

Citius Pharmaceuticals (NASDAQ/CTXR)

BUY: First Interim Analysis Reached – Lok’ed For Success

Citius announced that the Phase 3 trial evaluating Mino-Lok (salvaging catheters in patients with blood stream infections) has reached the 40% completion mark, which triggers the first interim analysis.

Investment Highlights

First Interim Reached: Citius announced that the first interim analysis point (37 catheter failures, which represents 40% of the anticipated events at ~ 58 patients) has been reached. The DSMB will now review the data and come back with analysis (in about six weeks). **We see the most likely recommendation being that the trial continues, unchanged.** The DSMB could recommend increasing the trial (add statistical power to see the signal with a p-value). 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.

Second Interim Analysis – Superiority. At 69 events, or 75% of the total events anticipated at ~108 patients, the DSMB will again review the trial. In this second analysis efficacy will be evaluated.

The FDA say’s “Go For it”. The FDA responded to the Company's proposal to refine the endpoints in the current Phase 3 pivotal trial for Mino-Lok. 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.

New Endpoint Saves Time and Money. The new proposed primary endpoint 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. **Citius believes that the change to the primary endpoint will result in fewer than 150 total subjects in Phase 3 trial and significant cost savings (up to \$10M).**

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. As such, we assume a 70% 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.

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Current Price \$0.65
 Price Target \$ 7.00

Estimates	F2019E	F2020E	F2021E
Expenses (\$000s)	\$ 15,912	\$ 22,772	\$ 39,194
1Q December	\$ 3,872	\$ 5,238	\$ 9,194
2Q March	\$ 3,642	\$ 5,553	\$ 9,496
3Q June	\$ 4,427	\$ 5,605	\$ 9,798
4Q September	\$ 3,971	\$ 6,376	\$ 10,706
	F2019E	F2020E	F2021E
EPS	\$ (0.60)	\$ (0.43)	\$ 0.94
1Q December	\$ (0.21)	\$ (0.10)	\$ 0.22
2Q March	\$ (0.09)	\$ (0.11)	\$ 0.22
3Q June	\$ (0.20)	\$ (0.11)	\$ 0.23
4Q September	\$ (0.09)	\$ (0.12)	\$ 0.27

EBITDA/Share	
EV/EBITDA (x)	
Stock Data	
52-Week Range	\$0.65 - \$1.85
Shares Outstanding (mil.)	29.9
Market Capitalization (mil.)	\$19
Enterprise Value (mil.)	\$0
Debt to Capital	0%
Book Value/Share	\$2.63
Price/Book	1.0
Average Three Months Trading Volume (K)	28
Insider Ownership	46.4%
Institutional Ownership	2.1%
Short interest (mil.)	0.8%
Dividend / Yield	\$0.00/0.0%

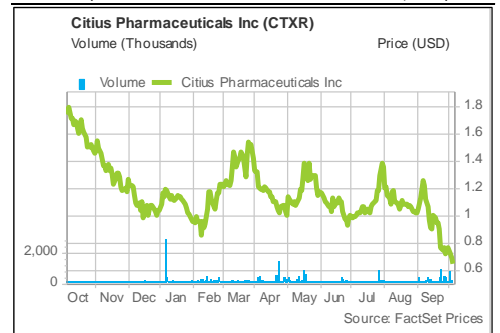


Exhibit 10. FCF Model

\$	7.00
Price Target \$	7.00
Year	2019

DCF Valuation Using FCF (mln):

units ('000 - Cnd\$)	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
EBIT (Earnings before income tax)	(15,912)	(22,772)	42,448	107,454	145,724	185,489	226,794	269,684	314,207	360,410
Tax Rate	0%	0%	5%	10%	15%	20%	25%	30%	35%	38%
EBIT(1-t) Earnings after income tax	(15,912)	(22,772)	40,326	96,709	123,866	148,391	170,095	188,779	204,234	223,454
CapEx (equipment)	-	-	-	-	-	-	-	-	-	-
Depreciation	-	-	-	-	-	-	-	-	-	-
Change in NWC	-	-	-	-	-	-	-	-	-	-
FCF	(15,912)	(22,772)	40,326	96,709	123,866	148,391	170,095	188,779	204,234	223,454
PV of FCF	(15,912)	(17,517)	23,861	44,019	43,369	39,966	35,240	30,085	25,037	21,072
Discount Rate	30%									
Long Term Growth Rate	1%									
Terminal Cash Flow	778,238									
Terminal Value YE2023	73,388									
NPV	302,606									
NPV-Debt	-									
Shares out ('000)	44,077									
NPV Per Share	\$ 6.87									

Source: Dawson James

Exhibit 11. Discounted EPS Model

Current Year	2019
Year of EPS	2028
Earnings Multiple	15
Discount Factor	30%
Selected Year EPS	\$ 5.07
NPV	\$ 7.17

