, the control group of 60 patients which had their infected CVCs removed and replaced experienced an 18% SAE rate, including bacterial relapses, complications from the removal/replacement procedures and development of deep-seated infections.

Citius initiated site recruitment for Phase 3 clinical trials of Mino-Lok in November 2016. It was, however, forced to amend the trial design when several institutions complained that the proposed control group was intended to receive a saline and heparin placebo that was below

their standard of care. In collaboration with the FDA, Citius redesigned the trial to make it open label with the goal of assessing the superiority of Mino-Lok to current standards of care. The Phase 3 trial commenced during the 2018 first quarter.

In October 2017, Citius received official notice from the FDA of Fast Track status for the Mino-Lok investigational program.

Also in October 2017, Citius presented data from an international study of Mino-Lok at the Infectious Disease Conference in San Diego, CA. The study showed that Mino-Lok therapy was 95% effective at salvaging, long-term infected CVCs in 44 cancer patients with CRBSIs with limited vascular access. That compared with an 83% success rate in the (unspecified) control group. The one Micro-Lok patient whose infection was not eradicated by Mino-Lok had Burkholderia cepacia, a type of bacteria that was resistant to all antibiotics tested.

Although Mino-Lok has achieved solid results as an alternative to removal and replacement of catheters, Citius has not yet provided any explanation of how it compares against existing antibiotic lock treatments. When medical personnel spot the formation of biofilm that usually precedes CRBSIs, they typically use other antibiotic lock solutions to prevent CRBSI. Stanford Hospital and Clinics, for example, in a 2011 paper (revised in 2015) specifies a combination of Heparin with various types of antibiotics as its standard of care. (Citius asserts that there is evidence that Heparin, a blood thinner, contributes to the formation of biofilms.)

Thus, most hospitals and clinics already employ an antibiotic lock therapy to head off CVC-related CRBSIs. Citius is positioning Mino-Lok first as a salvage therapy, to be used presumably when existing therapies do not prove effective in avoiding CRBSIs. But it is not clear whether more effective administration of existing antibiotic lock therapies or replacement of Heparin with some other chemical compound might reduce the incidence of CRBSIs. Alternatively, if Mino-Lok is determined to be effective in salvage situations, it could conceivably be used in place of existing therapies as a prophylactic measure. If so, the potential market for Mino-Lok might be significantly greater than the company estimates.

Citius estimates the potential market for Mino-Lok as follows:

	Short-Term CVCs	Long-Term CVCs	Total CVCs
Number of Catheters (000s)	3,000	4,000	7,000
Average Duration (Days)	12	100	
Catheter Days (000s)	36,000	400,000	436,000
Infection Rate	.2%	.1%	N/A
Catheters Infected (000s)	72	400	472
Flushes per Catheter per Treatment	5	7	6.7
Total Salvage Flushes (000s)	360	2,800	3,160

Source: Citius Pharmaceuticals' 2017 10-K

Short-term catheters have an infection rate of 0.2% per catheter day. Although double the infection rate of long-term catheters, this results in approximately 1.2% of all short-term catheters becoming infected during the course of a year.

Long-term catheters, which account for more than 10 times the number of catheter days in a year, produce an estimated 400,000 infections annually. Thus, 10% of all long-term catheters become infected each year, according to Citius. Together, the company estimates a potential market of 472,000 infected catheters with 3.16 million potential salvage flushes annually.

The company anticipates that it will be able to charge $300 per flush or $2,100 for the full 7-treatment course of Mino-Lok therapy. This is a significant savings considering that CRBSIs have a 12%-35% mortality rate and cost $35,000-$56,000 per episode. Citius estimates the cost of a successful remove and replace procedure to be between $8,000 and $10,000.

A price of $300 per Mino-Lok flush suggests a potential market opportunity of $948 million ($300 times 3.16 million flushes), assuming that Mino-Lok completely replaces catheter removals and replacements. The company estimates a potential market size of between $500 million and $1 billion in annual sales.

My admittedly simplified valuation model (given on the next page) provides a framework for evaluating the revenue and profit potential of Mino-Lok under various assumptions. In the base case, I utilize Citius's assessment of a total market potential of $750 million (at the midpoint of the range). I assume that this market will grow at a rate of 3% annually and that Citius will gain a market share of 25% by 2022.

My assumptions anticipate that the company will not generate any revenues until 2020. Although that may seem conservative, it is worth noting the nearly three-and-a-half-year lapse between the end of the Phase 2B trial and the beginning of the Phase 3 trial. Accordingly, the company does not seem to be living up to its name, which means Faster in Latin. (Citius Altius Fortius (Faster, Higher, Stronger) is the motto of the Olympic games.)

My projection model further assumes that the company's operating margin will grow to 21.5% by 2022, which I believe is on the low end of the range of specialty pharmaceutical companies.

A conservative operating profit margin may be warranted because Citius is likely to contract out both its manufacturing and sales & marketing functions until it gains sufficient scale to consider bringing them in-house. On the other hand, Mino-Lok uses chemical compounds, minocycline and edetate, that are well established and whose patent protection has almost certainly lapsed. Thus, the materials cost of Mino-Lok therapy should be low.

Under these assumptions (including a 20% tax rate), Citius would generate $36.3 million in earnings in 2021. With its share count projected to increase ten-fold to 140 million over the next three years, the company's 2022 EPS is forecasted to be $0.26. At an assumed 20.0 times

P/E multiple, the 2022 target price on the stock is $5.19. Compared with the current price of $1.51, that would result in a compounded annualized return of 36.2% over the next 4.3 years.

