

Member FINRA/SIPC

Toll-Free: 866-928-0928 ♦ www.DawsonJames.com ♦ 101 North Federal Highway - Suite 600 ♦ Boca Raton, FL 33432

Citius Pharmaceuticals (NASDAQ/CTXR)

November 2, 2023

BUY: LYMPHIR + PD1 Appears to Enhance Efficacy

Jason Kolbert
 Managing Director & Senior Analyst
 jkolbert@dawsonjames.com

A study published in "Frontiers in Immunology" suggests that an increase in T-reg cell infiltration induced by anti-PD-1 treatment can be counterbalanced by their depletion by LYMPHIR, creating synergistic activity, (as shown in solid tumor models). The results of the study showed that LYMPHIR administered in combination with an anti-PD-1 inhibitor, either sequentially or concurrently, led to significantly increased anti-tumor activity and prolonged survival compared to either treatment alone. Based on the strong signal of the study, two ongoing Phase I trials have been initiated by investigators at leading cancer research institutions.

Investment Highlights

How Does it Work? The primary role of Treg-targeted cancer immunotherapy is to transiently deplete Treg cells. It is believed that regulatory T cells (Tregs) in the tumor microenvironment play an important role in patient resistance to anti-PD-1 immunotherapy. Targeting Tregs with LYMPHIR during treatment with anti-PD-1/PDL1 checkpoint inhibitors may change the dynamics of the immune microenvironment, including anti-PD-1 sensitivity, in situations where Tregs are prominent. Consequently, the innovative preclinical study evaluated whether adding LYMPHIR improved the efficacy of anti-PD-1 antibody therapy. Syngeneic murine solid tumor models in colon cancer CT-26 and liver cancer H22 were used to conduct the study.

Citius also announced the company has received additional guidance from the FDA regarding the planned resubmission of the company's Biologics License Application (BLA) for LYMPHIR (denileukin diftitox), 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. The guidance from the FDA provides Citius with a path for completing to support the resubmission of the company's Biologics License Application (BLA) for denileukin diftitox. No additional clinical efficacy or safety trials have been requested by the FDA for resubmission.

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

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.



LIMITATIONS OF EXISTING TARGETED THERAPIES	Often discontinued due to toxicity / AEs	Limited duration of response / Development of resistance	"non-curative"
--	--	--	----------------

Source: Citius

Stock Data			
52-Week Range	\$0.60	-	\$1.71
Shares Outstanding (mil.)	158.9		
Market Capitalization (mil.)	\$122		
Enterprise Value (mil.)	\$103		
Debt to Capital	0%		
Book Value/Share	\$2.63		
Price/Book	1.7		
Average Three Months Trading Volume (K)	1,531		
Insider Ownership	7.7%		
Institutional Ownership	16.2%		
Short Interest (mil.)	10.8%		
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	3Q23A	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
Expenses																			
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	3,765	2,063	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	3,733	860	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	1,174	1,174	1,174	1,174	1,174	1,174	1,174	1,174	1,174	1,174	1,174	1,174	1,174
Total expenses	27,540	17,711	23,532	33,317	7,250	10,685	8,672	4,097	27,164	61,230	83,069	103,274	121,719	140,872	143,317	145,810	148,354	150,949	153,596
Oper. Inc. (Loss)	(27,540)	(17,711)	(23,532)	(33,317)	(7,250)	(10,685)	(8,672)	(4,097)	(27,164)	123,943	245,794	358,345	460,888	567,400	579,192	591,221	603,491	616,008	628,777
Interest Income	53	68	262	251	215	303	337	337	337	337	337	337	337	337	337	337	337	337	337
Gain (loss) on revaluation of derivative warrant liability		110	216		3,586														
Interest Expense	(16)	(16)	-		-														
Pre-tax income	(27,503)	(17,548)	(23,055)	(33,641)	(3,450)	(10,382)	(8,335)	(3,761)	(26,827)	124,280	246,131	358,682	461,225	567,737	579,529	591,557	603,828	616,345	629,114
Pretax Margin																			
Income Tax Benefit (Provision- Warrant)	-	-	1,451	-	144	144	144	-	-	12,177	36,543	71,234	114,678	169,568	173,105	176,714	180,395	184,150	187,981
Income Tax Expense																			
Tax Rate	0%	0%	5%		0%	0%	0%	0%	0%	10%	15%	20%	25%	30%	30%	30%	30%	30%	30%
GAAP Net Income (loss)	(27,474)	(30,976)	(42,834)	(33,641)	(3,594)	(10,526)	(8,479)	(3,761)	(26,827)	112,103	209,588	287,448	346,546	398,170	406,424	414,844	423,433	432,195	441,133
GAAP-EPS	(1.39)	(0.84)	(0.46)	(0.23)	(0.02)	(0.07)	(0.05)	(0.02)	(0.16)	0.73	1.11	1.39	1.57	1.72	1.70	1.68	1.66	1.64	1.62
Non GAAP EPS (dil)	(1.39)	(0.84)	(0.23)	(0.23)	(0.02)	(0.06)	(0.05)	(0.02)	(0.16)	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	153,775	153,929	150,042	154,314	154,933	155,553	156,176	156,802	157,430	158,061	158,694	159,330	159,968
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.

