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## Citius Pharmaceuticals (NASDAQ/CTXR)

February 4, 2020

### BUY: Halfway There – Pivotal Trial Rolls Forward

*Citius announced that the Mino-Lok pivotal trial (Mino-Lok vs. standard-of-care) has randomized its 72<sup>nd</sup> patient, passing the halfway point for enrollment in the pivotal trial.*

### 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. 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.

**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	\$1.10	
Price Target	\$ 7.00	
<b>Estimates</b>		
Expenses (\$000s)	F2019E	F2020E
1Q December	\$ 15,912	\$ 22,772
2Q March	\$ 3,872	\$ 5,238
3Q June	\$ 3,642	\$ 5,553
4Q September	\$ 4,427	\$ 5,605
	\$ 3,971	\$ 6,376
	<b>F2021E</b>	
	\$ 39,194	
EPS	F2019E	F2020E
1Q December	\$ (0.60)	\$ (0.43)
2Q March	\$ (0.21)	\$ (0.10)
3Q June	\$ (0.09)	\$ (0.11)
4Q September	\$ (0.20)	\$ (0.11)
	\$ (0.09)	\$ (0.12)
	<b>F2021E</b>	
	\$ 0.94	
	\$ 0.22	
	\$ 0.23	
	\$ 0.27	
<b>EBITDA/Share</b>		
EV/EBITDA (x)		
<b>Stock Data</b>		
52-Week Range	\$0.40	-
Shares Outstanding (mil.)		28.9
Market Capitalization (mil.)		\$32
Enterprise Value (mil.)		\$12
Debt to Capital		0%
Book Value/Share		\$2.63
Price/Book		0.9
Average Three Months Trading Volume (K)		48
Insider Ownership		47.9%
Institutional Ownership		12.7%
Short interest (mil.)		3.4%
Dividend / Yield		\$0.00/0.0%



**Exhibit 1. FCFF 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

Earnings Multiple	Discount Rate and Earnings Multiple Varies, Year is Constant 2028 EPS					
	7.50	5%	10%	15%	20%	25%
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 MM's	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)		December		March		June		Sept. YE									
YE Sept.		2017A	2018A	1Q19A	2Q19A	3Q19A	4Q19A	2019E	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 & LTCVC Revenues				-	-	-	-	-	-	-	-	-	-	-	-	-	-
Mino-Lok, CHina ST & LT CVC Revenues				-	-	-	-	-	-	81,642	166,566	212,392	259,994	309,423	360,734	413,983	469,227
<b>Expenses</b>																	
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	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
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
SG&A % of Revenue																	
Stock based comp. G & A		1,973	780	171	204	204	137	716									
<b>Total expenses</b>		<b>19,972</b>	<b>13,789</b>	<b>3,872</b>	<b>3,642</b>	<b>4,427</b>	<b>3,657</b>	<b>15,598</b>	<b>22,769</b>	<b>39,191</b>	<b>59,108</b>	<b>66,664</b>	<b>74,501</b>	<b>82,625</b>	<b>91,046</b>	<b>99,772</b>	<b>108,812</b>
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
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)	(4)	(16)									
<b>Pre-tax income</b>		<b>(20,769)</b>	<b>1,253</b>	<b>(3,875)</b>	<b>(3,632)</b>	<b>(4,406)</b>	<b>(3,650)</b>	<b>(15,562)</b>	<b>(22,769)</b>	<b>42,451</b>	<b>107,458</b>	<b>145,728</b>	<b>185,493</b>	<b>226,798</b>	<b>269,688</b>	<b>314,211</b>	<b>360,414</b>
Income Tax Benefit (Provision)		-	-	-	-	-	-	-	-	2,123	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%	10%	15%	20%	25%	30%	35%	38%
<b>GAAP Net Income (loss)</b>		<b>(4,952)</b>	<b>(12,537)</b>	<b>(3,875)</b>	<b>(3,632)</b>	<b>(4,406)</b>	<b>(3,650)</b>	<b>(15,562)</b>	<b>(22,769)</b>	<b>40,329</b>	<b>96,712</b>	<b>123,869</b>	<b>148,394</b>	<b>170,098</b>	<b>188,782</b>	<b>204,237</b>	<b>223,457</b>
<b>GAAP-EPS</b>		<b>(3.55)</b>	<b>(1.22)</b>	<b>(0.21)</b>	<b>(0.09)</b>	<b>(0.20)</b>	<b>(0.18)</b>	<b>(0.68)</b>	<b>(0.28)</b>	<b>0.98</b>	<b>2.35</b>	<b>3.00</b>	<b>3.58</b>	<b>4.08</b>	<b>4.52</b>	<b>4.87</b>	<b>5.30</b>
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
Wtd 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
Wtd 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

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.

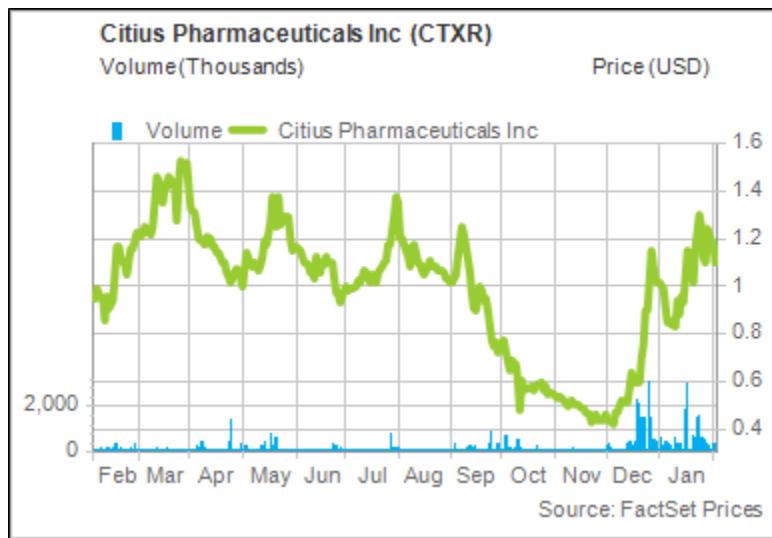
**Commercial risk.** There are no assurances that the company will be able to achieve significant market share and become profitable.

**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

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	<b># of Companies</b>	<b>% of Total</b>	<b># of Companies</b>	<b>% of Totals</b>
Market Outperform (Buy)	23	88%	3	13%
Market Perform (Neutral)	3	12%	1	33%
Market Underperform (Sell)	0	0%	0	0%
<b>Total</b>	<b>26</b>	<b>100%</b>	<b>4</b>	<b>15%</b>

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