Citius Pharmaceuticals

Hypothetical Projection and Valuation Model

	2018	2019	2020	2021	2022
Market opportunity	750.00	772.50	795.68	819.55	844.13
Growth rate		3.0%	3.0%	3.0%	3.0%
Market share		0.0%	5.0%	15.0%	25.0%
Revenues		**0.0**	**39.8**	**122.9**	**211.0**
Operating expenses					
Cost of sales		0.0	23.9	73.8	126.6
as % of revenues		60.0%	60.0%	60.0%	60.0%
Research and development	9.0	12.0	14.0	15.0	16.0
as % of revenues		#DIV/0!	35.2%	12.2%	7.6%
General and administrative	9.5	12.5	15.5	18.5	20.0
as % of revenues		#DIV/0!	39.0%	15.0%	9.5%
Stock-based compensation	1.2	1.5	2.0	2.5	3.0
Total operating expenses	19.7	26.0	55.4	109.8	165.6
Operating profit	(19.7)	(26.0)	(15.6)	13.2	45.4
Operating margin		#DIV/0!	-39.2%	10.7%	21.5%
Income taxes		(5.2)	(3.1)	2.6	9.1
Income tax rate		20.0%	20.0%	20.0%	20.0%
Net income	**(19.7)**	**(20.8)**	**(12.5)**	**10.5**	**36.3**
Wtd Avg Shares Outstanding	14.0				140.0
Earnings per share					**0.26**
Price-earnings multiple					20.00
Stock price	**1.51**				**5.19**

Source: Lark Research

Several comments are in order on this projection model: First, the assumption, as reflected in Citius's assessment of Mino-Lok's market potential, that 10% of all long-term catheters will become infected seems extraordinarily high.[1] If it is correct, then this high prevalence of infections is certainly worthy of the FDA's immediate attention.

Citius's estimate of market potential also includes CLABSIs, which have not yet been the subject of any clinical trials. Consequently, the potential for Mino-Lok to be designated as a treatment

[1] Infection rates for CVCs ranging from 1.6 to 7.6 per 1,000 catheter days were noted in a 2003 article in the New England Journal of Medicine. (see "Preventing Complications of Central Venous Catherization" by McGee and Gould, NEJM March 20, 2003). However, the researchers said that this affected only 1.0%-4.6% of catheters. I have been unable to reconcile this finding with the company's figures of 1.0 infections per 1,000 catheter days affecting 10% of catheters.

for CLABSIs will presumably be determined in a future clinical trial, after the current Phase 3 trials for CRBSIs.

Although Mino-Lok was shown to be nearly 100% effective in its Phase 2b and international clinical trials, it is not clear whether it can be effective in situations where the infection occurs as a result of improper procedures used in installing the catheter (i.e. when the infection occurs on the outside of the catheter and not in the lumen(s). Even so, if proven effective in future clinical trials, Mino-Lok could conceivably become a recommended first treatment in response to all CRBSIs, before opting for removal and replacement of the catheter.

Given the fuzziness of the market data, the limited public disclosure by Citius and all of the possible treatment permutations, it is difficult to assess Mino-Lok's market potential with a high degree of confidence.

As already noted, Citius completed an equity unit offering on August 9. Each unit consists of one share of its common stock and one common warrant to purchase one share of common stock at an exercise price of $1.15 per share. Each unit was valued at $1.275. In total, Citius sold 5,521,569 units for gross proceeds of $7.0 billion. It also offered 2,321,629 "pre-funded" units to existing shareholders at a price of $1.265 per share to allow them to keep their holdings below the 4.99% threshold. Total proceeds from the sale of prefunded units were $2.94 million, bringing total proceeds to just under $10.0 million. After underwriting discounts and commissions, Citius received net proceeds of $9.2 million from the offering.

The above analysis does not include any potential value for Citius's Hydro-Lido. As noted, Hydro-Lido is a topical formation of hydrocortisone and lidocaine for the treatment of hemorrhoids. Citius is not aware of any FDA-approved prescription drug products for the treatment of hemorrhoids and therefore believes that there is an opportunity in developing such a product. Physicians may sometimes prescribe topical steroids as an alternative to over-the-counter remedies. In addition, there are topical prescription products that combine hydrocortisone with either lidocaine or pramoxine, but these have not been evaluated for safety and efficacy and are not approved by the FDA for the treatment of hemorrhoids.

Hemorrhoids affect nearly 5% of the U.S. population. Approximately 10 million persons admit to having symptoms annually, with one-third of these consulting a physician. The disorder mostly affects those aged 45-65, with decreasing prevalence after the age of 65.

In 2015, Citius completed a Phase 2 study of six different formulations of Hydro-Lido in various strengths. The study was designed to demonstrate safety and efficacy as well as suggest the potential contribution of lidocaine hydrochloride and hydrocortisone acetate for the treatment of low grade hemorrhoids. The study showed achievement of "almost symptom free" or "symptom free" suggesting the possibility of a benefit for the formulation. The study also showed a low occurrence of adverse events. Yet, Citius said that it will evaluate re-formulating the product, perhaps by including higher potency steroids. It also said that it learned much

about the process of assessing safety and efficacy through the study's design framework that will help in future clinical trials.

Since it uses readily available and low-cost chemical compounds, Hydro-Lido fits the low-risk development profile that Citius seeks. However, Citius still has much more development work to complete on Hydro-Lido, including determining the optimal formulation, so the commercialization of the product is still likely to be at least a few years away.