

INSTITUTIONAL RESEARCH Specialty Pharma UPDATE REPORT

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Citius Pharmaceuticals (NASDAQ/CTXR)

BUY: Reports 2023 Results: \$37M Spent, \$25M in Cash

Citius in a 10k filing reported 4th Quarter results. The company spent \$36.7M in operating expenses last year and closed the year with \$26.5M in cash and cash equivalents. Our focus at the company is on Mino-Lok, which appears to have achieved the critical number of events for trial completion.

Investment Highlights

Mino-Lok Trial: The Mino-Lok Phase 3 pivotal superiority trial is a multicenter, randomized, open-label, blinded study to determine the efficacy and safety of Mino-Lok. The primary endpoint for this study is the time (in days following randomization) to a catheter failure event between randomization and TOC (Week 6) in the Intent-to-Treat (ITT) Population. Additional secondary outcome measures include overall success, microbiological eradication, and clinical cure, among others. Patients diagnosed with catheter-related bloodstream infections (CRBSI/CLABSI) and who meet all necessary criteria for the study are randomized in a 1:1 ratio to receive either Mino-Lok therapy or standard-of-care antibiotic lock therapy. Patients in the Mino-Lok arm receive one dose daily with a dwell time of two to four hours for a total of seven doses. For subjects in the Control arm, the investigator determines the antibiotic used in the lock, dose, dwell time, and number of days of administration based on institutional standards or Infectious Diseases Society of America (IDSA) guidelines.

What is Mino-Lok? (from Citius website): Mino-Lok is an antibiotic lock solution used to treat patients with catheter-related bloodstream infections (CRBSIs) and central line-associated bloodstream infections (CLABSIs). CRBSIs/CLABSIs are life-threatening conditions, especially in cancer patients receiving therapy through central venous catheters (CVCs) and in hemodialysis patients where venous access presents a challenge. Mino-Lok is intended to salvage the CVC, avoiding the need to remove and replace the infected catheter. Currently, there are few alternatives to removing and replacing a CVC once it becomes infected. Studies show that removal and reinsertion of CVCs have a 15% to 20% complication rate, including pneumothorax, misplacement, and arterial puncture. Mino-Lok is being developed to address the complications, discomfort and cost of CVC removal and replacement. There are currently no FDA-approved products to salvage infected CVCs.

Valuation. We 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 on top of a 15% risk rate in our therapeutic models for both products. We equal weight and average these metrics and then round to the nearest whole number to derive our \$8.00 price target.

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

January 2, 2024

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Exhibit 1. Income Statement

Citius Pharmaceuticals: Income Statement ('000)						December	March	June	Sept. YE										
YE Sept.	2019A	2020A	2021A	2022A	2023A	1Q24E	2Q24E	3Q24E	4Q24E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E
Mino-Lok, U.S. ST & LT CVC Revenues	-	-		-		24,204	25,257	26,309	29,466	105,236	214,702	328,526	446,839	569,775	581,228	592,910	604,828	616,985	629,386
CTCL Revenues	-	-		-		18,386	19,185	19,984	22,382	79,937	114,162	133,093	135,768	138,497	141,281	144,121	147,018	149,973	152,987
	-	-	-	-	-	42,590	44,442	46,293	51,848	185,173	328,863	461,619	582,607	708,272	722,509	737,031	751,845	766,957	782,373
Expenses			-		-														
Cost of goods sold	-	-	-	-	-	6,388	6,666	6,944	7,777	27,776	49,330	69,243	87,391	106,241	108,376	110,555	112,777	115,044	117,356
COGS % of Revenue						15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
Research and development	8,596	8,813	12,241	17,655	14,819	3,628	3,779	3,779	3,930	15,115	15,418	15,726	16,041	16,361	16,689	17,022	17,363	17,710	18,064
R&D % of Revenue																			
G&A SG&A % of Revenue	6,285	8,095	9,836	11,755	15,295	4,320	4,500	4,320	4,860	18,000	18,000	18,000	18,000	18,000	18,000	18,000	18,000	18,000	18,000
Stock based comp. G & A	715	803	1,455	3,906	6,617	6,617	6,617	6,617	6,617	6,617	6,617	6,617	6,617	6,617	6,617	6,617	6,617	6,617	6,617
Total expenses	27,540	17,711	23,532	33,317	36,731	20,953	21,562	21,660	23,184	67,508	89,364	109,586	128,048	147,219	149,682	152,194	154,756	157,370	160,037
Oper. Inc. (Loss)	(27,540)	(17,711)	(23,532)	(33,317)	(36,731)	21,637	22,880	24,634	28,664	117,665	239,500	352,033	454,559	561,053	572,827	584,837	597,089	609,587	622,336
Interest Income	53	68	262	251	1,179	1,179	1,179	1.179	1,179	1,179	1,179	1,179	1.179	1,179	1,179	1,179	1,179	1.179	1,179
Gain (loss) on revaluation of derivative warrant liability		110	216	_	3,586	3,586	3,586	3,586	3,586	3,586	3,586	3,586	3,586	3,586	3,586	3,586	3,586	3,586	3,586
Interest Expense	(16)	(16)	-																
Pre-tax income	(27,503)	(17,548)	(23,055)	(33,641)	(31,966)	26,402	27,644	29,398	33,429	122,430	244,264	356,798	459,323	565,818	577,592	589,602	601,854	614,352	627,101
Pretax Margin																			
Income Tax Benefit (Provision- Warrant)	-	-	1,451	-	-													-	
Income Tax Expense			-		576	2,640	2,764	2,940	3,343	11,687	35,806	70,248	113,442	168,079	171,611	175,214	178,889	182,639	186,463
TaxRate	0%	0%	5%		0%	10%	10%	10%	10%	10%	15%	20%	25%	30%	30%	30%	30%	30%	30%
GAAP Net Income (loss)	(27,474)	(30,976)	(42,834)	(33,641)	(33,694)	23,761	46,464	26,459	30,086	110,742	208,458	286,550	345,881	397,739	405,981	414,388	422,964	431,713	440,638
GAAP-EPS	(1.39)	(0.84)	(0.46)	(0.23)	(0.21)	0.13	0.26	0.15	0.17	0.71	1.09	1.37	1.56 1.56	1.71	1.69 1.69	1.67	1.65	1.63 1.63	1.61
Non GAAP EPS (dil) Wgtd Avg Shrs (Bas) - '000s	(1.39) 20,162	(0.84) 36,071	(0.23) 108,599	(0.23) 146,066	(0.20) 151,294	0.13 158.458	0.26 158,617	0.15 158,775	0.17 158,934	0.71 158,696	1.09 159,332	1.37 159.970	1.56 160.611	1.71 161.254	1.69	1.67 162,549	1.65 163,200	1.63 163,854	1.61 164,510
Watd Avg Shrs (Dil) - '000s	20,162	36,071	108,599	146,066	167.357	176,144	177,905	179.684	181,481	178,804	184.222	189,970	195,555	201.481	207.586	213.876	220.356	227.033	233,913

