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Citius Pharmaceuticals (NASDAQ/CTXR)

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BUY: Resubmits the BLA for LYMPHIR™ for CTCL

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Citius announced the resubmission of the Company's BLA for LYMPHIR™. This is an IL-2-based immunotherapy for treating patients with relapsed or refractory cutaneous T-cell lymphoma (CTCL) after at least one prior systemic therapy. The resubmission follows ongoing engagement with the FDA resulting from a Complete Response Letter (CRL) received on July 28, 2023. Citius believes it has addressed enhanced product testing and additional manufacturing controls noted in the letter. There were no safety or efficacy issues cited and no additional trials were required. Based on Center for Drug Evaluation and Research timelines, FDA acceptance of the completed resubmission package and issuance of a Prescription Drug User Fee Act (PDUFA) date is expected within 30 days of resubmission.

Investment Highlights

What was the Issue back in July? The FDA has requested some additional product testing and CMC product controls. The issues do not require re-tooling and as such likely represent a type I (2-month delay). As stated in the company's press release – "there were no concerns relating to the safety and efficacy clinical data package submitted with the BLA, or the proposed prescribing information".

What is it? LYMPHIR is an engineered IL-2-diphtheria toxin fusion protein (denileukin diftitox – E7777) for the treatment of rare forms of cancer. Citius has a purified reformulation of denileukin diftitox, (which is a previously FDA-approved cancer immunotherapy for the treatment of persistent or recurrent cutaneous T-cell lymphoma CTCL), a rare form of non-Hodgkin lymphoma. Improvements to the original formulation resulted in a therapy that maintains the same amino acid sequence but features greater purity and bioactivity.

Background: In 2011 and 2013, the FDA granted orphan drug designation to LYMPHIR for the treatment of PTCL and CTCL, respectively. In 2021, denileukin diftitox received regulatory approval in Japan for the treatment of CTCL and peripheral T-cell lymphoma (PTCL). Subsequently in 2021, Citius acquired an exclusive license with rights to develop and commercialize LYMPHIR in all markets except for Japan and certain parts of Asia.

Valuation. 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 \$8.00 price target.

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

Current Price	\$0.68
Price Target	\$8.00



Source: Citius

Stock Data			
52-Week Range	\$0.60	-	\$1.71
Shares Outstanding (mil.)	159.0		
Market Capitalization (mil.)	\$108		
Enterprise Value (mil.)	\$89		
Debt to Capital	0%		
Book Value/Share	\$2.63		
Price/Book	1.2		
Average Three Months Trading Volume (K)	347		
Insider Ownership	7.7%		
Institutional Ownership	16.7%		
Short interest (mil.)	7.3%		
Dividend / Yield	\$0.00/0.0%		



