

Citius Pharmaceuticals (NASDAQ/CTXR)

March 26, 2020

BUY: Compassionate Use in a Period of COVID, See What One Physician Had to Say Regarding Mino-Lok

We spoke with senior management of Citius in order to understand the news release today that Citius has initiated an Expanded Access protocol for Mino-Lok. It makes sense. In a period of constrained resources when patients have implanted catheters for weeks and sometimes months that can become infected, the need for the ability to salvage the device, in-place, quickly, rises sharply in a world of COVID. We see this as confirmation of the value proposition in Citius. See Exhibit 1. (next page) unsolicited feedback (an inbound e-mail) from one of the doctors on the ground.

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Investment Highlights

Expanded Access Makes Sense in a period of COVID. Through the Expanded Access protocol, an infected central venous catheter can now be treated with Citius' Mino-Lok, potentially avoiding the need for the removal and replacement procedure. Given the challenges at today's hospital environment (COVID) plus this brings advantages to conserving staff and resources and reducing exposure risks. Recently the company highlighted a new analysis (by DelveInsight) which suggests the Catheter-Related Blood Stream Infections or CRBSIs market could be as large as \$1.84 billion in 2028. The survey suggests that the total Incidence of CRBSI in the Global Market is estimated to be 4 million patients.

Back in October, Citius announced that the first interim analysis point (37 catheter failures, which represents 40% of the anticipated events at ~ 58 patients) had been reached. The DSMB has reviewed the data and, as we expected, advised that the trial continues, unchanged. We view the DSMB's update as positive. It tells us that the trial has been properly powered. The DSMB could have recommended increasing the trial (add statistical power to see the signal with a p-value). Recall that the trial is designed with 80% power for an assumed 17-day difference between active and standard of care (SOC). We typically expect the SOC arm to fail in 5-14 days.

OK, So what's Next? Topline data from the superior efficacy interim analysis should represent the next major milestone in the Mino-Lok trial. It is expected, based on the current events rate and enrollment, to occur soon. This second interim analysis is looking at efficacy, or in this case, superiority. The plan is to evaluate the data at 69 events or 75% of the total events anticipated at ~108 patients.

Trial Background. As a reminder, the current Phase 3 trial being conducted compares Mino-Lok therapy (MLT) to the standard of care, which is antibiotic lock therapy (ALT). This is used to disinfect colonized catheters causing bacteremia and keep the treated catheters functioning and infection-free for eight weeks post-therapy. The current primary endpoint in the study is planned to demonstrate a significant difference in the time to catheter failure when comparing MLT to ALT. This is clinically important because eliminating the source of infection enables antibiotic treatment of the bacteremia to work more effectively and expeditiously. Additionally, if a catheter can be maintained for the time that it is needed, the patient does not need to be subjected to the procedures for removing and replacing the catheter that are associated with some serious adverse events.

Current Price \$0.92
 Price Target \$ 7.00

Estimates	F2019E	F2020E	F2021E
Expenses (\$000s)	\$ 15,596	\$ 23,636	\$ 39,190
1Q December	\$ 3,872	\$ 4,448	\$ 9,192
2Q March	\$ 3,642	\$ 5,552	\$ 9,495
3Q June	\$ 4,427	\$ 5,604	\$ 9,797
4Q September	\$ 3,655	\$ 8,032	\$ 10,705
	F2019E	F2020E	F2021E
EPS	\$ (0.53)	\$ (0.54)	\$ 0.94
1Q December	\$ (0.21)	\$ (0.15)	\$ 0.22
2Q March	\$ (0.09)	\$ (0.14)	\$ 0.22
3Q June	\$ (0.13)	\$ (0.11)	\$ 0.23
4Q September	\$ (0.10)	\$ (0.15)	\$ 0.27

EBITDA/Share	
EV/EBITDA (x)	
Stock Data	
52-Week Range	\$0.40 - \$1.50
Shares Outstanding (mil.)	45.2
Market Capitalization (mil.)	\$41
Enterprise Value (mil.)	\$22
Debt to Capital	0%
Book Value/Share	\$2.63
Price/Book	0.9
Average Three Months Trading Volume (K)	450
Insider Ownership	36.4%
Institutional Ownership	5.6%
Short interest (mil.)	2.6%
Dividend / Yield	\$0.00/0.0%

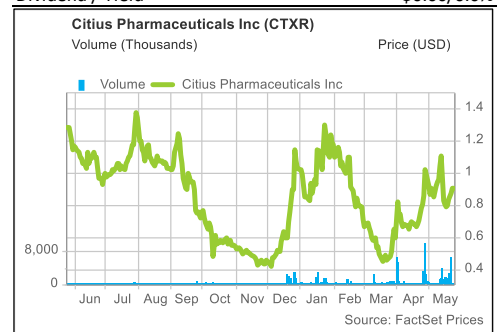


Exhibit 1. An Inbound letter from a physician regarding Expanded Access.

