

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)

May 18, 2023

BUY: Reports the Quarter – Mino-Lok and I/ONTAK Updates

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

Citius spent \$10.6M in fiscal 2Q23 and closed the period with \$29M in cash and equivalents. Citius also raised capital (May 8, 2023) raising gross proceeds of \$15M for 12.5M shares and an equal number of warrants. The company highlighted (press release): “Achieved 85 of 92 required events in the Mino-Lok® Phase 3 trial as of April 24, 2023, with 16 patients in active treatment or pending study completion data review”; and: “Continued efforts to spin off oncology asset, I/ONTAK, into a standalone public company; the biologics license application (BLA) for I/ONTAK is under review by the FDA, with a targeted decision date (PDUFA) set for July 28, 2023”.

Investment Highlights

Mino-Lok is approaching the finish line: Management has now updated us on the number of catheter failure events; 85 of a target 92 events have been reached. We believe the decision to include sites in India is making the difference.

About the Trial: The Mino-Lok Phase 3 pivotal superiority trial is a multi-center, randomized, open-label, blinded study to determine the efficacy and safety of Mino-Lok. The primary endpoint for this study is the time (in days following randomization) to a catheter failure event between randomization and TOC (Week 6) in the Intent-to-Treat (ITT) Population. Additional secondary outcome measures include overall success, microbiological eradication, and clinical cure, among others. Patients diagnosed with catheter related blood stream infections (CRBSI/CLABSI) and who meet all necessary criteria for the study are randomized in a 1:1 ratio to receive either Mino-Lok therapy or standard of care antibiotic lock therapy. Patients in the Mino-Lok arm receive one dose daily with a dwell time of two to four hours for a total of seven doses. For subjects in the Control arm, the investigator determines the antibiotic used in the lock, dose, dwell time, and number of days of administration based on institutional standards or Infectious Diseases Society of America (IDSA) guidelines.

ONTAK BLA Under Review. The U.S. Food and Drug Administration (FDA) is currently reviewing a biologics license application (BLA) for I/ONTAK and has set a targeted decision date (PDUFA) of July 28, 2023. **As we have stated in the past,** management is now planning to spin-out IONTAK into a new company and raise capital to support the product’s commercialization. Recall that Citius paid \$40M upfront and has an obligation for \$40M in milestones, and we assume a 10% royalty. Given the opportunity, combined with what we view as a low-risk therapeutic, we believe management can realize a significant return on its investment.

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.



Please find Important Disclosures beginning on Page 3.

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		
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	3,500	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		
Total expenses	27,540	17,711	23,532	33,317	7,250	10,685	7,663	5,089	27,155	61,222	83,061	103,265	121,711	140,864	143,308	145,802	148,346	150,941	153,588		
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)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
Pre-tax income	(27,503)	(17,548)	(23,055)	(33,641)	(3,450)	(10,382)	(7,360)	(4,786)	(26,852)	124,255	246,106	358,657	461,200	567,712	579,504	591,532	603,803	616,320	629,089		
Pretax Margin																					
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																					
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)	(7,360)	(4,786)	(26,852)	112,088	209,578	287,443	346,546	398,175	406,429	414,849	423,438	432,200	441,138		
GAAP-EPS	(1.39)	(0.84)	(0.46)	(0.23)	(0.02)	(0.07)	(0.04)	(0.03)	(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)	(0.04)	(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.

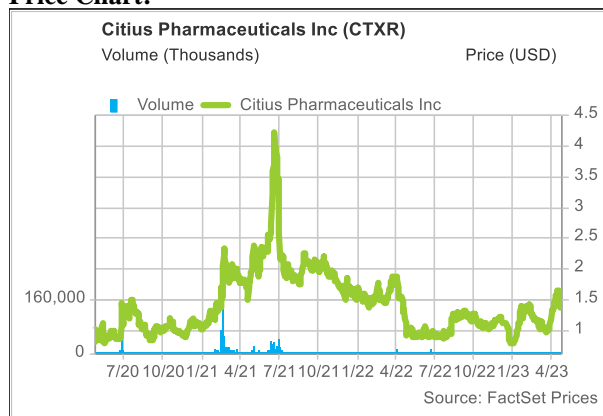
Liquidity Risk. The stock is thinly traded. We note that management owns a significant percentage of the Company.

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

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 April 17, 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 1-May-23

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	26	72%	2	6%
Market Perform (Neutral)	10	28%	1	3%
Market Underperform (Sell)	0	0%	0	0%
Total	36	100%	3	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.