Exhibit 1. Income Statement

Citius Pharmaceuticals: Income Statement ('000)						December	March	June	Sept. YE										
YE Sept.	2019A	2020A	2021A	2022A	2023A	1Q24E	2Q24E	3Q24E	4Q24E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E
Mino-Lok, U.S. ST & LT CVC Revenues	-	-	-	-	-	24,204	25,257	26,309	29,466	105,236	214,702	328,526	446,839	569,775	581,228	592,910	604,828	616,985	629,386
CTCL Revenues	-	-	-	-	-	18,386	19,185	19,984	22,382	79,937	114,162	133,093	135,768	138,497	141,281	144,121	147,018	149,973	152,987
	-	-	-	-	-	42,590	44,442	46,293	51,848	185,173	328,863	461,619	582,607	708,272	722,509	737,031	751,845	766,957	782,373
Expenses																			
Cost of goods sold	-	-	-	-	-	6,388	6,666	6,944	7,777	27,776	49,330	69,243	87,391	106,241	108,376	110,555	112,777	115,044	117,356
COGS % of Revenue						15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
Research and development	8,596	8,813	12,241	17,655	14,819	3,628	3,779	3,779	3,930	15,115	15,418	15,726	16,041	16,361	16,689	17,022	17,363	17,710	18,064
R&D % of Revenue																			
G&A	6,285	8,095	9,836	11,755	15,295	4,320	4,500	4,320	4,860	18,000	18,000	18,000	18,000	18,000	18,000	18,000	18,000	18,000	18,000
SG&A % of Revenue																			
Stock based comp. G & A	715	803	1,455	3,906	6,617	6,617	6,617	6,617	6,617	6,617	6,617	6,617	6,617	6,617	6,617	6,617	6,617	6,617	6,617
Total expenses	27,540	17,711	23,532	33,317	36,731	20,953	21,562	21,660	23,184	67,508	89,364	109,586	128,048	147,219	149,682	152,194	154,756	157,370	160,037
Oper. Inc. (Loss)	(27,540)	(17,711)	(23,532)	(33,317)	(36,731)	21,637	22,880	24,634	28,664	117,665	239,500	352,033	454,559	561,053	572,827	584,837	597,089	609,587	622,336
Interest Income	53	68	262	251	1,179	1,179	1,179	1,179	1,179	1,179	1,179	1,179	1,179	1,179	1,179	1,179	1,179	1,179	1,179
Gain (loss) on revaluation of derivative warrant liability		110	216		3,586	3,586	3,586	3,586	3,586	3,586	3,586	3,586	3,586	3,586	3,586	3,586	3,586	3,586	3,586
Interest Expense	(16)	(16)	-																
Pre-tax income	(27,503)	(17,548)	(23,055)	(33,641)	(31,966)	26,402	27,644	29,398	33,429	122,430	244,264	356,798	459,323	565,818	577,592	589,602	601,854	614,352	627,101
Pretax Margin																			
Income Tax Benefit (Provision- Warrant)	-	-	1,451	-	-														
Income Tax Expense					576	2,640	2,764	2,940	3,343	11,687	35,806	70,248	113,442	168,079	171,611	175,214	178,889	182,639	186,463
Tax Rate	0%	0%	5%		0%	10%	10%	10%	10%	10%	15%	20%	25%	30%	30%	30%	30%	30%	30%
GAAP Net Income (loss)	(27,474)	(30,976)	(42,834)	(33,641)	(33,694)	23,761	46,464	26,459	30,086	110,742	208,458	286,550	345,881	397,739	405,981	414,388	422,964	431,713	440,638
GAAP-EPS	(1.39)	(0.84)	(0.46)	(0.23)	(0.21)	0.13	0.26	0.15	0.17	0.71	1.09	1.37	1.56	1.71	1.69	1.67	1.65	1.63	1.61
Non GAAP EPS (dil)	(1.39)	(0.84)	(0.23)	(0.23)	(0.20)	0.13	0.26	0.15	0.17	0.71	1.09	1.37	1.56	1.71	1.69	1.67	1.65	1.63	1.61
Wgtd Avg Shrs (Bas) - '000s	20,162	36,071	108,599	146,066	151,294	158,458	158,617	158,775	158,934	158,696	159,332	159,970	160,611	161,254	161,900	162,549	163,200	163,854	164,510
Wgtd Avg Shrs (Dil) - '000s				146,067	167,357	176,144	177,905	179,684	181,481	178,804	184,222	189,804	195,555	201,481	207,586	213,876	220,356	227,033	233,913

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.

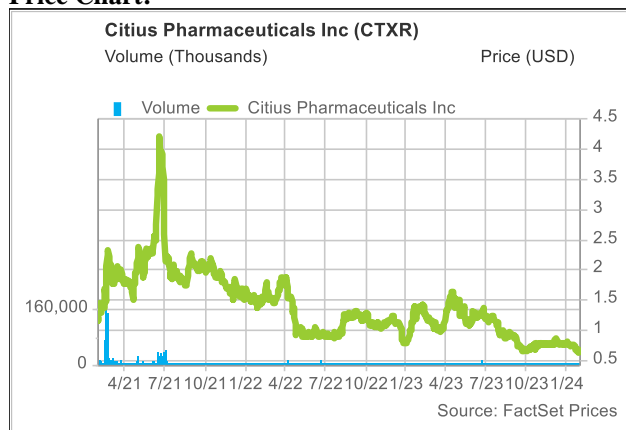
Liquidity Risk. The stock is thinly traded. We note that management owns a significant percentage of the Company.

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:

- 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
Update – Buy – 5/4/2023 – Price Target Change \$10.00 to \$8.00
Update – Buy – 5/18/2023 – Price Target \$8.00
Update – Buy – 6/21/2023 – Price Target \$8.00
Update – Buy – 7/31/2023 – Price Target \$8.00
Update – Buy – 8/15/2023 – Price Target \$8.00
Update – Buy – 9/11/2023 – Price Target \$8.00
Update – Buy – 10/24/2023 – Price Target \$8.00
Update – Buy – 11/2/2023 – Price Target \$8.00
Update – Buy – 1/2/2024 – Price Target \$8.00
Update – Buy – 1/11/2024 – Price Target \$8.00
Update – Buy – 1/31/2024 – Price Target \$8.00
Update – Buy – 2/14/2024 – Price Target \$8.00

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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;
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Current as of 30-Jan-24

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	20	58.82%	4	11.80%
Market Perform (Neutral)	14	41.18%	2	5.90%
Market Underperform (Sell)	0	0%	0	0.00%
Total	34	100%	6	17.70%

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