NEWS RELEASE

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

2024-12-27

CRANFORD, N.J., Dec. 27, 2024 /PRNewswire/ -- Citius Oncology, Inc. ("Citius Oncology" or the "Company") (Nasdaq: CTOR), a specialty biopharmaceutical company focused on the development and commercialization of novel targeted oncology therapies, 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);

- Began trading on the Nasdaq exchange under the ticker symbol CTOR on August 13, 2024, following completion of the merger of Citius Pharma's oncology subsidiary with TenX Keane to form Citius Oncology, Inc., a standalone publicly traded company;

- Advanced manufacturing, marketing and sales activities in preparation for commercial launch of LYMPHIR in the first half of 2025; key activities included:
    - Manufactured initial inventory for launch and finalized supply chain agreements,

    - Initiated recruitment of targeted field force with contract sales organization,

- Launched a marketing awareness campaign and engaged with all leading CTCL prescribers,

- Applied for a unique J-code within the Healthcare Common Procedure Coding System (HCPCS) to facilitate accurate reimbursement,

- Secured inclusion of LYMPHIR in the National Comprehensive Cancer Network (NCCN) guidelines, critical to clinical decision-making in oncology and hematology, influencing treatment practices and payor reimbursement in the U.S., and

- Initiated development of the patient support center to help patients access LYMPHIR expeditiously;

- 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; and,

- 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.
    - The combination of these two immunomodulatory agents showed clinical benefit in relapsed or refractory gynecological neoplasms, resulting in:
        - 27% objective response rate and 33% clinical benefit rate with median progression free survival of 57 weeks (range: 30-96 weeks), and

        - A manageable safety profile whereby the regimen was well-tolerated with reversible treatment emergent adverse events and no definitive immune-related adverse events greater than or equal to grade 3 documented.

Financial Highlights

- R&D expenses were $4.9 million for the full year ended September 30, 2024, compared to $4.2 million for the full year ended September 30, 2023;

- G&A expenses were $8.1 million for the full year ended September 30, 2024, compared to $5.9 million for the full year ended September 30, 2023;

- Stock-based compensation expense was $7.5 million for the full year ended September 30, 2024, compared

to $2.0 million for the full year ended September 30, 2023; and,

- Net loss was $21.1 million, or ($0.31) per share for the full year ended September 30, 2024 compared to a net loss of $12.7 million, or ($0.19) per share for the full year ended September 30, 2023.

"Reflecting on 2024, Citius Oncology has achieved pivotal milestones that underscore our commitment to advancing cancer therapeutics," stated Leonard Mazur, Chairman and CEO of Citius Oncology. "The FDA's approval of LYMPHIR for the treatment of cutaneous T-cell lymphoma marks a significant advancement in providing new options for patients battling this challenging disease. It is the only targeted systemic therapy approved for CTCL patients since 2018 and the only therapy with a mechanism of action that targets the IL-2 receptor. Additionally, the successful merger forming Citius Oncology, now trading on Nasdaq under the ticker CTOR, strengthens our position in the oncology sector. We expect it to facilitate greater access to capital to fund LYMPHIR's launch and the Company's future growth. With a Phase I investigator-initiated clinical trial combining LYMPHIR with pembrolizumab demonstrating promising preliminary results, indicating potential for enhanced treatment efficacy in recurrent solid tumors, and preliminary results expected from a second investigator trial with CAR-T therapies in 2025, we remain excited about the potential of LYMPHIR as a combination immunotherapy."

"These accomplishments reflect the dedication of our team and the trust of our investors. As we look ahead, we remain steadfast in our mission to develop innovative therapies that improve the lives of cancer patients worldwide," added Mazur.

FULL YEAR 2024 FINANCIAL RESULTS:

Research and Development (R&D) Expenses

R&D expenses were $4.9 million for the full year ended September 30, 2024, compared to $4.2 million for the full year ended September 30, 2023. The increase reflects development activities completed for the resubmission of the Biologics License Application of LYMPHIR in January 2024, which were associated with the complete response letter remediation.

General and Administrative (G&A) Expenses

G&A expenses were $8.1 million for the full year ended September 30, 2024, compared to $5.9 million for the full year ended September 30, 2023. The increase was primarily due to costs associated with pre-commercial and commercial launch activities of LYMPHIR including market research, marketing, distribution and drug product reimbursement from health plans and payers.

Stock-based Compensation Expense

For the full year ended September 30, 2024, stock-based compensation expense was $7.5 million as compared to $2.0 million for the prior year. The primary reason for the $5.5 million increase was due to the amounts being realized over 12 months in the year ended September 30, 2024, as compared to three months post-plan adoption in the year ended September 30, 2023.

