



NEWS RELEASE

Citius Pharmaceuticals, Inc. Reports Fiscal Full Year 2024 Financial Results and Provides Business Update

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Clinical and regulatory success in 2024 expected to drive value in 2025

CRANFORD, N.J., Dec. 27, 2024 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("Citius Pharma" or the "Company") (Nasdaq: CTXR), a biopharmaceutical company dedicated to the development and commercialization of first-in-class critical care products today reported business and financial results for the fiscal full year ended September 30, 2024.

Fiscal Full Year 2024 Business Highlights and Subsequent Developments

- Achieved U.S. Food and Drug Administration (FDA) approval of LYMPHIR™ (denileukin diftitox-cxdl), an immunotherapy for the treatment of adults with relapsed or refractory cutaneous T-cell lymphoma (CTCL);
- Advanced manufacturing, marketing and sales activities in preparation for commercial launch of LYMPHIR in the first half of 2025;
- Completed the merger of Citius Pharma's oncology subsidiary with TenX Keane to form Citius Oncology, Inc., a standalone publicly traded company which began trading on the Nasdaq exchange under the ticker symbol CTOR on August 13, 2024;
- Supported two investigator-initiated trials to explore LYMPHIR's potential as an immuno-oncology combination therapy being conducted at the University of Pittsburgh Medical Center and the University of Minnesota;
- Shared interim trial results with the clinical community at the Society for Immunotherapy of Cancer Conference (SITC) of University of Pittsburgh Medical Center's Phase I trial of LYMPHIR with checkpoint

inhibitor pembrolizumab; and,

- Met primary and secondary endpoints in the Phase 3 Pivotal Trial of Mino-Lok[®], demonstrating a statistically significant improvement in time to catheter failure of infected catheters compared to other physician-selected anti-infective lock solutions.

Financial Highlights

- Cash and cash equivalents of \$3.3 million as of September 30, 2024;
- R&D expenses were \$11.9 million for the full year ended September 30, 2024, compared to \$14.8 million for the full year ended September 30, 2023;
- G&A expenses were \$18.2 million for the full year ended September 30, 2024, compared to \$15.3 million for the full year ended September 30, 2023;
- Stock-based compensation expense was \$11.8 million for the full year ended September 30, 2024, compared to \$6.6 million for the full year ended September 30, 2023; and,
- Net loss was \$39.4 million, or (\$5.97) per share for the full year ended September 30, 2024 compared to a net loss of \$32.5 million, or (\$5.57) per share for the full year ended September 30, 2023.

"In fiscal year 2024 we drove tremendous progress in our pipeline. It was a transformative year, marked by our first FDA approval and significant clinical milestones. The approval of LYMPHIR[™] and the positive Phase 3 results for Mino-Lok[®] underscore our commitment to developing innovative therapies. Our team successfully responded to FDA comments related to the biologics license application for LYMPHIR and ultimately gained FDA approval. Productive engagement with the FDA regarding the positive results of our Phase 3 Mino-Lok[®] trial and Phase 2 Halo-Lido trial clarified our next steps for both programs. We anticipate continued engagement with the agency in the coming year and look forward to their guidance. Additionally, we are exploring strategic partnerships and licensing opportunities to maximize the potential of our portfolio and bring these important therapies to market efficiently," stated Leonard Mazur, Chairman and CEO of Citius Pharma.

"Looking ahead, our priorities for fiscal year 2025 include launching LYMPHIR[™] through our majority-owned subsidiary, Citius Oncology, driving the clinical and regulatory strategies for Mino-Lok[®] and Halo-Lido, fortifying our financial position, and applying a disciplined approach to resource allocation. We expect to launch LYMPHIR in the first half of 2025 and distribute CTOR shares to Citius Pharma shareholders by the end of the year, pending favorable market conditions. Our goal remains to deliver value for patients, healthcare providers, and shareholders. With a clear vision and a strong team, we are well-positioned to execute on our mission of bringing innovative therapies to market," added Mazur.

FULL YEAR 2024 FINANCIAL RESULTS:

Liquidity

As of September 30, 2024, the Company had \$3.3 million in cash and cash equivalents.

As of September 30, 2024, the Company had 7,247,243 common shares outstanding, as adjusted for the 1-for-25 reverse stock split of the Company's common stock, effected on November 25, 2024.

During the year ended September 30, 2024, the Company received net proceeds of \$13.8 million from the issuance of equity. The Company expects to raise additional capital to support operations.

Research and Development (R&D) Expenses

R&D expenses were \$11.9 million for the full year ended September 30, 2024, compared to \$14.8 million for the full year ended September 30, 2023. The decrease in R&D expenses primarily reflects the completion of the Halo-Lido trial and completion of activities related to the regulatory resubmission for LYMPHIR, offset by shutdown costs associated with the end of the Phase 3 trial for Mino-Lok.

