

Citius Pharmaceuticals (NASDAQ/CTXR)

December 19, 2019

BUY: DSMB – Proceed as Planned, Positive for the Trial Design

Back in October, 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 triggered the first interim analysis. We now know those results- “Proceed as Planned”- No Changes to the Trial’s Design.

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Investment Highlights

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 in the first half of 2020. This second interim analysis is looking at efficacy, or in this case, superiority. 69 events, or 75% of the total events anticipated at ~108 patients triggers the read-out.

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.

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.

Current Price \$0.60
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	\$0.40 - \$1.79
Shares Outstanding (mil.)	28.9
Market Capitalization (mil.)	\$17
Enterprise Value (mil.)	-\$2
Debt to Capital	0%
Book Value/Share	\$2.63
Price/Book	0.9
Average Three Months Trading Volume (K)	142
Insider Ownership	46.4%
Institutional Ownership	12.2%
Short interest (mil.)	0.9%
Dividend / Yield	\$0.00/0.0%

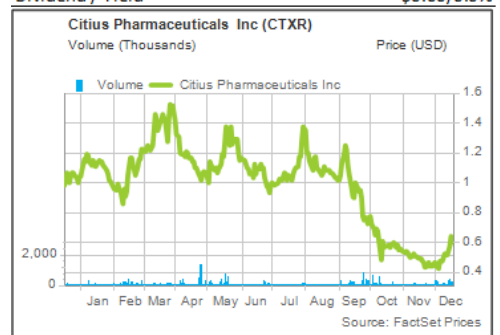


Exhibit 1. FCF Model

	\$ 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)	(15,562)	(22,769)	42,451	107,458	145,728	185,493	226,798	269,688	314,211	360,414
Tax Rate	0%	0%	5%	10%	15%	20%	25%	30%	35%	38%
EBIT(1-t) Earnings after income tax	(15,562)	(22,769)	40,329	96,712	123,869	148,394	170,098	188,782	204,237	223,457
CapEx (equipment)	-	-	-	-	-	-	-	-	-	-
Depreciation	-	-	-	-	-	-	-	-	-	-
Change in NWC	-	-	-	-	-	-	-	-	-	-
FCF	(15,562)	(22,769)	40,329	96,712	123,869	148,394	170,098	188,782	204,237	223,457
PV of FCF	(15,562)	(17,514)	23,863	44,020	43,370	39,967	35,240	30,085	25,037	21,072
Discount Rate	30%									
Long Term Growth Rate	1%									
Terminal Cash Flow	778,247									
Terminal Value YE2023	73,388									
NPV	302,967									
NPV-Debt	-									
Shares out ('000)	42,114 2028E									
NPV Per Share	\$ 7.19									

Source: Dawson James

Exhibit 2. Discounted EPS Model

Current Year	2019
Year of EPS	2028
Earnings Multiple	15
Discount Factor	30%
Selected Year EPS	\$ 5.30
NPV	\$ 7.50

Discount Rate and Earnings Multiple Varies, Year is Constant							
2028 EPS							
Earnings Multiple	7.50	5%	10%	15%	20%	25%	30%
5		\$17.09	\$11.24	\$7.54	\$5.14	\$3.56	\$ 2.50
10		\$34.18	\$22.49	\$15.07	\$10.28	\$7.12	\$ 5.00
15		\$51.27	\$33.73	\$22.61	\$15.41	\$10.67	\$ 7.50
20		\$68.35	\$44.97	\$30.14	\$20.55	\$14.23	\$ 10.00
25		\$85.44	\$56.21	\$37.68	\$25.69	\$17.79	\$ 12.50
30		\$102.53	\$67.46	\$45.21	\$30.83	\$21.35	\$ 15.00
35		\$119.62	\$78.70	\$52.75	\$35.96	\$24.91	\$ 17.50
40		\$136.71	\$89.94	\$60.29	\$41.10	\$28.46	\$ 20.00

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%	\$469	\$1,618
						\$6.59
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						42
Total						\$6.59

