

Citius Pharmaceuticals (NASDAQ/CTXR)

November 30, 2020

BUY: Yes, The Combo is the Key in Staphylococcal Biofilms

Citius announced the completion of a "Boston Analytical Study" that evaluated the effectiveness of all three components of Mino-Lok (30 mg/mL EDTA, 19.5% ethanol and 1 mg/mL minocycline) versus EDTA/ethanol (30 mg/mL EDTA and 19.5% ethanol) on *Staphylococcus aureus*. Results found the triple combination was more effective ($p=0.0598$) than the doublet. Staph infections remain extremely dangerous, especially in catheter-related infections.

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Investment Highlights

What is Mino-Lok? Three active drug substances (minocycline, ethanol, and EDTA), which are combined into two vials, MLT01 (minocycline) and MLT02 (ethanol and EDTA). Citius has manufactured three registration lots of Mino-Lok using the commercial manufacturing process, part of the planned New Drug Application (NDA). Citius has placed all registration lots on stability at the appropriate ICH (The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) conditions to support the NDA filing. Citius has also developed a new exclusive synthesis process for disodium edetate, a chelating agent that supplants heparin as the anti-clotting agent in Mino-Lok.

Trial Background. 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.

DMC Said Keep Going as Planned. This past September, the DMC recommended continuing the trial without any modifications. The DMC further requested to have an ad hoc meeting in the near future. Recall that the trial (Sept. 2019) reached the first interim analysis point of 37 catheter failures representing 40% of the anticipated events at ~58 patients. 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.

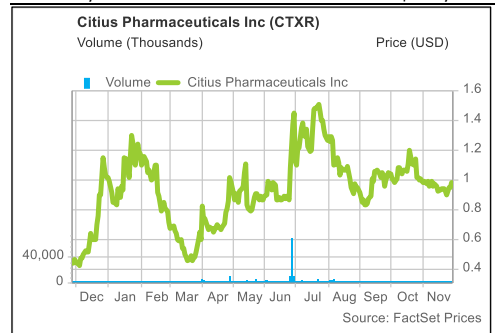
Valuation. Please see our complete valuation metrics (next page).

Risk Factors: These include Clinical Risk, Partnership Risk, Investment and Financial Risk, Regulatory Risk, Market Share Risk, and Legal and Commercial Risks.

Current Price \$1.00
 Price Target \$ 7.00

Estimates	F2019A	F2020E	F2021E
Expenses (\$000s)	\$ 15,596	\$ 18,525	\$ 31,190
1Q December	\$ 3,872	\$ 4,448	\$ 7,352
2Q March	\$ 3,642	\$ 4,433	\$ 7,575
3Q June	\$ 4,427	\$ 4,689	\$ 7,797
4Q September	\$ 3,655	\$ 4,955	\$ 8,465
	F2019A	F2020E	F2021E
EPS	\$ (0.53)	\$ (0.49)	\$ 1.01
1Q December	\$ (0.21)	\$ (0.15)	\$ 0.23
2Q March	\$ (0.09)	\$ (0.13)	\$ 0.24
3Q June	\$ (0.13)	\$ (0.11)	\$ 0.25
4Q September	\$ (0.10)	\$ (0.11)	\$ 0.28

EBITDA/Share	
EV/EBITDA (x)	
Stock Data	
52-Week Range	\$0.40 - \$1.97
Shares Outstanding (mil.)	55.5
Market Capitalization (mil.)	\$55
Enterprise Value (mil.)	\$36
Debt to Capital	0%
Book Value/Share	\$2.63
Price/Book	0.9
Average Three Months Trading Volume (K)	10,578
Insider Ownership	25.0%
Institutional Ownership	1.7%
Short interest (mil.)	1.3%
Dividend / Yield	\$0.00/0.0%



Valuation. Our valuation is based on our therapeutic models and associated assumptions projected to 2028. 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