Dear [REDACTED],

My name is Dr [REDACTED]. I'm an intensivist at [REDACTED] Hospital and the site sub-investigator for the Mino-Lok study, run by the incredible trauma research team at [REDACTED]. [REDACTED] and [REDACTED] (study coordinators) are cc'd to this message and they passed along your contact information. I wanted to share with you a brief anecdote that really made us feel good about our roles as investigators, particularly in regards to improvement in patient outcomes and quality of life.

The Mino-Lok study is a huge, multi-center trial investigating the use of antibiotic lock therapy in patients with infected indwelling lines that we are trying to save. Normally, when an indwelling catheter is infected, it should be removed, but this can come at a huge cost to the system as well as inconvenience and risk to the patient given that those lines are needed for potentially life-saving therapies, such as chemotherapy, fluids and other infusions. Mino-Lok aims to preserve those lines by "cleaning them out" with a special antibiotic treatment.

Our patient enrolled at the [REDACTED] Hospital site had booked a dream cruise from the West Coast, around/through the Panama Canal and back up to the East Coast. Patient and spouse had spent thousands of dollars and had been looking forward to this trip for months. The patient was hospitalized with a line infection and the recommendation was to remove the line. They were ready, reluctantly, to cancel their trip, have another central line placed, etc., but, thanks to the incredible efforts of XXX and YYYY, the patient was enrolled in the Mino-Lok study, went through the line-saving treatment and—as of writing—was cured of the infection. Not only was the patient able to preserve the indwelling line, but patient and spouse were able to go on their dream vacation.

I saw the patient in clinic last week. Both, patient and spouse credit enrollment in this study as the reason they could do what they did. Their comments really struck me as the perfect example of why we do what we do on the research end—to try to find innovative therapies that can help people live their lives with a sense of happiness and freedom.

Regards,

Source: Citius

Valuation. Our valuation is based on our therapeutic models and associated assumptions projected to 2030. Our model assumes multiple financial raises, and as such, our share count is based on a fully diluted out year basis. The lead product, Mini-Lok, is now in a Phase 3 trial. We conservatively assume just 50% probability of success in our models. On top of this, we also use a 30% risk rate in our free cash flow to the firm (FCFF), our discounted EPS (dEPS) and sum-of-the-parts (SOP) models. We equal weight and average these metrics and then round to the nearest whole number to derive our \$7.00 price target.

Exhibit 1. FCFF Model

	\$	7.00
Price Target	\$	7.00
Year		2020

DCF Valuation Using FCF (min):

units ('000 - Cnd\$)	2019A	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
EBIT (Earnings before income tax)	(15,562)	(15,892)	23,578	16,442	68,356	96,043	124,814	154,704	185,745	217,971
Tax Rate	0%	0%	5%	10%	15%	20%	25%	30%	35%	38%
EBIT(1-t) Earnings after income tax	(15,562)	(15,892)	22,399	14,797	58,103	76,834	93,611	108,293	120,734	135,142
CapEx (equipment)	-	-	-	-	-	-	-	-	-	-
Depreciation	-	-	-	-	-	-	-	-	-	-
Change in NWC	-	-	-	-	-	-	-	-	-	-
FCF	(15,562)	(15,892)	22,399	14,797	58,103	76,834	93,611	108,293	120,734	135,142
PV of FCF	(20,231)	(15,892)	17,230	8,756	26,447	26,902	25,212	22,436	19,241	16,567
Discount Rate	30%									
Long Term Growth Rate	1%									
Terminal Cash Flow	470,666									
Terminal Value YE2023	57,699									
NPV	204,597									
NPV-Debt	-									
Shares out ('000)	30,602 2028E									
NPV Per Share	\$ 6.69									

Source: Dawson James

Exhibit 2. Discounted EPS Model

Current Year	2020
Year of EPS	2028
Earnings Multiple	15
Discount Factor	30%
Selected Year EPS	\$ 4.41
NPV	\$ 8.11

