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## Citius Pharmaceuticals (NASDAQ/CTXR)

April 26, 2022

### BUY: Halo-Lido for Hemorrhoids-First Patient Enrolled

*Citius announced that the first patient has been enrolled in the Company's Phase 2b clinical study of Halo-Lido for the treatment of hemorrhoids. If approved, Halo-Lido would be the first FDA-approved prescription product indicated for the treatment of hemorrhoids.*

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### Investment Highlights

**Trial Design:** The Phase 2b study is a multi-center, randomized, dose-ranging, double-blind, parallel group comparison clinical trial. Five cohorts of adults with a clinical diagnosis of symptomatic Goligher's classification Grade II or Grade III hemorrhoids will be dosed. Approximately 60 patients per cohort are expected to be enrolled, for a total of 300 patients.

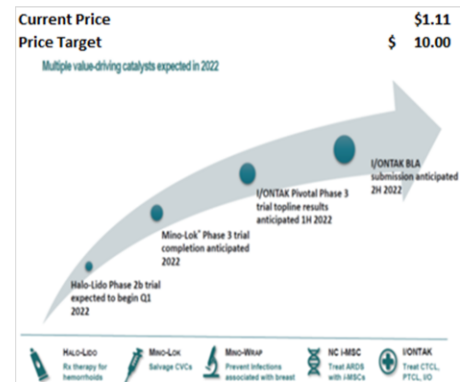
**What is Hydro-Lido?** It is a combination of two drugs typically used to treat the symptoms of hemorrhoids, Lidocaine, and a steroid. The product could be the first new prescription therapy for hemorrhoids.

**Background on hemorrhoids:** In the United States, over 12 million people have hemorrhoids, with the highest incidence in adults over 50 years of age. Annually, approximately 22 million over-the-counter products and 4 million prescription products are sold for the treatment of hemorrhoids. Because all of the currently sold therapies, which provide symptomatic relief, do not address the underlying cause of hemorrhoids; there are no estimates on the potential recurrence rate once hemorrhoids have been treated. However, in light of the pathophysiology of hemorrhoids, it would be reasonable to expect a high recurrence rate, thereby necessitating repeat courses of therapy, potentially as often as 3x-5x per year. Therefore, we believe it is more appropriate to view the hemorrhoids market as a chronic therapy market, rather than a single-use therapy market.

**Where is the Market Today?** There are no FDA-approved drugs for the treatment of hemorrhoids. The existing treatment pharmacologic treatment options, which mainly consist of over-the-counter products, including Preparation H, stool softeners, and prescription products, including analgesics and topical steroids (Anusol), were "grandfathered" by the FDA due to their presence on the market prior 1962, do not have efficacy data to support use, and provide only temporary symptomatic relief. Despite these shortcomings, and the lack of reimbursement, there is significant patient and physician demand for these products, as demonstrated by the sales of nearly 26 million units of both OTC and prescription products annually.

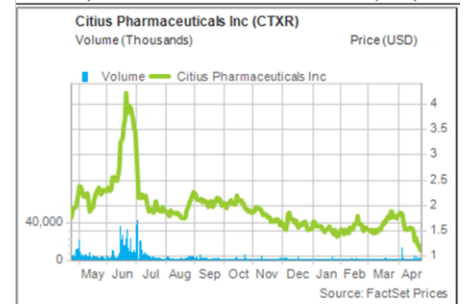
**Valuation.** Our valuation is based on our therapeutic models and associated assumptions projected to 2028. The lead product, Mini-Lok, is now in a Phase 3 trial, as is E7777. We use a 30% risk rate in our free cash flow to the Firm (FCFF), our discounted EPS (dEPS), and sum-of-the-parts (SOP) models 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	\$1.08	-	\$4.56
Shares Outstanding (mil.)	146.0		
Market Capitalization (mil.)	\$162		
Enterprise Value (mil.)	\$143		
Debt to Capital	0%		
Book Value/Share	\$2.63		
Price/Book	2.2		
Average Three Months Trading Volume (K)	1,475		
Insider Ownership	8.4%		
Institutional Ownership	18.6%		
Short Interest (mil.)	6.4%		
Dividend / Yield	\$0.00/0.0%		



**Please find Important Disclosures beginning on Page 4.**

**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
<b>Expenses</b>												
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							
<b>Total expenses</b>	<b>19,972</b>	<b>13,789</b>	<b>15,596</b>	<b>17,462</b>	<b>23,532</b>	<b>34,323</b>	<b>49,476</b>	<b>75,841</b>	<b>99,998</b>	<b>120,926</b>	<b>140,110</b>	<b>142,922</b>
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)								
<b>Pre-tax income</b>	<b>(20,769)</b>	<b>1,253</b>	<b>(15,560)</b>	<b>(17,299)</b>	<b>(23,055)</b>	<b>(34,323)</b>	<b>85,031</b>	<b>214,567</b>	<b>336,216</b>	<b>450,201</b>	<b>554,207</b>	<b>565,350</b>
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%
<b>GAAP Net Income (loss)</b>	<b>(4,952)</b>	<b>(12,537)</b>	<b>(15,560)</b>	<b>(17,299)</b>	<b>(24,505)</b>	<b>(31,783)</b>	<b>72,276</b>	<b>171,654</b>	<b>252,162</b>	<b>315,141</b>	<b>360,235</b>	<b>350,517</b>
<b>GAAP-EPS</b>	<b>(3.55)</b>	<b>(1.22)</b>	<b>(0.53)</b>	<b>(0.46)</b>	<b>(0.25)</b>	<b>(0.19)</b>	<b>0.41</b>	<b>0.96</b>	<b>1.36</b>	<b>1.65</b>	<b>1.83</b>	<b>1.73</b>
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.

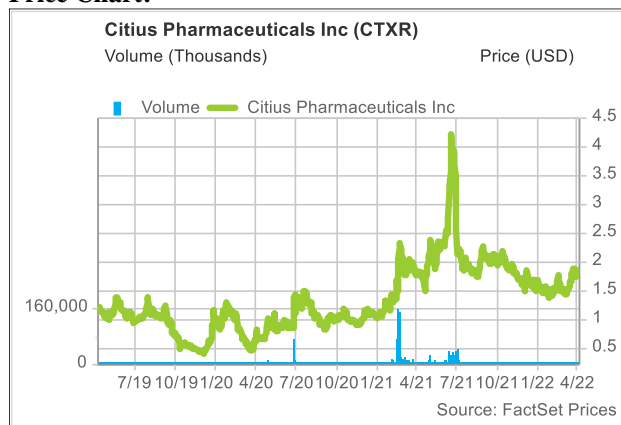
**Liquidity Risk.** The stock is thinly traded. We note that management owns a significant percentage of the company.

**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
- 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

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**Information about valuation methods and risks can be found in the "VALUATION" and "RISK ANALYSIS" sections of this report.**

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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... 26-Apr-22

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	32	74%	4	13%
Market Perform (Neutral)	11	26%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	43	100%	4	9%

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