Average \$	7.00
Price Target \$	9.00
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)	(15,560)	(18,525)	50,452	117,459	155,929	195,898	237,411	280,513	325,253	371,677
Tax Rate	0%	0%	5%	10%	15%	20%	25%	30%	35%	38%
EBIT(1-t) Earnings after income tax	(15,560)	(18,525)	47,930	105,713	132,540	156,718	178,058	196,359	211,414	230,440
CapEx (equipment)	-	(2)	-	-	-	-	-	-	-	-
Depreciation	-	429	-	-	-	-	-	-	-	-
Change in NWC	-	-	-	-	-	-	-	-	-	-
FCF	(15,560)	(18,098)	47,930	105,713	132,540	156,718	178,058	196,359	211,414	230,440
PV of FCF	(20,228)	(18,098)	36,869	62,552	60,328	54,871	47,956	40,681	33,692	28,249
Discount Rate	30%									
Long Term Growth Rate	1%									
Terminal Cash Flow	802,566									
Terminal Value YE2023	98,386									
NPV	425,260									
NPV-Debt	-									
Shares out ('000)	48,739	2028E								
NPV Per Share	\$ 8.73									

Source: Dawson James estimates

Exhibit 2. Discounted EPS Model

Current Year	2020
Year of EPS	2028
Earnings Multiple	10
Discount Factor	30%
Selected Year EPS	\$ 4.72
NPV	\$ 5.79

Discount Rate and Earnings Multiple Varies, Year is Constant							
2028 EPS							
Earnings Multiple	5.79	5%	10%	15%	20%	25%	30%
5	\$15.99	\$11.02	\$7.72	\$5.49	\$3.96	\$2.90	
10	\$31.98	\$22.04	\$15.44	\$10.99	\$7.93	\$5.79	
15	\$47.97	\$33.06	\$23.17	\$16.48	\$11.89	\$8.69	
20	\$63.96	\$44.08	\$30.89	\$21.98	\$15.85	\$11.58	
25	\$79.95	\$55.10	\$38.61	\$27.47	\$19.82	\$14.48	
30	\$95.93	\$66.12	\$46.33	\$32.96	\$23.78	\$17.38	
35	\$111.92	\$77.14	\$54.06	\$38.46	\$27.74	\$20.27	
40	\$127.91	\$88.16	\$61.78	\$43.95	\$31.71	\$23.17	

Source: Dawson James estimates

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%	\$469	\$1,618
						\$5.70
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						49
Total						\$5.70