Discount Rate and Earnings Multiple Varies, Year is Constant								
		2028 EPS						
		8.11	5%	10%	15%	20%	25%	30%
Earnings Multiple	5	\$14.93	\$10.29	\$7.21	\$5.13	\$3.70	\$ 2.70	
	10	\$29.87	\$20.58	\$14.42	\$10.26	\$7.40	\$ 5.41	
	15	\$44.80	\$30.88	\$21.64	\$15.39	\$11.10	\$ 8.11	
	20	\$59.73	\$41.17	\$28.85	\$20.52	\$14.81	\$ 10.82	
	25	\$74.66	\$51.46	\$36.06	\$25.66	\$18.51	\$ 13.52	
	30	\$89.60	\$61.75	\$43.27	\$30.79	\$22.21	\$ 16.23	
	35	\$104.53	\$72.05	\$50.49	\$35.92	\$25.91	\$ 18.93	
	40	\$119.46	\$82.34	\$57.70	\$41.05	\$29.61	\$ 21.64	

Source: Dawson James

Exhibit 3. Sum of the Parts Model

	LT Gr	Discount Rate	Yrs. to Peak	% Success	Peak Sales MMs	Term Val
MiniLok LT & ST CVC U.S.	1%	30%	4	70%	\$302	\$1,040
						\$5.83
MiniLok LT & ST CVC E.U.	1%	30%	6	80%	\$0	\$0
						\$0.00
MiniLok LT & ST CVC China	1%	30%	7	80%	\$0	\$0
						\$0.00
Hydro-Lido	1%	30%	5	0%	\$0	\$0
Pre-Clinical Pipeline						\$0.00
Net Margin						70%
MM Shrs OS						31
Total						\$5.83

Source: Dawson James

Exhibit 4. Income Statement

Citius Pharmaceuticals: Income Statement (\$000)																				
YE Sept.	2017A	2018A	2019A	December 1Q20A	March 2Q20E	June 3Q20E	Sept. YE 4Q20E	2020E	December 1Q21E	March 2Q21E	June 3Q21E	Sept. YE 4Q21E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Mno-Lok, U.S. ST & LT CVC Revenues			-	-	-	-	-	-	18,778	19,594	20,410	22,860	81,642	166,566	212,392	259,994	309,423	360,734	413,983	469,227
Mno-Lok, E.U. ST & LT CVC Revenues			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Mno-Lok, China ST & LT CVC Revenues			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Expenses									18,778	19,594	20,410	22,860	81,642	166,566	212,392	259,994	309,423	360,734	413,983	469,227
Cost of goods sold			-	-	-	-	-	-	2,817	2,939	3,062	3,429	12,246	24,985	31,859	38,999	46,413	54,110	62,097	70,384
COGS % of Revenue				15%	15%	15%	15%		15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
Research and development	5,873	6,563	8,597	2,665	2,192	2,105	2,455	8,769	2,236	2,236	2,236	2,236	8,944	9,123	9,306	9,492	9,682	9,875	10,073	10,274
R&D % of Revenue																				
G&A	12,126	6,447	6,285	1,563	1,560	2,000	2,000	7,123	3,450	3,600	3,750	4,200	15,000	25,000	25,500	26,010	26,530	27,061	27,602	28,154
SG&A % of Revenue																				
Stock based comp. G & A	1,973	780	716	220				220												
Total expenses	19,972	13,789	15,598	4,448	3,752	4,105	4,455	15,892	8,503	8,775	9,048	9,865	36,191	59,108	66,664	74,501	82,625	91,046	99,772	108,812
Oper. Inc. (Loss)	(19,972)	(13,789)	(15,598)	(4,448)	(3,752)	(4,105)	(4,455)	(15,892)	10,275	10,819	11,363	12,995	45,451	107,458	145,728	185,493	226,798	269,688	314,211	360,414
Interest Income	47	818	53	110																
Gain (loss) on revaluation of derivative warrant liability		450		19																
Interest Expense		(16)	(16)	(4)																
Pre-tax income	(20,769)	1,253	(15,562)	(4,322)	(3,752)	(4,105)	(4,455)	(15,892)	10,275	10,819	11,363	12,995	45,451	107,458	145,728	185,493	226,798	269,688	314,211	360,414
Income Tax Benefit (Provision)	-	-	-	-	-	-	-	-	514	541	568	650	2,273	10,746	21,859	37,099	56,699	80,906	109,974	136,957
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	5%	5%	5%	5%	5%	10%	15%	20%	25%	30%	35%	38%
GAAP Net Income (loss)	(4,952)	(12,537)	(15,562)	(4,322)	(3,752)	(4,105)	(4,455)	(16,634)	9,761	10,278	10,795	12,345	43,179	96,712	123,869	148,394	170,098	188,782	204,237	223,457
GAAP-EPS	(3.55)	(1.22)	(0.67)	(0.15)	(0.09)	(0.10)	(0.11)	(0.45)	0.33	0.35	0.36	0.41	1.45	3.23	4.13	4.92	5.62	6.21	6.70	7.30
Non GAAP EPS (dil)	(3.55)	(1.22)	(0.67)	(0.15)	(0.09)	(0.10)	(0.11)	(0.45)	0.33	0.35	0.36	0.41	1.45	3.23	4.13	4.92	5.62	6.21	6.70	7.30
Wgtd Avg Shrs (Bas) - '000s	5,842	10,731	20,162	29,198	29,227	29,256	29,286	29,242	29,315	29,344	29,374	29,403	29,359	29,477	29,595	29,713	29,832	29,952	30,072	30,192
Wgtd Avg Shrs (Dil) - '000s	5,842	10,731	20,162	29,198	39,950	40,350	40,753	37,563	29,315	29,608	29,904	30,203	29,758	29,877	29,997	30,117	30,237	30,358	30,480	30,602

