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## Citius Pharmaceuticals (NASDAQ/CTXR)

July 31, 2023

### BUY: I/ONTAK (E7777-LYMPHIR) Hits a Speed Bump

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*Citius announced that the FDA has issued a Complete Response Letter regarding the Company's Biologics License Application (BLA) seeking approval for denileukin diftiox ("LYMPHIRTM"), an engineered IL-2-diphtheria toxin fusion protein for the treatment of patients with relapsed or refractory cutaneous T-cell lymphoma (CTCL) after at least one prior systemic therapy. Our understanding is that the issues do not relate to efficacy or clinical data and are likely to be resolved "quickly". The original PDUFA was July 28, 2023.*

### Investment Highlights

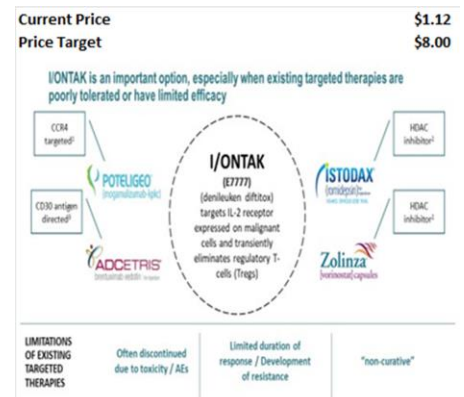
**What's the Issue?** The FDA has requested some additional product testing and CMC product controls. The issues do not require re-tooling and as such likely represent a type I (2-month delay). As stated in the company's press release – "there were no concerns relating to the safety and efficacy clinical 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 diftiox – E7777) for the treatment of rare forms of cancer. Citius has a purified reformulation of denileukin diftiox, (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:** (press release); In 2011 and 2013, the FDA granted orphan drug designation to LYMPHIR for the treatment of PTCL and CTCL, respectively. In 2021, denileukin diftiox 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.



