Citius Pharmaceuticals (NASDAQ/CTXR)

August 15, 2022

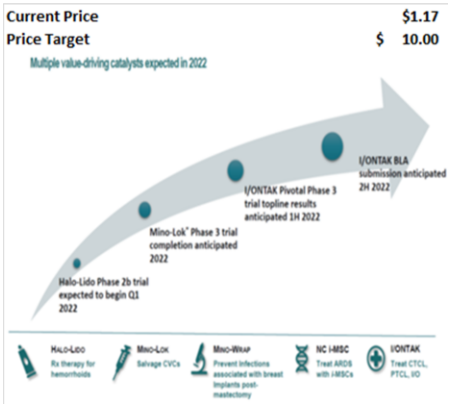
BUY: Reports Fiscal 3Q22: $48M in Cash

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

Highlights (Press Release):

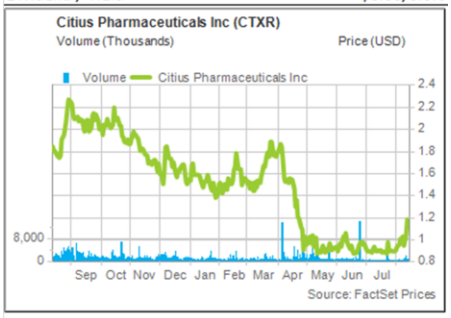
- *Mino-Lok Phase 3 trial recruitment approached pre-Covid-19 pace; international trial sites engaged to accelerate trial enrollment; Company reiterates 92 failure events required for trial completion;*
- *Halo-Lido Phase 2b trial initiated; enrollment completion anticipated by end of 2022;*
- *I/ONTAK (denileukin diftitox) topline results show no new safety signals and are consistent with prior formulation (ONTAK);*
- *Pre-BLA meeting held with the FDA for I/ONTAK; biologics license application (BLA) remains on track for submission in the second half of 2022; and,*
- *Announced intention to spinoff I/ONTAK into standalone oncology-focused publicly traded company.*

Click on the link to listen to an open discussion with management about what's ahead: https://dawsonjames.com/webinars/



Source: Citius

Stock Data			
52-Week Range	$0.83	-	$2.35
Shares Outstanding (mil.)			146.1
Market Capitalization (mil.)			$171
Enterprise Value (mil.)			$152
Debt to Capital			0%
Book Value/Share			$2.63
Price/Book			2.2
Average Three Months Trading Volume (K)			2,425
Insider Ownership			8.4%
Institutional Ownership			10.9%
Short interest (mil.)			6.8%
Dividend / Yield			$0.00/0.0%



Investment Highlights

Two Pivotal Programs:

Mino-Lok is currently in a Phase 3 pivotal trial. The compound has been granted QIDP and Fast Track designation by the FDA and has patent protection through 2024 and formulation patent protection through 2036. The phase 3 Pivotal trial was completed last December; top-line results are anticipated soon with a biologics license application (BLA) submission expected shortly thereafter.

The I/ONTAK Program: The program remains on track with an anticipated BLA submission later this year. Topline results for the Phase 3 trial of I/ONTAK were consistent with the prior FDA-approved formulation (ONTAK) and we believe there remains a significant unmet medical need in the market for CTCL patients. The company has announced plans to spin off the company into a publicly traded entity.

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)																
YE Sept.	2017A	2018A	2019A	2020A	2021A	1Q22A	2Q22A	3Q22A	4Q22E	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	12,241	5,458	3,452	4,888	4,888	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	2,897	3,117	3,025	3,025	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	905	1,020	1,004								
Total expenses	19,972	13,789	15,596	17,462	23,532	9,259	7,590	8,917	7,913	33,679	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)	(9,259)	(7,590)	(8,917)	(7,913)	(33,679)	85,031	214,567	336,216	450,201	554,207	565,350
Interest Income	47	818	53	68	262	34	30	53								
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)	(9,225)	(7,561)	(8,864)	(7,913)	(33,679)	85,031	214,567	336,216	450,201	554,207	565,350
Income Tax Benefit (Provision- Warrant)	-	-	-	-	1,451				(791)	(791)	12,755	42,913	84,054	135,060	193,972	214,833
Tax Rate	0%	0%	0%	0%	5%	10%	10%	10%	10%	10%	15%	20%	25%	30%	35%	38%
GAAP Net Income (loss)	(4,952)	(12,537)	(15,560)	(17,299)	(24,505)	(9,225)	(7,561)	(8,864)	(7,122)	(32,771)	72,276	171,654	252,162	315,141	360,235	350,517
GAAP-EPS	(3.55)	(1.22)	(0.53)	(0.46)	(0.25)	(0.06)	(0.05)	(0.05)	(0.04)	(0.20)	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)	(0.06)	(0.04)	(0.05)	(0.04)	(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	146,012	146,041	146,129	146,275	146,114	146,641	147,229	147,818	148,411	149,005	149,602
Wgtd Avg Shrs (Dil) - '000s	5,842	10,731	35,000	39,165	129,901	166,650	168,317	170,000	171,700	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.

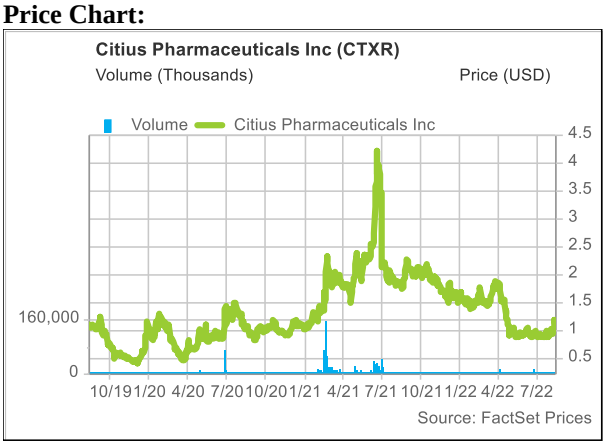
Liquidity Risk. The stock is thinly traded. We note that management owns a significant percentage of the Company.

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
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

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 August 1, 2022 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 8-Aug-22

	Company Coverage		**Investment Banking**	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	29	66%	4	14%
Market Perform (Neutral)	14	32%	0	0%
Market Underperform (Sell)	1	2%	0	0%
Total	44	100%	4	9%

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.