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Citius Pharmaceuticals (NASDAQ/CTXR)

February 15, 2022

BUY: Halo-Lido Advances to a Phase 2b Trial

Citius advances Halo-Lido to a Phase 2b trial. We see this as a logical and pragmatic move as the company sports a cash balance of \$65M and as such, alleviated constraints that were holding this product back from advancing. 2022 holds great promise as I/ONTAK top line data arrives in 2H22 and the Mino-Lok pivotal trial completes, also in 2H22.

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Investment Highlights

The Phase 2b Study: The study is designed as a multi-center, randomized, dose-ranging, double-blind, parallel group comparison. Five cohorts of adults with a clinical diagnosis of symptomatic Goligher's classification Grade II or Grade III hemorrhoids will be dosed. Approximately 60 subjects per cohort are expected to be enrolled, for a total of 300 subjects. The primary endpoint of the study will be the reduction in hemorrhoidal symptoms (including: pain, burning, itching, and swelling) following treatment. The secondary endpoint will be the reduction in hemorrhoidal bother (such as bowel movement interference and pressure) following treatment.

What is Halo-Lido? It is a proprietary topical formulation of halobetasol (a potent corticosteroid) and lidocaine (pain blocker) that is intended to provide symptomatic relief to individuals suffering from hemorrhoids.

First Quarter 2022 Results: R&D Expenses were \$5.5M supporting I/ONTAK and Mino-Lok. We note that management expensed a \$5M license fee paid to Novellus. R&D is expected to rise as the P3 trials for Mino-Lok® and I/ONTAK as well as the Halo-Lido product candidates move forward plus continued development costs related to ARDS and Mino-Wrap. G&A Expenses were \$2.9M as the company builds its employees. The company closed the period with \$65M on the balance sheet.

Other Key Events to Watch:

- Pivotal Phase 3 trial of I/ONTAK (E7777) completed in December 2021 with topline results anticipated in the first half of 2022 and a biologics license application (BLA) submission planned in the second half of 2022;
- Mino-Lok Phase 3 trial completion anticipated in 2022;

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	\$1.31	-	\$4.56
Shares Outstanding (mil.)	146.0		
Market Capitalization (mil.)	\$228		
Enterprise Value (mil.)	\$208		
Debt to Capital	0%		
Book Value/Share	\$2.63		
Price/Book	2.2		
Average Three Months Trading Volume (K)	1,518		
Insider Ownership	8.4%		
Institutional Ownership	16.9%		
Short interest (mil.)	7.3%		
Dividend / Yield	\$0.00/0.0%		



Exhibit 1. Income Statement

Citius Pharmaceuticals: Income Statement (\$000)												
YE Sept.	2017A	2018A	2019A	2020A	2021A	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Mino-Lok, U.S. ST & LT CVC Revenues			-	-		-	103,162	210,471	322,052	438,034	558,548	569,775
CTCL Revenues			-	-		-	31,345	79,937	114,162	133,093	135,768	138,497
			-	-	-	-	134,507	290,409	436,214	571,127	694,317	708,272
Expenses												
Cost of goods sold		-	-	-	-	-	20,176	43,561	65,432	85,669	104,147	106,241
COGS % of Revenue						#DIV/0!	15%	15%	15%	15%	15%	15%
Research and development	5,873	6,563	8,596	8,813	12,241	13,000	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	15,000	15,300	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							
Total expenses	19,972	13,789	15,596	17,462	23,532	34,323	49,476	75,841	99,998	120,926	140,110	142,922
Oper. Inc. (Loss)	(19,972)	(13,789)	(15,596)	(17,462)	(23,532)	(34,323)	85,031	214,567	336,216	450,201	554,207	565,350
Interest Income	47	818	53	68	262							
Gain (loss) on revaluation of derivative warrant liability		450		110	216							
Interest Expense		(16)	(16)	(16)								
Pre-tax income	(20,769)	1,253	(15,560)	(17,299)	(23,055)	(34,323)	85,031	214,567	336,216	450,201	554,207	565,350
Income Tax Benefit (Provision- Warrant)	-	-	-	-	1,451	(2,506)	12,755	42,913	84,054	135,060	193,972	214,833
Tax Rate	0%	0%	0%	0%	5%	10%	15%	20%	25%	30%	35%	38%
GAAP Net Income (loss)	(4,952)	(12,537)	(15,560)	(17,299)	(24,505)	(31,783)	72,276	171,654	252,162	315,141	360,235	350,517
GAAP-EPS	(3.55)	(1.22)	(0.53)	(0.46)	(0.25)	(0.19)	0.41	0.96	1.36	1.65	1.83	1.73
Non GAAP EPS (dil)	(3.55)	(1.22)	(0.61)	(0.46)	(0.23)	(0.19)	0.41	0.96	1.36	1.65	1.83	1.73
Wgt'd Avg Shrs (Bas) - '000s	5,842	10,731	20,162	39,165	108,599	146,231	146,817	147,405	147,996	148,588	149,184	149,781
Wgt'd Avg Shrs (Dil) - '000s	5,842	10,731	35,000	39,165	129,901	169,166	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.

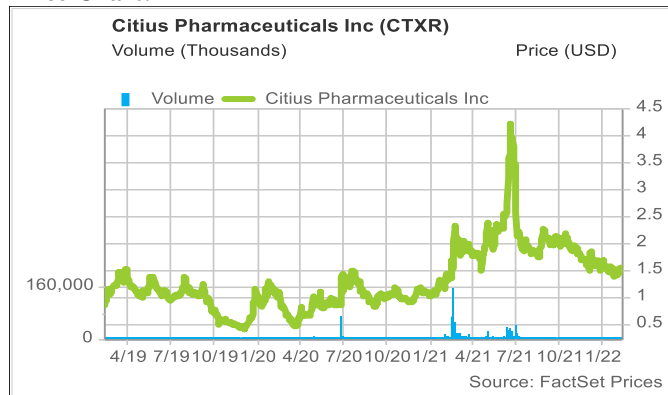
Liquidity Risk. The stock is thinly traded. We note that management owns a significant percentage of the company.

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

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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... 8-Feb-22

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	31	76%	6	19%
Market Perform (Neutral)	10	24%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	41	100%	6	15%

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