Source: Dawson James estimates, 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.

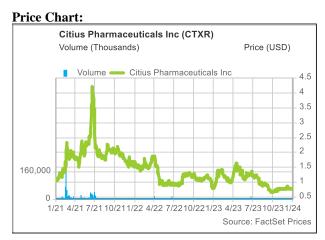
Financial risk. The Company may need to raise capital in the marketplace, and there can be no assurances that the Company will be able to successfully raise capital and or do so at favorable terms.

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 target and rating changes over the past three years:

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
Update – Buy – 5/21/2021 – Price Target \$8.00
Update – Buy – 6/9/2021 – Price Target \$8.00
Update – Buy – 7/1/2021 – Price Target \$8.00
Price Target Change – Buy – 9/9/2021 – Price Target \$10.00
Update – Buy – 12/6/2021 – Price Target \$10.00
Update – Buy – 2/11/2022 – Price Target \$10.00



Update – Buy – 2/15/2022 – Price Target \$10.00
Update – Buy – 4/6/2022 – Price Target \$10.00
Update – Buy – 4/18/2022 – Price Target \$10.00
Update – Buy – 4/26/2022 – Price Target \$10.00
Update – Buy – 5/5/2022 – Price Target \$10.00
Update – Buy – 5/13/2022 – Price Target \$10.00
Update – Buy – 5/25/2022 – Price Target \$10.00
Update – Buy – 7/12/2022 – Price Target \$10.00
Update – Buy – 8/15/2022 – Price Target \$10.00
Update – Buy – 9/28/2022 – Price Target \$10.00
Update – Buy – 12/6/2022 – Price Target \$10.00
Update – Buy – 12/23/2022 – Price Target \$10.00
Update – Buy – 2/14/2023 – Price Target \$10.00
Update – Buy – 3/31/2023 – Price Target \$10.00
Update – Buy – 4/25/2023 – Price Target \$10.00
Update – Buy – 5/4/2023 – Price Target Change \$10.00 to \$8.00
Update – Buy – 5/18/2023 – Price Target \$8.00
Update – Buy – 6/21/2023 – Price Target \$8.00
Update – Buy – 7/31/2023 – Price Target \$8.00
Update – Buy – 8/15/2023 – Price Target \$8.00
Update – Buy – 9/11/2023 – Price Target \$8.00
Update – Buy – 10/24/2023 – Price Target \$8.00
Update – Buy – 11/2/2023 – Price Target \$8.00
Update – Buy – 1/2/2024 – Price Target \$8.00

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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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Current as of	14-Dec-23			
	Company		Investment	
	Coverage		Banking	
				% of
Ratings Distribution	# of Companies	% of Total	# of Companies	Totals
Market Outperform (Buy)	21	61.76%	4	11.80%
Market Perform (Neutral)	13	38.24%	2	5.90%
Market Underperform (Sell)	0	0%	0	0.00%
Total	34	100%	6	17.70%

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