We expect research and development expenses to decrease in fiscal year 2025 as we continue to focus on the commercialization of LYMPHIR through our majority-owned subsidiary, Citius Oncology and because we have completed the Phase 3 trial for Mino-Lok.

General and Administrative (G&A) Expenses

G&A expenses were \$18.2 million for the full year ended September 30, 2024, compared to \$15.3 million for the full year ended September 30, 2023. The increase was primarily due to costs associated with pre-launch and market research activities associated with LYMPHIR. General and administrative expenses consist primarily of compensation costs, professional fees for legal, regulatory, accounting and corporate development services, and investor relations expenses.

Stock-based Compensation Expense

For the full year ended September 30, 2024, stock-based compensation expense was \$11.8 million as compared to \$6.6 million for the prior year. The increase of \$5.2 million is largely due to the grant of options under the Citius Oncology stock plan. Stock-based compensation expense under the Citius Oncology stock plan was \$7.5 million during the year ended September 30, 2024, compared to \$2.0 million for the year ended September 30, 2023, as the plan was initiated in July 2023. For the years ended September 30, 2024 and 2023, stock-based compensation expense also includes \$47,547 and \$130,382, respectively, for the NoveCite stock option plan. In fiscal years 2023

and 2024, we granted options to our new employees and additional options to other employees, our directors, and consultants.

Net loss

Net loss was \$39.4 million, or (\$5.97) per share for the year ended September 30, 2024, compared to a net loss of \$32.5 million, or (\$5.57) per share for the year ended September 30, 2023, as adjusted for the reverse stock split. The increase in net loss reflects an increase in operating expense of \$5.3 million offset by a decrease of \$1.6 million in other income. Operating expense increased due to increases in stock-based compensation and general and administrative expenses, which were offset by decreased research and development expense.

About Citius Pharmaceuticals, Inc.

Citius Pharma is a biopharmaceutical company dedicated to the development and commercialization of first-in-class critical care products. In August 2024, the FDA approved LYMPHIR™, a targeted immunotherapy for an initial indication in the treatment of cutaneous T-cell lymphoma. Citius Pharma's late-stage pipeline also includes Mino-Lok®, an antibiotic lock solution to salvage catheters in patients with catheter-related bloodstream infections, and CITI-002 (Halo-Lido), a topical formulation for the relief of hemorrhoids. A Pivotal Phase 3 Trial for Mino-Lok and a Phase 2b trial for Halo-Lido were completed in 2023. Mino-Lok met primary and secondary endpoints of its Phase 3 Trial. Citius Pharma is actively engaged with the FDA to outline next steps for both programs. For more information, please visit www.citiuspharma.com.

Forward-Looking Statements

This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements are made based on our expectations and beliefs concerning future events impacting Citius Pharma. You can identify these statements by the fact that they use words such as "will," "anticipate," "estimate," "expect," "plan," "should," and "may" and other words and terms of similar meaning or use of future dates. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from those currently anticipated, and, unless noted otherwise, that apply to Citius Pharma are: our ability to raise additional money to fund our operations for at least the next 12 months as a going concern; our ability to commercialize LYMPHIR through our majority-owned subsidiary and any of our other product candidates that may be approved by the FDA; the estimated markets for our product candidates and the acceptance thereof by any market; the ability of our product candidates to impact the quality of life of our target patient populations; risks related to research using our assets but conducted by third parties; risks relating to the results of research and development

activities, including those from our existing and any new pipeline assets; our ability to maintain compliance with Nasdaq's continued listing standards; our dependence on third-party suppliers; our ability to procure cGMP commercial-scale supply; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; uncertainties relating to preclinical and clinical testing; the early stage of products under development; market and other conditions; risks related to our growth strategy; patent and intellectual property matters; our ability to identify, acquire, close and integrate product candidates and companies successfully and on a timely basis; government regulation; competition; as well as other risks described in our Securities and Exchange Commission ("SEC") filings. These risks have been and may be further impacted by any future public health risks. Accordingly, these forward-looking statements do not constitute guarantees of future performance, and you are cautioned not to place undue reliance on these forward-looking statements. Risks regarding our business are described in detail in our SEC filings which are available on the SEC's website at www.sec.gov, including in Citius Pharma's Annual Report on Form 10-K for the year ended September 30, 2024, filed with the SEC on December 27, 2024, as updated by our subsequent filings with the SEC. These forward-looking statements speak only as of the date hereof, and we expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

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-- Financial Tables Follow --