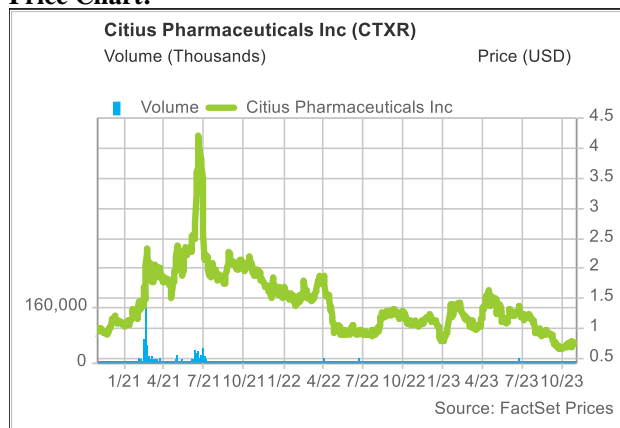
Liquidity Risk. The stock is thinly traded. We note that management owns a significant percentage of the Company.

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:

- 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

Dawson James Securities, Inc. (the "Firm") is a member of the Financial Industry Regulatory Authority ("FINRA") and the Securities Investor Protection Corporation ("SIPC").

The Firm does not make a market in the securities of the subject company(s). The Firm has NOT engaged in investment banking relationships with the subject company in the prior twelve months, as a manager or co-manager of a public offering and has NOT received compensation resulting from those relationships. The Firm may seek compensation for investment banking services in the future from the subject company(s). The Firm has received other compensation from the subject company(s) in the last 12 months for services unrelated to managing or co-managing of a public offering.

Neither the research analyst(s) whose name appears on this report nor any member of his (their) household is an officer, director or advisory board member of these companies. The Firm and/or its directors and employees may own securities of the Company (s) in this report and may increase or decrease holdings in the future. As of September 27, 2023, the Firm as a whole did not beneficially own 1% or more of any class of common equity securities of the subject Company (s) of this report. The Firm, its officers, directors, analysts or employees may affect transactions in and have long or short positions in the securities (or options or warrants related to those securities) of the Company (s) subject to this report. The Firm may affect transactions as principal or agent in those securities.

Analysts receive no direct compensation in connection with the Firm's investment banking business. All Firm employees, including the analyst(s) responsible for preparing this report, may be eligible to receive non-product or service-specific monetary bonus compensation that is based upon various factors, including total revenues of the Firm and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.

Although the statements in this report have been obtained from and are based upon recognized statistical services, issuer reports or communications, or other sources that the Firm believes to be reliable, we cannot guarantee their accuracy. All opinions and estimates included in this report constitute the analyst's judgment as of the date of this report and are subject to change without notice.

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

The securities of the Company discussed in this report may be unsuitable for investors depending on their specific investment objectives and financial position. This report is offered for informational purposes only and does not constitute an offer or solicitation to buy or sell any securities discussed herein in any jurisdiction where such would be prohibited. Additional information is available upon request.

Rating Definitions:

- 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 27-Sep-23

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	22	64.70%	3	8.80%
Market Perform (Neutral)	12	35.30%	3	8.80%
Market Underperform (Sell)	0	0%	0	0.00%
Total	34	100%	6	17.60%

Analyst Certification:

The analyst(s) whose name appears on this research report certifies that 1) all of the views expressed in this report accurately reflect his (their) personal views about any and all of the subject securities or issuers discussed; and 2) no part of the research analyst's compensation was, is, or will be directly or indirectly related to the specific recommendations or views expressed by the research analyst in this research report; and 3) all Dawson James employees, including the analyst(s) responsible for preparing this research report, may be eligible to receive non-product or service-specific monetary bonus compensation that is based upon various factors, including total revenues of Dawson James and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.