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Citius Pharmaceuticals (NASDAQ/CTXR)

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BUY: ONTAK is ONTRACK as Phase 3 Completes Enrollment

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Citius announced that it has completed patient enrollment in its Pivotal Phase 3 trial of I/ONTAK, an engineered IL-2-diphtheria toxin fusion protein, for the treatment of patients with persistent or recurrent cutaneous T-cell lymphoma (CTCL). Topline results are expected in H1-22 with a BLA H2-22.

Investment Highlights

- **E7777 – CTCL (Cutaneous T-Cell Lymphoma).** This is a pivotal orphan drug currently (acquired from Eisai through Dr. Reddy's) for the U.S. The compound has been recently approved in Japan (commercialization is underway) with a similar path projected in the U.S. We see the current Phase 3 trial as a bridging study to validate a manufacturing change, dose confirmation, and efficacy in CTCL patients
- **Trial Design:** This is a N=70 P3 multicenter, open-label, single-arm Pivotal study of I/ONTAK in participants with recurrent or persistent CTCL. The trial is supported by the prior P2 trial (N=21) study. The primary outcome measure for the main study is the Objective Response Rate (ORR). The primary endpoint and quality of life analyses of the study will be performed on the combined data set from subjects in the main study plus subjects in the lead-in part of the study who received 9 micrograms per kilogram through the data cutoff date. Multiple secondary endpoints including duration of response, time to response, and safety will be evaluated.
- **E7777 is an Orphan.** That's good. We anticipate high pricing given that the CTCL market is small (3-4,000 patients) and that CTCL is an unmet medical need.
- **What is it?** E7777 is an engineered IL-2-diphtheria toxin fusion protein. It is an improved formulation of an oncology agent, ONTAK, which was previously approved by the U.S. Food and Drug Administration (FDA) for the treatment of patients with persistent or recurrent CTCL. The last patient in a Pivotal trial of E7777 has been enrolled, and a biologics license application (BLA) for E7777's first indication in CTCL is expected to be filed with the FDA by the end of 2022.
- **Does E7777 Work?** CTCL remains a terminal disease and an unmet medical need. E7777 clinical data suggests a 40% ORR (Overall Response Rate), and regulators believe this supports approval, especially when coupled with a benign adverse events profile versus other compounds used (off-label).

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.

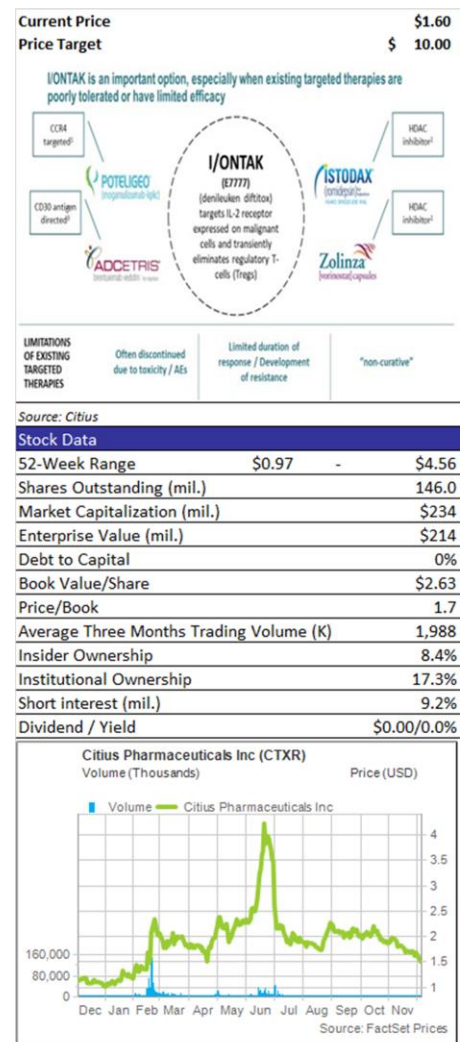


Exhibit 1. Income Statement

Citius Pharmaceuticals: Income Statement (\$000)					December	March	June	Sept. YE								
YE Sept.	2017A	2018A	2019A	2020A	1Q21A	2Q21A	3Q21A	4Q21E	2021E	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					15%	15%	15%	15%		#DIV/0!	15%	15%	15%	15%	15%	15%
Research and development	5,873	6,563	8,596	8,813	6,191	1,551	2,204	2,500	12,446	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	1,689	2,293	3,407	3,400	10,789	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	277	342	374	375	1,367							
Total expenses	19,972	13,789	15,596	17,462	8,156	4,186	5,984	5,900	24,227	28,000	49,476	75,841	99,998	120,926	140,110	142,922
Oper. Inc. (Loss)	(19,972)	(13,789)	(15,596)	(17,462)	(8,156)	(4,186)	(5,984)	(5,900)	(24,227)	(28,000)	85,031	214,567	336,216	450,201	554,207	565,350
Interest Income	47	818	53	68	13	69	60									
Gain (loss) on revaluation of derivative warrant liability		450		110	(4)	(4)	100									
Interest Expense		(16)	(16)	(16)												
Pre-tax income	(20,769)	1,253	(15,560)	(17,299)	(8,147)	(4,121)	(5,824)	(5,900)	(24,227)	(28,000)	85,031	214,567	336,216	450,201	554,207	565,350
Income Tax Benefit (Provision- Warrant)	-	-	-	-	-	(206)	1,451	(295)	950	(2,800)	12,755	42,913	84,054	135,060	193,972	214,833
Tax Rate	0%	0%	0%	0%	5%	5%	5%	5%	5%	10%	15%	20%	25%	30%	35%	38%
GAAP Net Income (loss)	(4,952)	(12,537)	(15,560)	(17,299)	(8,147)	(3,915)	(7,275)	(5,605)	(24,941)	(25,200)	72,276	171,654	252,162	315,141	360,235	350,517
GAAP-EPS	(3.55)	(1.22)	(0.53)	(0.46)	(0.15)	(0.03)	(0.04)	(0.03)	(0.25)	(0.15)	0.41	0.96	1.36	1.65	1.83	1.73
Non GAAP EPS (dil)	(3.55)	(1.22)	(0.61)	(0.46)	(0.15)	(0.03)	(0.04)	(0.03)	(0.25)	(0.15)	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	55,577	95,997	137,151	137,288	106,504	137,632	138,183	138,737	139,293	139,851	140,411	140,973
Wgtd Avg Shrs (Dil) - '000s	5,842	10,731	35,000	39,165	55,577	132,379	165,000	166,650	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.

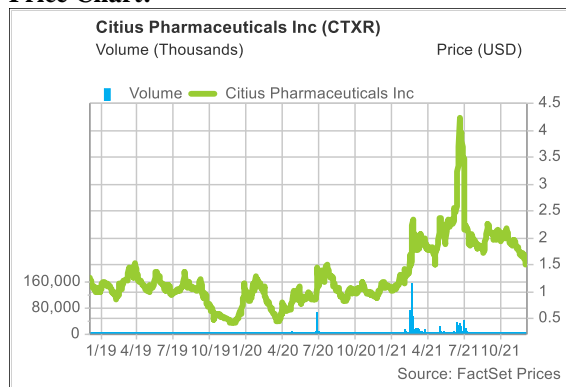
Liquidity Risk. The stock is thinly traded. We note that management owns a significant percentage of the company.

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

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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... 1-Dec-21

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	24	67%	5	21%
Market Perform (Neutral)	12	33%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	36	100%	5	14%

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