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Citius Pharmaceuticals (NASDAQ/CTXR)

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BUY: Cash Reduces Risk – Take Manufacturing, for Example

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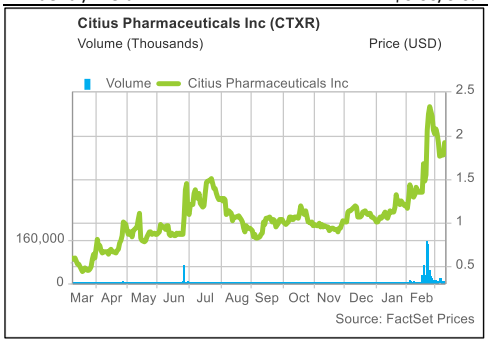
Citius now has almost $100M in cash; we spoke with management on plans to use that cash to reduce risk (i.e., to ensure there are no hiccups in areas such as manufacturing, which has just delayed competitor CorMedix (CRMD – Not Rated). We concluded our discussion with a sense of comfort that this management team is highly focused on the launch and commercialization for Mino-Lok.

Current Price	**$1.92**
Price Target	**$ 8.00**

Estimates	F2020A	F2021E	F2022E
Expenses ($000s)	$ 17,462	$ 35,041	$ 36,661
1Q December	$ 4,448	$ 8,156	$ 8,915
2Q March	$ 4,433	$ 8,591	$ 9,040
3Q June	$ 4,689	$ 8,691	$ 9,165
4Q September	$ 3,892	$ 9,603	$ 9,540
	F2020A	F2021E	F2022E
EPS	$ (0.46)	$ (0.34)	$ 0.31
1Q December	$ (0.15)	$ (0.15)	$ 0.07
2Q March	$ (0.13)	$ (0.06)	$ 0.07
3Q June	$ (0.11)	$ (0.06)	$ 0.08
4Q September	$ (0.08)	$ (0.07)	$ 0.09
EBITDA/Share			
EV/EBITDA (x)			

Stock Data	
52-Week Range	$0.42 - $2.90
Shares Outstanding (mil.)	125.8
Market Capitalization (mil.)	$242
Enterprise Value (mil.)	$222
Debt to Capital	0%
Book Value/Share	$2.63
Price/Book	1.7
Average Three Months Trading Volume (K)	3,061
Insider Ownership	16.4%
Institutional Ownership	10.9%
Short interest (mil.)	8.0%
Dividend / Yield	$0.00/0.0%



Investment Highlights

Management is Focused and Understands. Now is the time to spend money on resources, FDA consultants and the like to ensure that all elements of the rolling NDA are up to par, from the culmination of component studies to CMC details, record keeping and, of course, a focus on the potential for the pivotal trial to be stopped early for efficacy.

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 Harmonization 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 catheters that are associated with some serious adverse events.

Could the DMC halt the study early for Efficacy? We think so. 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.

Valuation. Our valuation is based on our therapeutic models and associated assumptions projected to 2028. The lead product, Mini-Lok, is now in a Phase 3 trial. We conservatively assume just 50% probability of success in our therapeutic model. 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 $8.00 price target.

Exhibit 1. FCFF Model

	Average	$ 8.00

Price Target	$	8.00
Year		2022

DCF Valuation Using FCF (mln):

units ('000 - Cnd$)	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
EBIT (Earnings before income tax)	(15,560)	(17,299)	(35,041)	46,622	119,775	159,017	199,788	242,135	286,103	371,624
Tax Rate	0%	0%	5%	10%	15%	20%	25%	30%	35%	38%
EBIT(1-t) Earnings afer income tax	(15,560)	(17,299)	(33,289)	41,959	101,808	127,214	149,841	169,494	185,967	230,407
CapEx (equipment)	-	(2)	1	-	-	-				
Depreciation	-	529	-	-	-	-				
Change in NWC										
FCF	(15,560)	(16,772)	(33,289)	41,959	101,808	127,214	149,841	169,494	185,967	230,407
PV of FCF	(23,664)	(22,181)	(38,282)	41,959	88,529	96,192	98,523	96,909	92,458	99,611
Discount Rate	15%									
Long Term Growth Rate	1%									
Terminal Cash Flow	1,662,223									
Terminal Value YE2023	718,625									
NPV	1,248,679									
NPV-Debt	-									
Shares out ('000)	163,966	2028E								
NPV Per Share	$ 7.62									

Source: Dawson James estimates

Exhibit 2. Discounted EPS Model

Current Year		2022
Year of EPS		2028
Earnings Multiple		15
Discount Factor		15%
Selected Year EPS	$	1.40
NPV	$	9.11

	Discount Rate and Earnings Multiple Varies, Year is Constant 2028 EPS						
Earnings Multiple	9.11	5%	10%	15%	20%	25%	30%
5		$5.24	$3.96	$3.04	$2.35	$1.84	$ 1.45
10		$10.48	$7.93	$6.07	$4.70	$3.68	$ 2.91
15		$15.72	$11.89	$9.11	$7.05	$5.52	$ 4.36
20		$20.96	$15.85	$12.14	$9.41	$7.36	$ 5.82
25		$26.20	$19.82	$15.18	$11.76	$9.20	$ 7.27
30		$31.43	$23.78	$18.21	$14.11	$11.04	$ 8.73
35		$36.67	$27.74	$21.25	$16.46	$12.88	$ 10.18
40		$41.91	$31.71	$24.28	$18.81	$14.72	$ 11.64