Source: Dawson James

Risk Analysis

In addition to the typical risks associated with development stage specialty pharmaceutical companies, potential risks specific to Citius Pharmaceuticals, Inc. are as follows:

Partnership risk. Citius Pharmaceuticals, Inc. is in discussions with possible partners today, but there can be no assurances that the company will be able to secure a favorable partnership.

Commercial risk. There are no assurances that the company will be able to achieve significant market share and become profitable.

Clinical and regulatory risk. Lead products have to complete clinical trials. Trials may not produce results sufficient for regulatory approval.

Financial risk. The company may need to raise capital in the marketplace, and there can be no assurances that the company will be able to successfully raise capital and/or do so, at favorable terms.

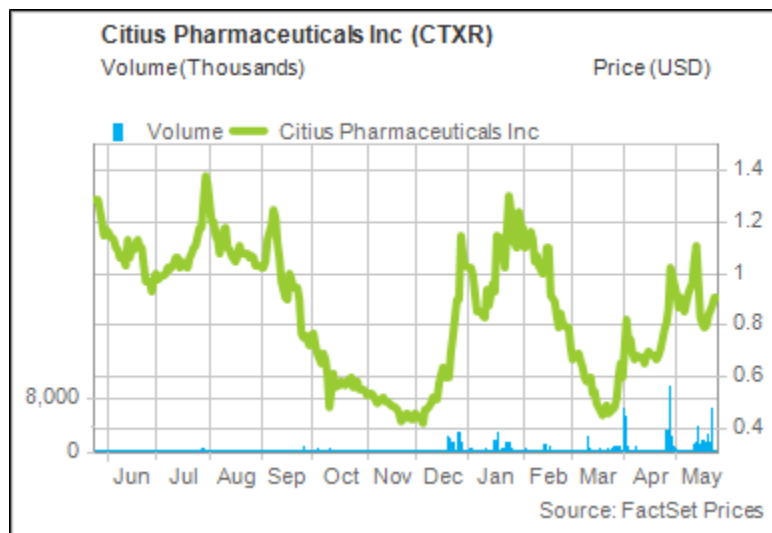
Liquidity Risk. The stock is thinly traded. We note that management owns a significant percentage of the company.

Legal and intellectual property risk. The company may have to defend its patents and technical know-how, and there can be no assurances that the patents will not be infringed or will be held as valid if challenged, and/or that the company may infringe on third parties' patents.

Companies mentioned in this report

Important Disclosures:

Price Chart:



Price target and rating changes over the past three years:

- Initiation – Buy – 12/15/2017 – Price Target \$10.00
- Update – Buy – 7/6/2018 – Price Target \$10.00
- Transfer – Buy – 9/6/2019 – Price Target \$7.00
- Update – Buy – 10/7/2019 – Price Target \$7.00
- Update – Buy – 12/19/2019 – Price Target \$7.00
- Update – Buy – 2/4/2020 – Price Target \$7.00
- Update – Buy – 2/25/2020 – Price Target \$7.00
- Update – Buy – 5/26/2020 – Price Target \$7.00

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Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	22	88%	3	14%
Market Perform (Neutral)	3	12%	1	33%
Market Underperform (Sell)	0	0%	0	0%
Total	25	100%	4	16%

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