Source: Dawson James

Exhibit 4. Income Statement

Citius Pharmaceuticals: Income Statement (\$000)																	
YE Sept.	2017A	2018A	December		March	June	Sept. YE	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
			1Q19A	2Q19A	3Q19A	4Q19A											
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%	15%	15%	15%
Research and development	5,873	6,563	2,113	1,700	2,766	2,018	8,597	8,769	8,944	9,123	9,306	9,492	9,682	9,875	10,073	10,274	10,274
R&D % of Revenue																	
G&A	12,126	6,447	1,588	1,738	1,456	1,503	6,285	14,000	18,000	25,000	25,500	26,010	26,530	27,061	27,602	28,154	28,154
SG&A % of Revenue																	
Stock based comp. G & A	1,973	780	171	204	204	137	716										
Total expenses	19,972	13,789	3,872	3,642	4,427	3,657	15,598	22,769	39,191	59,108	66,664	74,501	82,625	91,046	99,772	108,812	108,812
Oper. Inc. (Loss)	(19,972)	(13,789)	(3,872)	(3,642)	(4,427)	(3,657)	(15,598)	(22,769)	42,451	107,458	145,728	185,493	226,798	269,688	314,211	360,414	360,414
Interest Income	47	818	2	14	25	12	53										
Gain (loss) on revaluation of derivative warrant liability		450															
Interest Expense		(16)	(4)	(4)	(4)	(4)	(16)										
Pre-tax income	(20,769)	1,253	(3,875)	(3,632)	(4,406)	(3,650)	(15,562)	(22,769)	42,451	107,458	145,728	185,493	226,798	269,688	314,211	360,414	360,414
Income Tax Benefit (Provision)	-	-	-	-	-	-	-	-	2,123	10,746	21,859	37,099	56,699	80,906	109,974	136,957	136,957
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	5%	10%	15%	20%	25%	30%	35%	38%	38%
GAAP Net Income (loss)	(4,952)	(12,537)	(3,875)	(3,632)	(4,406)	(3,650)	(15,562)	(22,769)	40,329	96,712	123,869	148,394	170,098	188,782	204,237	223,457	223,457
GAAP-EPS	(3.55)	(1.22)	(0.21)	(0.09)	(0.20)	(0.18)	(0.68)	(0.28)	0.98	2.35	3.00	3.58	4.08	4.52	4.87	5.30	5.30
Non GAAP EPS (dil)	(3.55)	(1.22)	(0.21)	(0.09)	(0.20)	(0.18)	(0.68)	(0.28)	0.98	2.35	3.00	3.58	4.08	4.52	4.87	5.30	5.30
Wgtd Avg Shrs (Bas) - '000s	5,842	10,731	18,481	28,500	22,000	20,162	22,286	40,242	40,404	40,565	40,728	40,891	41,055	41,219	41,384	41,550	41,550
Wgtd Avg Shrs (Dil) - '000s	5,842	10,731	18,481	38,666	22,000	20,162	24,827	81,393	40,952	41,116	41,281	41,446	41,612	41,779	41,946	42,114	42,114

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.

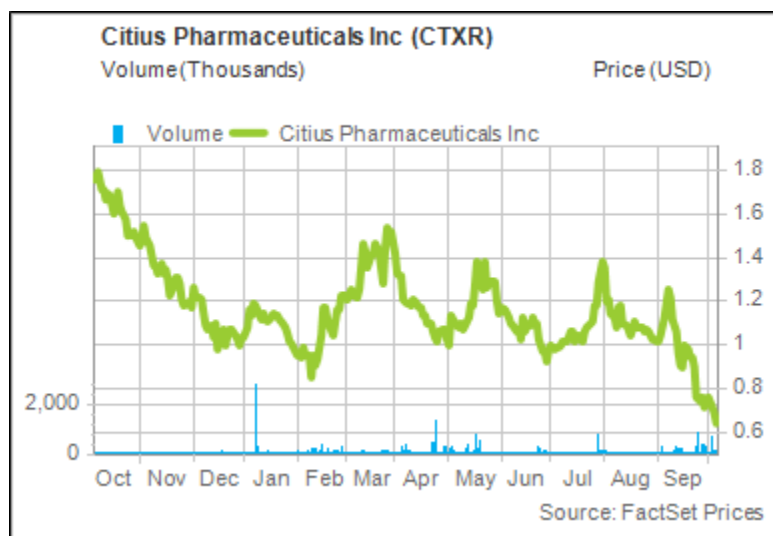
Liquidity Risk. The stock is thinly traded. We note that management owns a significant percentage of the company.

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

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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)	26	90%	3	12%
Market Perform (Neutral)	3	10%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	29	100%	3	10%

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