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Citius Pharmaceuticals (NASDAQ/CTXR)

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BUY: 92 Event Threshold Likely Achieved in Mino-Lok Trial

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Citius reported 3rd Quarter (period ending June 30th) results. The company reported a loss of \$8.5M. Citius closed the period with \$33M in cash and equivalents, reflecting a \$15M capital raise in May. Our focus at the company is on both Mino-Lok, which appears to have achieved the critical number of events for trial completion, and the resubmission of LYMPHIR.

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.

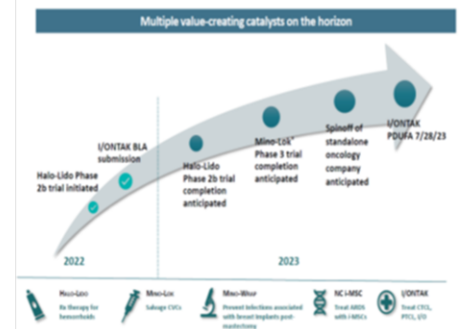
What's the Issue with LYMPHIR? The FDA has requested some additional product testing and CMC product controls. The issues do not require re-tooling and as such likely represent a type I (2-month delay). As stated in the company's press release – "there were no concerns relating to the safety and efficacy clinical data package submitted with the BLA, or the proposed prescribing information".

Background: (press release); In 2011 and 2013, the FDA granted orphan drug designation to LYMPHIR for the treatment of PTCL and CTCL, respectively. In 2021, denileukin diftitox received regulatory approval in Japan for the treatment of CTCL and peripheral T-cell lymphoma (PTCL). Subsequently in 2021, Citius acquired an exclusive license with rights to develop and commercialize LYMPHIR in all markets except for Japan and certain parts of Asia.

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.

Current Price	\$0.92
Price Target	\$8.00



Stock Data			
52-Week Range	\$0.77	-	\$1.71
Shares Outstanding (mil.)	158.9		
Market Capitalization (mil.)	\$147		
Enterprise Value (mil.)	\$127		
Debt to Capital	0%		
Book Value/Share	\$2.63		
Price/Book	1.7		
Average Three Months Trading Volume (K)	3,103		
Insider Ownership	7.5%		
Institutional Ownership	15.2%		
Short interest (mil.)	13.1%		
Dividend / Yield	\$0.00/0.0%		