Source: Dawson James estimates

Exhibit 4. Income Statement

Citius Pharmaceuticals: Income Statement (\$'000)																
YE Sept.	2017A	2018A	2019A	1Q20A	2Q20A	3Q20A	4Q20E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Mino-Lok, U.S. ST & LT CVC Revenues			-	-	-	-	-	-	81,642	166,566	212,392	259,994	309,423	360,734	413,983	469,227
Mino-Lok, E.U. ST & LT CVC Revenues			-	-	-	-	-	-	-	-	-					
Mino-Lok, CHINA ST & LT CVC Revenues			-	-	-	-	-	-	81,642	166,566	212,392	259,994	309,423	360,734	413,983	469,227
Expenses																
Cost of goods sold		-	-	-	-	-	-	-	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%
Research and development	5,873	6,563	8,596	2,665	2,016	2,644	2,455	8,768	8,943	9,122	9,305	9,491	9,680	9,874	10,072	10,273
R&D % of Revenue																
G&A	12,126	6,447	6,285	1,563	2,258	1,870	2,500	8,191	10,000	15,000	15,300	15,606	15,918	16,236	16,561	16,892
SG&A % of Revenue																
Stock based comp. G & A	1,973	780	715	220	159	175	175	729								
Total expenses	19,972	13,789	15,596	4,448	4,433	4,689	4,955	18,525	31,190	49,107	56,463	64,096	72,012	80,221	88,730	97,549
Oper. Inc. (Loss)	(19,972)	(13,789)	(15,596)	(4,448)	(4,433)	(4,689)	(4,955)	(18,525)	50,452	117,459	155,929	195,898	237,411	280,513	325,253	371,677
Interest Income	47	818	53	110	12	13										
Gain (loss) on revaluation of derivative warrant liability		450		19												
Interest Expense		(16)	(16)	(4)	(4)	(4)										
Pre-tax income	(20,769)	1,253	(15,560)	(4,323)	(4,425)	(4,680)	(4,955)	(18,525)	50,452	117,459	155,929	195,898	237,411	280,513	325,253	371,677
Income Tax Benefit (Provision)	-	-	-	-	-	-	-	-	2,523	11,746	23,389	39,180	59,353	84,154	113,838	141,237
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	5%	10%	15%	20%	25%	30%	35%	38%
GAAP Net Income (loss)	(4,952)	(12,537)	(15,560)	(4,323)	(4,425)	(4,680)	(4,955)	(18,383)	47,930	105,713	132,540	156,718	178,058	196,359	211,414	230,440
GAAP-EPS	(3.55)	(1.22)	(0.53)	(0.15)	(0.13)	(0.11)	(0.11)	(0.49)	1.01	2.22	2.77	3.26	3.69	4.06	4.35	4.72
Non GAAP EPS (dil)	(3.55)	(1.22)	(0.61)	(0.11)	(0.13)	(0.11)	(0.11)	(0.46)	1.01	2.22	2.77	3.26	3.69	4.06	4.35	4.72
Wgtd Avg Shrs (Bas) - '000s	5,842	10,731	20,162	29,197	34,319	41,600	46,642	37,940	46,759	46,946	47,134	47,323	47,513	47,703	47,894	48,086
Wgtd Avg Shrs (Dil) - '000s	5,842	10,731	35,000	39,197	34,319	41,600	47,016	40,533	47,394	47,584	47,774	47,966	48,158	48,351	48,544	48,739

Source: Dawson James, company reports

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.

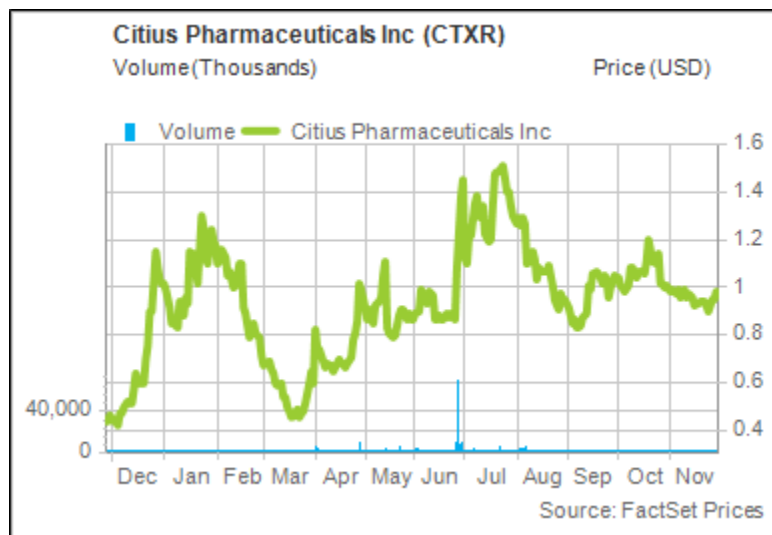
Liquidity Risk. The stock is thinly traded. We note that management owns a significant percentage of the company.

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
- Update – Buy – 9/28/2020 – Price Target \$7.00
- Update – Buy – 9/29/2020 – Price Target \$7.00
- Update – Buy – 11/30/2020 – 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)	21	78%	4	19%
Market Perform (Neutral)	6	22%	1	17%
Market Underperform (Sell)	0	0%	0	0%
Total	27	100%	5	19%

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