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UPDATE REPORT

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Citius Pharmaceuticals (NASDAQ/CTXR)

April 6, 2022

BUY: OnTak Phase 3 (Bridge Study) Shows Consistency

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Citius announced topline results from the P3 trial of I/ONTAK (E7777) that demonstrated consistency with prior formulations. This clears the path for Citius to file a biologics license application (BLA) with the FDA in the second half of 2022.

Investment Highlights

What was the Trial Design? The study was a two-part pivotal, multicenter, open-label, single-arm study of I/ONTAK (E7777) in subjects with persistent or recurrent CTCL (NCT01871727). All subjects were diagnosed with Mycosis Fungoides or Sézary Syndrome, with tumors assessed as positive for expression of the CD25 subunit of the IL-2 receptor. A total of 91 subjects with Stage I-IV CTCL were enrolled in the Main Study.

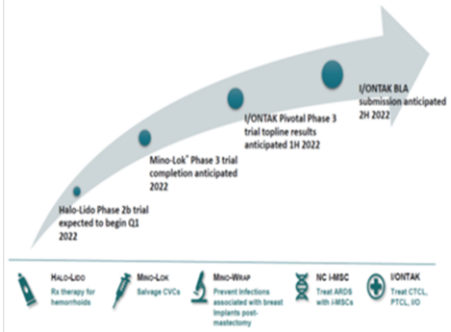
Does it Work? The primary outcome measure of Study 302 is the Objective Response Rate (ORR) based on the Global Response Score (GRS) (Olsen, JCO 2011).

- According to the trial protocol, the treatment would be considered efficacious and demonstrate clinical benefit if the lower limit of the 2-sided 95% exact confidence interval (CI) of the observed ORR exceeds 25.0%, as determined by the Independent Review Committee (IRC);
- In this study, the IRC determined the study achieved an ORR of 36.2%, 95% confidence interval (25.0%, 48.7%) (25 patients out of 69);
- An Investigator Efficacy Analysis determined that the study achieved an ORR of 42.3%, 95% confidence interval (30.6%, 54.6%) (30 patients out of 71);
- The FDA recently provided additional written comments indicating that their efficacy evaluation will be based on study results showing the lower limit of a 95% confidence interval to exceed a clinically relevant response rate (determined during BLA review) which may be supported with data from from the prior ONTAK study that led to ONTAK's initial approval. In our trial ORR will need to be supported by adequate magnitude of duration of response and an acceptable risk/benefit ratio;
- Overall rates of adverse events and serious adverse events were consistent with published data of previously approved ONTAK. Most common adverse events included: nausea, fatigue, increased alanine aminotransferase, chills and peripheral oedema. No new safety concerns were identified.

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.

Current Price	$1.84
Price Target	$ 10.00



Source: Citius

Stock Data			
52-Week Range	$1.31	-	$4.56
Shares Outstanding (mil.)			146.0
Market Capitalization (mil.)			$269
Enterprise Value (mil.)			$249
Debt to Capital			0%
Book Value/Share			$2.63
Price/Book			2.2
Average Three Months Trading Volume (K)			1,105
Insider Ownership			8.4%
Institutional Ownership			18.6%
Short interest (mil.)			6.2%
Dividend / Yield			$0.00/0.0%

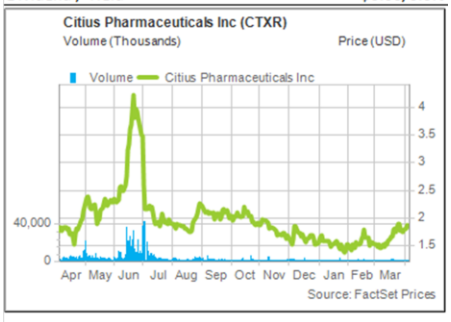


Exhibit 1. Income Statement

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
Wgtd 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
Wgtd 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.

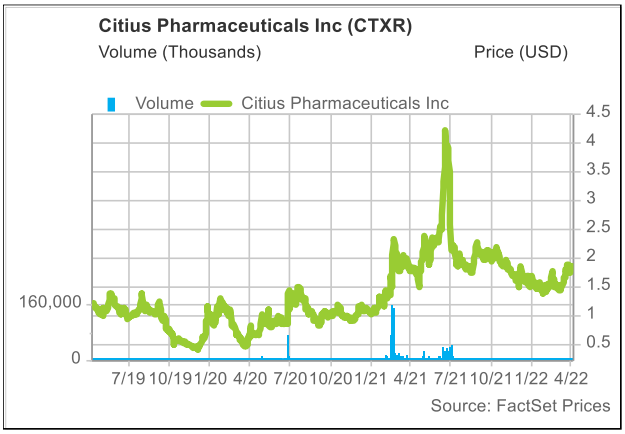
Liquidity Risk. The stock is thinly traded. We note that management owns a significant percentage of the company.

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

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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.

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… 15-Mar-22

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	31	74%	4	13%
Market Perform (Neutral)	11	26%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	42	100%	4	10%

Analyst Certification:

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