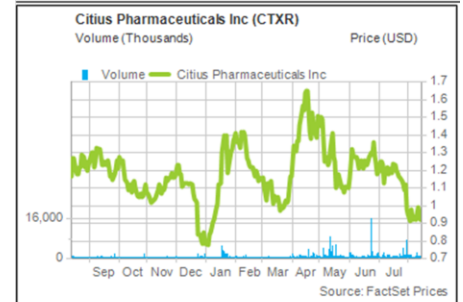


Exhibit 1. Income Statement

Citius Pharmaceuticals: Income Statement ('000)																				
YE Sept.	2019A	2020A	2021A	2022A	December 1Q23A	March 2Q23A	June 3Q23A	Sept. YE 4Q23E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	
Mino-Lok, U.S. ST & LT CVC Revenues	-	-	-	-	-	-	-	-	-	105,236	214,702	328,526	446,839	569,775	581,228	592,910	604,828	616,985	629,386	
CTCL Revenues	-	-	-	-	-	-	-	-	-	79,937	114,162	133,093	135,768	138,497	141,281	144,121	147,018	149,973	152,987	
	-	-	-	-	-	-	-	-	-	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	-	-	-	-	-	-	-	-	-	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	3,446	4,727	3,765	2,063	14,000	14,280	14,566	14,857	15,154	15,457	15,766	16,082	16,403	16,731	17,066	
R&D % of Revenue																				
G&A	6,285	8,095	9,836	11,755	2,603	4,793	3,733	860	11,990	18,000	18,000	18,000	18,000	18,000	18,000	18,000	18,000	18,000	18,000	
SG&A % of Revenue																				
Stock based comp. G & A	715	803	1,455	3,906	1,201	1,166	1,174	1,174	1,174	1,174	1,174	1,174	1,174	1,174	1,174	1,174	1,174	1,174	1,174	
Total expenses	27,540	17,711	23,532	33,317	7,250	10,685	8,672	4,097	27,164	61,230	83,069	103,274	121,719	140,872	143,317	145,810	148,354	150,949	153,596	
Oper. Inc. (Loss)	(27,540)	(17,711)	(23,532)	(33,317)	(7,250)	(10,685)	(8,672)	(4,097)	(27,164)	123,943	245,794	358,345	460,888	567,400	579,192	591,221	603,491	616,008	628,777	
Interest Income	53	68	262	251	215	303	337	337	337	337	337	337	337	337	337	337	337	337	337	
Gain (loss) on revaluation of derivative warrant liability		110	216		3,586															
Interest Expense	(16)	(16)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Pre-tax income	(27,503)	(17,548)	(23,055)	(33,641)	(3,450)	(10,382)	(8,335)	(3,761)	(26,827)	124,280	246,131	358,682	461,225	567,737	579,529	591,557	603,828	616,345	629,114	
Pretax Margin																				
Income Tax Benefit (Provision- Warrant)	-	-	1,451	-																
Income Tax Expense					144	144	144			12,177	36,543	71,234	114,678	169,568	173,105	176,714	180,395	184,150	187,981	
Tax Rate	0%	0%	5%		0%	0%	0%	0%	0%	10%	15%	20%	25%	30%	30%	30%	30%	30%	30%	
GAAP Net Income (loss)	(27,474)	(30,976)	(42,834)	(33,641)	(3,594)	(10,526)	(8,479)	(3,761)	(26,827)	112,103	209,588	287,448	346,546	398,170	406,424	414,844	423,433	432,195	441,133	
GAAP-EPS	(1.39)	(0.84)	(0.46)	(0.23)	(0.02)	(0.07)	(0.05)	(0.02)	(0.16)	0.73	1.11	1.39	1.57	1.72	1.70	1.68	1.66	1.64	1.62	
Non GAAP EPS (dil)	(1.39)	(0.84)	(0.23)	(0.23)	(0.02)	(0.06)	(0.05)	(0.02)	(0.16)	0.73	1.11	1.39	1.57	1.72	1.70	1.68	1.66	1.64	1.62	
Wgtd Avg Shrs (Bas) - '000s	20,162	36,071	108,599	146,066	146,211	146,252	153,775	153,929	150,042	154,314	154,933	155,553	156,176	156,802	157,430	158,061	158,694	159,330	159,968	
Wgtd Avg Shrs (Dil) - '000s				146,067	146,211	172,673	174,400	176,144	167,357	178,804	184,222	189,804	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.

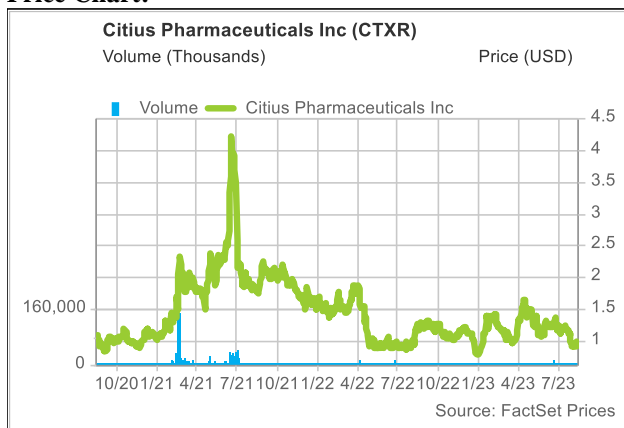
Liquidity Risk. The stock is thinly traded. We note that management owns a significant percentage of the Company.

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 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
- 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

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- 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 3-Aug-23

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	24	69%	3	8.60%
Market Perform (Neutral)	10	31%	3	8.60%
Market Underperform (Sell)	0	0%	0	0.00%
Total	35	100%	6	17.2%

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