Discount Rate and Earnings Multiple Varies, Year is Constant							
2028 EPS							
Earnings Multiple	7.17	5%	10%	15%	20%	25%	30%
5		\$16.33	\$10.74	\$7.20	\$4.91	\$3.40	\$ 2.39
10		\$32.65	\$21.48	\$14.40	\$9.82	\$6.80	\$ 4.78
15		\$48.98	\$32.23	\$21.60	\$14.73	\$10.20	\$ 7.17
20		\$65.31	\$42.97	\$28.80	\$19.64	\$13.60	\$ 9.55
25		\$81.64	\$53.71	\$36.00	\$24.54	\$17.00	\$ 11.94
30		\$97.96	\$64.45	\$43.20	\$29.45	\$20.40	\$ 14.33
35		\$114.29	\$75.19	\$50.40	\$34.36	\$23.80	\$ 16.72
40		\$130.62	\$85.94	\$57.60	\$39.27	\$27.20	\$ 19.11

Source: Dawson James

Exhibit 12. 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
						\$6.30
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						44
Total						\$6.30

Source: Dawson James

Exhibit 1. Income Statement

		December	March	June	Sept. YE										
2017A	2018A	1Q19A	2Q19A	3Q19A	4Q19E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
					-	-	-	81,642	166,566	212,392	259,994	309,423	360,734	413,983	469,227
		-	-	-	-	-	-	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	81,642	166,566	212,392	259,994	309,423	360,734	413,983	469,227
	-	-	-	-	-	-	-	12,246	24,985	31,859	38,999	46,413	54,110	62,097	70,384
5,873	6,563	2,113	1,700	2,766	2,021	8,600	8,772	8,948	9,127	9,309	9,495	9,685	9,879	10,077	10,278
		15%	15%	15%	15%			15%	15%	15%	15%	15%	15%	15%	15%
12,126	6,447	1,588	1,738	1,456	1,750	6,533	14,000	18,000	25,000	25,500	26,010	26,530	27,061	27,602	28,154
1,973	780	171	204	204	200	779									
19,972	13,789	3,872	3,642	4,427	3,971	15,912	22,772	39,194	59,112	66,668	74,504	82,629	91,050	99,776	108,816
(19,972)	(13,789)	(3,872)	(3,642)	(4,427)	(3,971)	(15,912)	(22,772)	42,448	107,454	145,724	185,489	226,794	269,684	314,207	360,410
47	818	2	14	25											
	450														
	(16)	(4)	(4)	(4)											
(20,769)	1,253	(3,875)	(3,632)	(4,406)	(3,971)	(15,912)	(22,772)	42,448	107,454	145,724	185,489	226,794	269,684	314,207	360,410
-	-	-	-	-	-	-	-	2,122	10,745	21,859	37,098	56,698	80,905	109,972	136,956
0%	0%	0%	0%	0%	0%	0%	0%	5%	10%	15%	20%	25%	30%	35%	38%
(4,952)	(12,537)	(3,875)	(3,632)	(4,406)	(3,971)	(15,883)	(22,772)	40,326	96,709	123,866	148,391	170,095	188,779	204,234	223,454
(3.55)	(1.22)	(0.21)	(0.09)	(0.20)	(0.09)	(0.60)	(0.43)	0.94	2.25	2.86	3.42	3.90	4.31	4.65	5.07
(3.55)	(1.22)	(0.21)	(0.09)	(0.20)	(0.09)	(0.60)	(0.43)	0.94	2.25	2.86	3.42	3.90	4.31	4.65	5.07
5,842	10,731	18,481	28,500	22,000	32,022	25,251	42,118	42,286	42,456	42,626	42,796	42,968	43,140	43,313	43,486
5,842	10,731	18,481	38,666	22,000	42,220	30,342	52,840	42,860	43,032	43,205	43,378	43,551	43,726	43,901	44,077

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.

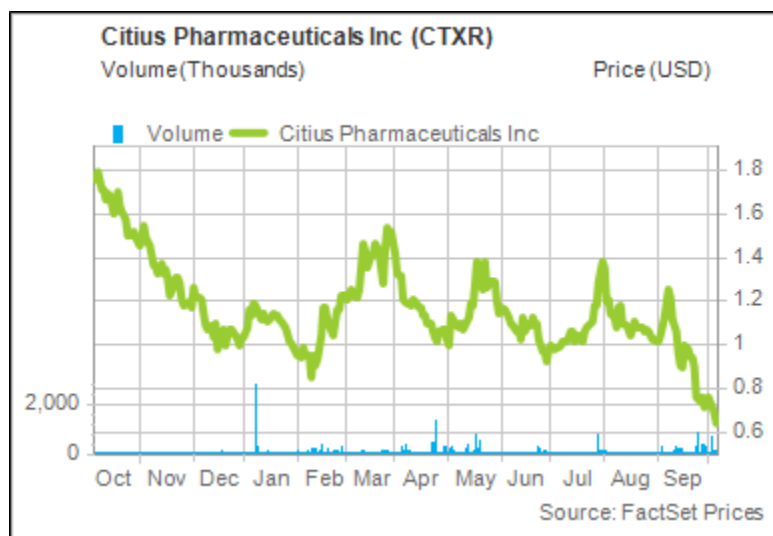
Liquidity Risk. The stock is thinly traded. We note that management owns a significant percentage of the company.

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

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- 1) **Buy:** The analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months;
- 2) **Neutral:** The analyst believes the price of the stock is fairly valued for the next 12-18 months;
- 3) **Sell:** The analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

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Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	27	82%	5	19%
Market Perform (Neutral)	6	18%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	33	100%	5	15%

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