	2024	2023
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 3,251,880	\$ 26,480,928
Inventory	8,268,766	—
Prepaid expenses	2,700,000	7,889,506
Total Current Assets	<u>14,220,646</u>	<u>34,370,434</u>
Property and equipment, net	—	1,432
Operating lease right-of-use asset, net	<u>246,247</u>	<u>454,426</u>
Other Assets:		
Deposits	38,062	38,062
In-process research and development	92,800,000	59,400,000
Goodwill	9,346,796	9,346,796
Total Other Assets	<u>102,184,858</u>	<u>68,784,858</u>
Total Assets	<u>\$ 116,651,751</u>	<u>\$ 103,611,150</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 4,927,211	\$ 2,927,334
License payable	28,400,000	—
Accrued expenses	17,027	476,300
Accrued compensation	2,229,018	2,156,983
Operating lease liability	241,547	218,380
Total Current Liabilities	<u>35,814,803</u>	<u>5,778,997</u>
Deferred tax liability	6,713,800	6,137,800
Operating lease liability – non current	21,318	262,865
Total Liabilities	<u>42,549,921</u>	<u>12,179,662</u>
Commitments and Contingencies		
Stockholders' Equity:		
Preferred stock - \$0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock - \$0.001 par value; 16,000,000 shares authorized; 7,247,243 and 6,354,371 shares issued and outstanding at September 30, 2024 and 2023, respectively	7,247	6,354
Additional paid-in capital	271,440,421	253,056,133
Accumulated deficit	<u>(201,370,218)</u>	<u>(162,231,379)</u>
Total Citius Pharmaceuticals, Inc. Stockholders' Equity	70,077,450	90,831,108
Non-controlling interest	4,024,380	600,380
Total Equity	<u>74,101,830</u>	<u>91,431,488</u>
Total Liabilities and Equity	<u>\$ 116,651,751</u>	<u>\$ 103,611,150</u>

Reflects a 1-for-25 reverse stock split effective November 25, 2024.

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED SEPTEMBER 30, 2024 AND 2023

	2024	2023
Revenues	\$ —	\$ —
Operating Expenses:		
Research and development	11,906,601	14,819,729
General and administrative	18,249,402	15,295,584
Stock-based compensation – general and administrative	11,839,678	6,616,705
Total Operating Expenses	<u>41,995,681</u>	<u>36,732,018</u>

Operating Loss	<u>(41,995,681)</u>	<u>(36,732,018)</u>
Other Income:		
Interest income, net	758,000	1,179,417
Gain on sale of New Jersey net operating losses	<u>2,387,842</u>	<u>3,585,689</u>
Total Other Income Net	<u>3,145,842</u>	<u>4,765,106</u>
Loss before Income Taxes	<u>(38,849,839)</u>	<u>(31,966,912)</u>
Income tax expense	<u>576,000</u>	<u>576,000</u>
Net Loss	<u>(39,425,839)</u>	<u>(32,542,912)</u>
Net loss attributable to non-controlling interest	287,000	-
Deemed dividend on warrant extension	<u>(1,047,312)</u>	<u>(1,151,208)</u>
Net Loss Applicable to Common Stockholders	\$ (40,186,151)	(33,694,120)
Net Loss Per Share Applicable to Common Stockholders - Basic and Diluted	\$ (5.97)	(5.57)
Weighted Average Common Shares Outstanding		
Basic and diluted	6,726,999	6,051,789

Reflects a 1-for-25 reverse stock split effective November 25, 2024.

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED SEPTEMBER 30, 2024 AND 2023

	<u>2024</u>	<u>2023</u>
Cash Flows From Operating Activities:		
Net loss	\$ (39,425,839)	\$ (32,542,912)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	11,839,678	6,616,705
Issuance of common stock for services	284,176	102,000
Amortization of operating lease right-of-use asset	208,179	191,648
Depreciation	1,432	2,668
Deferred income tax expense	576,000	576,000
Changes in operating assets and liabilities:		
Inventory	(2,133,871)	-
Prepaid expenses	(945,389)	(5,036,926)
Accounts payable	1,999,877	1,761,956
Accrued expenses	(459,273)	(929,094)
Accrued compensation	72,035	394,732
Operating lease liability	<u>(218,380)</u>	<u>(196,989)</u>
Net Cash Used In Operating Activities	<u>(28,201,375)</u>	<u>(29,060,212)</u>
Cash Flows From Investing Activities:		
License payment	<u>(5,000,000)</u>	-
Net Cash Used In Investing Activities	<u>(5,000,000)</u>	-
Cash Flows From Financing Activities:		
Proceeds from common stock option exercises	-	31,267
Merger, net	(3,831,357)	-
Net proceeds from registered direct offerings	<u>13,803,684</u>	<u>13,798,183</u>
Net Cash Provided By Financing Activities	<u>9,972,327</u>	<u>13,829,450</u>
Net Change in Cash and Cash Equivalents	<u>(23,229,048)</u>	<u>(15,230,762)</u>
Cash and Cash Equivalents – Beginning of Year	<u>26,480,928</u>	<u>41,711,690</u>
Cash and Cash Equivalents – End of Year	\$ 3,251,880	\$ 26,480,928
Supplemental Disclosures of Cash Flow Information and Non-cash Activities:		
IPR&D Milestones included in License Payable	\$ 28,400,000	\$ -
Prepaid Manufacturing transferred to Inventory	\$ 6,134,895	\$ -

Reflects a 1-for-25 reverse stock split effective November 25, 2024.

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