Source: Dawson James estimates

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%	15%	2	70%	$469	$3,352
						$7.57
MiniLok LT & ST CVC E.U.	1%	30%	4	80%	$0	$0
						$0.00
MiniLok LT & ST CVC China	1%	30%	4	80%	$0	$0
						$0.00
Hydro-Lido	1%	30%	5	0%	$0	$0
Pre-Clinical Pipeline						$0.00
Net Margin						70%
MM Shrs OS						164
Total						$7.57

Source: Dawson James estimates

Exhibit 4. Income Statement

Citius Pharmaceuticals: Income Statement ($000)					December	March	June	Sept. YE											
YE Sept.	2017A	2018A	2019A	2020A	1Q21A	2Q21E	3Q21E	4Q21E	2021E	1Q22E	2Q22E	3Q22E	4Q22E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Mino-Lok, U.S. ST & LT CVC Revenues			-	-						19,155	19,988	20,821	23,319	83,283	169,914	216,661	265,220	315,642	367,985	469,227
Mino-Lok, E.U. ST & LT CVC Revenues			-	-	-	-	-	-	-	-	-	-	-	-	-					
Mino-Lok, CHina ST & LT CVC Revenues																				
			-	-	-	-	-	-	-	19,155	19,988	20,821	23,319	83,283	169,914	216,661	265,220	315,642	367,985	469,227
Expenses																				
Cost of goods sold		-	-	-	-	-	-	-	-	2,873	2,998	3,123	3,498	12,492	25,487	32,499	39,783	47,346	55,198	70,384
COGS % of Revenue					15%	15%	15%	15%	#DIV/0!	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
Research and development	5,873	6,563	8,596	8,813	6,191	6,191	6,191	6,191	8,989	2,292	2,292	2,292	2,292	9,169	9,352	9,539	9,730	9,925	10,123	10,326
R&D % of Revenue																				
G&A	12,126	6,447	6,285	8,095	1,689	2,400	2,500	3,411	10,000	3,750	3,750	3,750	3,750	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	803	277															
Total expenses	**19,972**	**13,789**	**15,596**	**17,462**	**8,156**	**8,591**	**8,691**	**9,603**	**35,041**	**8,915**	**9,040**	**9,165**	**9,540**	**36,661**	**50,139**	**57,644**	**65,431**	**73,507**	**81,882**	**97,602**
Oper. Inc. (Loss)	(19,972)	(13,789)	(15,596)	(17,462)	(8,156)	(8,591)	(8,691)	(9,603)	(35,041)	10,240	10,948	11,655	13,779	46,622	119,775	159,017	199,788	242,135	286,103	371,624
Interest Income	47	818	53	68	13															
Gain (loss) on revaluation of derivative warrant liability		450		110	(4)															
Interest Expense		(16)	(16)	(16)																
Pre-tax income	**(20,769)**	**1,253**	**(15,560)**	**(17,299)**	**(8,147)**	**(8,591)**	**(8,691)**	**(9,603)**	**(35,041)**	**10,240**	**10,948**	**11,655**	**13,779**	**46,622**	**119,775**	**159,017**	**199,788**	**242,135**	**286,103**	**371,624**
Income Tax Benefit (Provision)	-	-	-	-	-	(430)	(435)	(480)	(1,344)	1,024	1,095	1,166	1,378	4,662	17,966	31,803	49,947	72,640	100,136	141,217
Tax Rate	0%	0%	0%	0%	5%	5%	5%	5%	5%	10%	10%	10%	10%	10%	15%	20%	25%	30%	35%	38%
GAAP Net Income (loss)	**(4,952)**	**(12,537)**	**(15,560)**	**(17,299)**	**(8,147)**	**(8,162)**	**(8,257)**	**(9,122)**	**(33,688)**	**9,216**	**9,853**	**10,490**	**12,401**	**41,959**	**101,808**	**127,214**	**149,841**	**169,494**	**185,967**	**230,407**
GAAP-EPS	**(3.55)**	**(1.22)**	**(0.53)**	**(0.46)**	**(0.15)**	**(0.06)**	**(0.06)**	**(0.07)**	**(0.34)**	**0.07**	**0.07**	**0.08**	**0.09**	**0.31**	**0.72**	**0.87**	**1.00**	**1.10**	**1.17**	**1.40**
Non GAAP EPS (dil)	(3.55)	(1.22)	(0.61)	(0.46)	(0.15)	(0.06)	(0.06)	(0.07)	(0.34)	0.07	0.07	0.08	0.09	0.31	0.72	0.87	1.00	1.10	1.17	1.40
Wgtd Avg Shrs (Bas) - '000s	5,842	10,731	20,162	39,165	55,577	106,463	106,570	106,676	93,821	106,783	106,890	106,997	107,104	106,943	107,372	107,802	108,234	108,667	109,102	109,539
Wgtd Avg Shrs (Dil) - '000s	5,842	10,731	35,000	39,165	55,577	132,379	133,702	135,039	114,174	135,039	136,390	137,754	139,131	137,079	141,232	145,512	149,921	154,464	159,144	163,966

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:

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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
Update – Buy – 1/26/2021 – Price Target $6.00
Price Target Change – Buy – 2/18/2021 – Price Target $8.00
Update – Buy – 3/10/2021 – Price Target $8.00

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Total	29	100%	6	21%

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