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Citius Pharmaceuticals (NASDAQ/CTXR)

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BUY: Mino-Lok P3 – Reaches 85 of 92 Events

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The Mino-Lok trial is approaching the finish line. The trial has now reached 85 of the required 92 events. The trial has enrolled 190 patients, of which 16 patients are in active treatment or pending study completion data review, which may result in additional events. The multi-center Mino-Lok Phase 3 trial continues to recruit patients at 35 clinical trial sites in the U.S. and India.

Investment Highlights

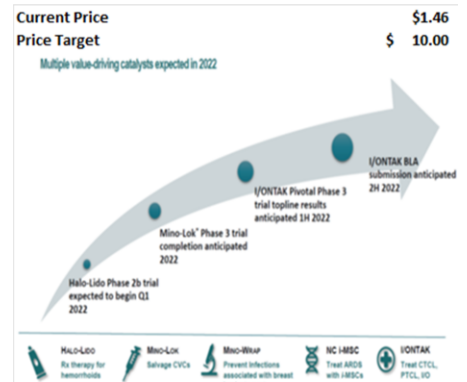
Mino-Lok is approaching the finish line: Management has now updated us on the number of catheter failure events; 85 of a target 92 events have been reached. We believe the decision to include sites in India is making the difference.

About the Trial: The Mino-Lok Phase 3 pivotal superiority trial is a multi-center, 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 blood stream 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.

ONTAK BLA Under Review. The U.S. Food and Drug Administration (FDA) is currently reviewing a biologics license application (BLA) for I/ONTAK and has set a targeted decision date (PDUFA) of July 28, 2023. **As we have stated in the past,** management is now planning to spin-out IONTAK into a new company and raise capital to support the product's commercialization. Recall that Citius paid \$40M upfront and has an obligation for \$40M in milestones, and we assume a 10% royalty. Given the opportunity, combined with what we view as a low-risk therapeutic, we believe management can realize a significant return on its investment.

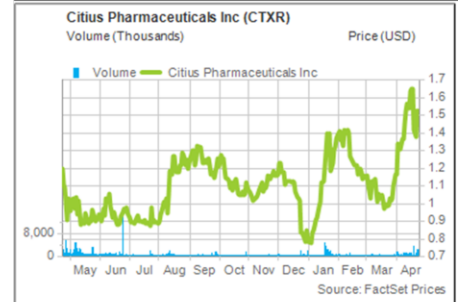
Valuation. Our valuation is based on our therapeutic models and associated assumptions projected to 2028. The lead product, Mini-Lok, is now in a Phase 3 trial, as is E7777. We use a 30% risk rate in our free cash flow to the Firm (FCFF), our discounted EPS (dEPS), and sum-of-the-parts (SOP) models on 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 \$10.00 price target.

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



Source: Citius

Stock Data			
52-Week Range	\$0.77	-	\$1.71
Shares Outstanding (mil.)	146.3		
Market Capitalization (mil.)	\$214		
Enterprise Value (mil.)	\$194		
Debt to Capital	0%		
Book Value/Share	\$2.63		
Price/Book	1.7		
Average Three Months Trading Volume (K)	2,067		
Insider Ownership	8.4%		
Institutional Ownership	9.7%		
Short Interest (mil.)	8.2%		
Dividend / Yield	\$0.00/0.0%		