Source: Citius

Stock Data			
52-Week Range	\$0.77	-	\$1.71
Shares Outstanding (mil.)	158.9		
Market Capitalization (mil.)	\$178		
Enterprise Value (mil.)	\$158		
Debt to Capital	0%		
Book Value/Share	\$2.63		
Price/Book	1.7		
Average Three Months Trading Volume (K)	1,110		
Insider Ownership	7.7%		
Institutional Ownership	9.1%		
Short interest (mil.)	12.8%		
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	1Q23A	2Q23A	3Q23E	4Q23E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E		
Mino-Lok, U.S. ST & LT CVC Revenues	-	-	-	-	-	-	-	-	-	105,236	214,702	328,526	446,839	569,775	581,228	592,910	604,828	616,985	629,386		
CTCL Revenues	-	-	-	-	-	-	-	-	-	79,937	114,162	133,093	135,768	138,497	141,281	144,121	147,018	149,973	152,987		
	-	-	-	-	-	-	-	-	-	185,173	328,863	461,619	582,607	708,272	722,509	737,031	751,845	766,957	782,373		
<b>Expenses</b>																					
Cost of goods sold	-	-	-	-	-	-	-	-	-	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	3,446	4,727	3,500	2,328	14,000	14,280	14,566	14,857	15,154	15,457	15,766	16,082	16,403	16,731	17,066		
R&D % of Revenue																					
G&A	6,285	8,095	9,836	11,755	2,603	4,793	2,997	1,596	11,990	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	1,201	1,166	1,166	1,166	1,166	1,166	1,166	1,166	1,166	1,166	1,166	1,166	1,166	1,166	1,166		
<b>Total expenses</b>	<b>27,540</b>	<b>17,711</b>	<b>23,532</b>	<b>33,317</b>	<b>7,250</b>	<b>10,685</b>	<b>7,663</b>	<b>5,089</b>	<b>27,155</b>	<b>61,222</b>	<b>83,061</b>	<b>103,265</b>	<b>121,711</b>	<b>140,864</b>	<b>143,308</b>	<b>145,802</b>	<b>148,346</b>	<b>150,941</b>	<b>153,588</b>		
Oper. Inc. (Loss)	(27,540)	(17,711)	(23,532)	(33,317)	(7,250)	(10,685)	(7,663)	(5,089)	(27,155)	123,951	245,803	358,353	460,896	567,409	579,200	591,229	603,500	616,017	628,786		
Interest Income	53	68	262	251	215	303	303	303	303	303	303	303	303	303	303	303	303	303	303		
Gain (loss) on revaluation of derivative warrant liability		110	216		3,586																
Interest Expense	(16)	(16)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
<b>Pre-tax income</b>	<b>(27,503)</b>	<b>(17,548)</b>	<b>(23,055)</b>	<b>(33,641)</b>	<b>(3,450)</b>	<b>(10,382)</b>	<b>(7,360)</b>	<b>(4,786)</b>	<b>(26,852)</b>	<b>124,255</b>	<b>246,106</b>	<b>358,657</b>	<b>461,200</b>	<b>567,712</b>	<b>579,504</b>	<b>591,532</b>	<b>603,803</b>	<b>616,320</b>	<b>629,089</b>		
<b>Pretax Margin</b>																					
Income Tax Benefit (Provision- Warrant)	-	-	1,451	-	144	144				12,167	36,528	71,214	114,653	169,538	173,075	176,684	180,365	184,120	187,951		
Income Tax Expense																					
<b>Tax Rate</b>	<b>0%</b>	<b>0%</b>	<b>5%</b>		<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>10%</b>	<b>15%</b>	<b>20%</b>	<b>25%</b>	<b>30%</b>	<b>30%</b>	<b>30%</b>	<b>30%</b>	<b>30%</b>	<b>30%</b>		
<b>GAAP Net Income (loss)</b>	<b>(27,474)</b>	<b>(30,976)</b>	<b>(42,834)</b>	<b>(33,641)</b>	<b>(3,594)</b>	<b>(10,526)</b>	<b>(7,360)</b>	<b>(4,786)</b>	<b>(26,852)</b>	<b>112,088</b>	<b>209,578</b>	<b>287,443</b>	<b>346,546</b>	<b>398,175</b>	<b>406,429</b>	<b>414,849</b>	<b>423,438</b>	<b>432,200</b>	<b>441,138</b>		
<b>GAAP-EPS</b>	<b>(1.39)</b>	<b>(0.84)</b>	<b>(0.46)</b>	<b>(0.23)</b>	<b>(0.02)</b>	<b>(0.07)</b>	<b>(0.04)</b>	<b>(0.03)</b>	<b>(0.16)</b>	<b>0.73</b>	<b>1.11</b>	<b>1.39</b>	<b>1.57</b>	<b>1.72</b>	<b>1.70</b>	<b>1.68</b>	<b>1.66</b>	<b>1.64</b>	<b>1.62</b>		
Non GAAP EPS (dil)	(1.39)	(0.84)	(0.23)	(0.23)	(0.02)	(0.06)	(0.04)	(0.03)	(0.15)	0.73	1.11	1.39	1.57	1.72	1.70	1.68	1.66	1.64	1.62		
Wgtd Avg Shrs (Bas) - '000s	20,162	36,071	108,599	146,066	146,211	146,252	158,898	159,057	152,605	159,455	160,094	160,735	161,379	162,026	162,675	163,326	163,981	164,638	165,297		
Wgtd Avg Shrs (Dil) - '000s				146,067	146,211	172,673	174,400	176,144	167,357	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.

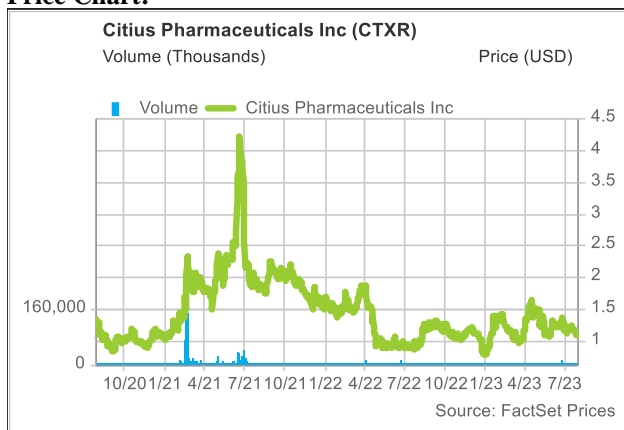
**Liquidity Risk.** The stock is thinly traded. We note that management owns a significant percentage of the Company.

**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:

- 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  
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

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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 28-Jul-23

	<b>Company Coverage</b>		<b>Investment Banking</b>	
<b>Ratings Distribution</b>	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	25	71%	2	6.00%
Market Perform (Neutral)	10	29%	2	6.00%
Market Underperform (Sell)	0	0%	0	0.00%
Total	35	100%	4	11.00%

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