Source: FactSet Prices

Exhibit 1. Income Statement

Citius Pharmaceuticals: Income Statement (\$'000)							December	March	June	Sept. YE						
YE Sept.	2017A	2018A	2019A	2020A	2021A	2022A	1Q23A	2Q23E	3Q23E	4Q23E	2023E	2024E	2025E	2026E	2027E	2028E
Mino-Lok, U.S. ST & LT CVC Revenues			-	-	-	-	-	-	-	-		210,471	322,052	438,034	558,548	569,775
CTCL Revenues			-	-	-	-	-	-	-	-		79,937	114,162	133,093	135,768	138,497
			-	-	-	-	-	-	-	-		290,409	436,214	571,127	694,317	708,272
Expenses																
Cost of goods sold			-	-	-	-	-	-	-	-		43,561	65,432	85,669	104,147	106,241
COGS % of Revenue							15%	15%	15%	15%		15%	15%	15%	15%	15%
Research and development	5,873	6,563	8,596	8,813	12,241	17,655	3,446	3,446	3,446	3,446	14,000	14,280	14,566	14,857	15,154	15,457
R&D % of Revenue																
G&A	12,126	6,447	6,285	8,095	9,836	11,755	2,603	2,603	2,603	2,603	11,990	18,000	20,000	20,400	20,808	21,224
SG&A % of Revenue																
Stock based comp. G & A	1,973	780	715	803	1,455	3,906	1,201									
Total expenses	19,972	13,789	15,596	17,462	23,532	33,317	7,250	6,049	6,049	6,049	25,990	75,841	99,998	120,926	140,110	142,922
Oper. Inc. (Loss)	(19,972)	(13,789)	(15,596)	(17,462)	(23,532)	(33,317)	(7,250)	(6,049)	(6,049)	(6,049)	(25,990)	214,567	336,216	450,201	554,207	565,350
Interest Income	47	818	53	68	262	251	215									
Gain (loss) on revaluation of derivative warrant liability		450		110	216		3,586									
Interest Expense		(16)	(16)	(16)												
Pre-tax income	(20,769)	1,253	(15,560)	(17,299)	(23,055)	(33,641)	(3,450)	(6,049)	(6,049)	(6,049)	(25,990)	214,567	336,216	450,201	554,207	565,350
Income Tax Benefit (Provision- Warrant)	-	-	-	-	1,451	-	(144)	(907)	(907)	(907)	(2,866)	42,913	84,054	135,060	193,972	214,833
Tax Rate	0%	0%	0%	0%	5%		15%	15%	15%	15%	15%	20%	25%	30%	35%	38%
GAAP Net Income (loss)	(4,952)	(12,537)	(15,560)	(17,299)	(24,505)	(33,641)	(3,594)	(5,141)	(5,141)	(5,141)	(19,018)	171,654	252,162	315,141	360,235	350,517
GAAP-EPS	(3.55)	(1.22)	(0.53)	(0.46)	(0.25)	(0.23)	(0.02)	(0.03)	(0.03)	(0.03)	(0.11)	0.96	1.36	1.65	1.83	1.73
Non GAAP EPS (dil)	(3.55)	(1.22)	(0.61)	(0.46)	(0.23)	(0.20)	(0.02)	(0.03)	(0.03)	(0.03)	(0.11)	0.96	1.36	1.65	1.83	1.73
Wgtd Avg Shrs (Bas) - '000s	5,842	10,731	20,162	39,165	108,599	146,082	146,211	146,357	146,504	146,650	146,431	147,017	147,606	148,197	148,791	149,387
Wgtd Avg Shrs (Dil) - '000s	5,842	10,731	35,000	39,165	129,901	169,166	171,700	173,417	175,151	176,902	174,292	179,574	185,015	190,621	196,397	202,348

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.

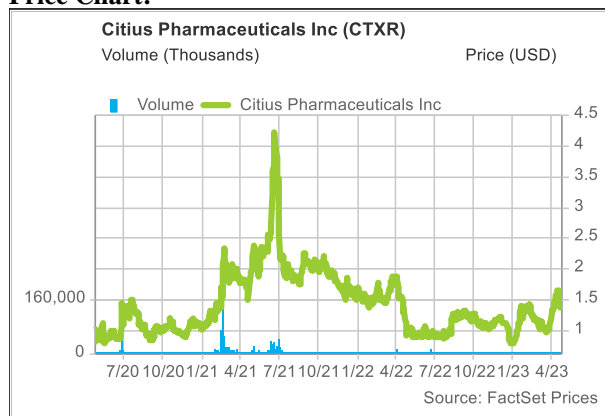
Liquidity Risk. The stock is thinly traded. We note that management owns a significant percentage of the Company.

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

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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.

The following chart reflects the range of current research report ratings for all companies followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

Current as of 17-Apr-23

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	25	69%	1	3%
Market Perform (Neutral)	11	31%	2	6%
Market Underperform (Sell)	0	0%	0	0%
Total	36	100%	3	9%

Analyst Certification:

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