Net loss

Net loss was $21.1 million, or ($0.31) per share for the year ended September 30, 2024, compared to a net loss of $12.7 million, or ($0.19) per share for the year ended September 30, 2023. The $8.5 million increase in net loss was primarily due to the increase in our operating expenses.

About Citius Oncology, Inc.

Citius Oncology specialty is a biopharmaceutical company focused on developing and commercializing novel targeted oncology therapies. In August 2024, its primary asset, LYMPHIR, was approved by the FDA for the treatment of adults with relapsed or refractory CTCL who had had at least one prior systemic therapy. Management estimates the initial market for LYMPHIR currently exceeds $400 million, is growing, and is underserved by existing therapies. Robust intellectual property protections that span orphan drug designation, complex technology, trade secrets and pending patents for immuno-oncology use as a combination therapy with checkpoint inhibitors would further support Citius Oncology's competitive positioning. Citius Oncology is a publicly traded subsidiary of Citius Pharmaceuticals. For more information, please visit **www.citiusonc.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 Oncology. 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 Oncology 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 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; our dependence on third-party suppliers; our ability to procure cGMP commercial-scale supply; risks related to research using our assets but conducted by third parties; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; uncertainties relating to preclinical and clinical testing; 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 Oncology'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 –

CITIUS ONCOLOGY, INC.
CONSOLIDATED BALANCE SHEETS
SEPTEMBER 30, 2024 AND 2023

	2024	2023
Current Assets:		

Cash and cash equivalents	$ 112	$ —
Inventory	8,268,766	—
Prepaid expenses	2,700,000	7,734,895
Total Current Assets	10,968,878	7,734,895
Other Assets:		
In-process research and development	73,400,000	40,000,000
Total Other Assets	73,400,000	40,000,000
Total Assets	$ 84,368,878	$ 47,734,895
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 3,711,622	$ 1,289,045
License payable	28,400,000	—
Accrued expenses	—	259,071
Due to related party	588,806	19,499,119
Total Current Liabilities	32,700,429	21,047,235
Deferred tax liability	1,728,000	1,152,000
Note payable to related party	3,800,111	—
Total Liabilities	38,228,540	22,199,235
Stockholders' Equity:		
Preferred stock - $0.0001 par value; 10,000,000 shares authorized: no shares issued and outstanding	—	—
Common stock - $0.0001 par value; 100,000,000; 71,552,402 and 67,500,000 shares issued and outstanding at September 30, 2024 and 2023, respectively	7,155	6,750
Additional paid-in capital	85,411,771	43,658,750
Accumulated deficit	(39,278,587)	(18,129,840)
Total Stockholders' Equity	46,140,339	25,535,660
Total Liabilities and Stockholders' Equity	$ 84,368,878	$ 47,734,895

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

	2024	2023
Revenues	$ —	$ —
Operating Expenses:		
Research and development	4,925,001	4,240,451
General and administrative	8,148,929	5,915,290
Stock-based compensation – general and administrative	7,498,817	1,965,500
Total Operating Expenses	20,572,747	12,121,241
Loss before Income Taxes	(20,572,747)	(12,121,241)
Income tax expense	576,000	576,000
Net Loss	$ (21,148,747)	$ (12,697,241)
Net Loss Per Share – Basic and Diluted	$ (0.31)	$ (0.19)
Weighted Average Common Shares Outstanding – Basic and Diluted	68,053,607	67,500,000

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

	2024	2023
Cash Flows From Operating Activities:		
Net loss	$ (21,148,747)	$ (12,697,241)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Stock-based compensation expense	7,498,817	1,965,500
Deferred income tax expense	576,000	576,000
Changes in operating assets and liabilities:		
Inventory	(2,133,871)	-
Prepaid expenses	(1,100,000)	(5,044,713)
Accounts payable	2,422,577	1,196,734
Accrued expenses	(259,071)	(801,754)
Due to related party	14,270,648	14,805,474
Net Cash Provided By Operating Activities	126,353	-
Cash Flows From Investing Activities:		
License payment	(5,000,000)	-
Net Cash Used In Investing Activities	(5,000,000)	-
Cash Flows From Financing Activities:		
Cash contributed by parent	3,827,944	-
Merger, net	(2,754,296)	-
Proceeds from issuance of note payable to related party	3,800,111	-
Net Cash Provided By Financing Activities	4,873,759	-
Net Change in Cash and Cash Equivalents	112	-
Cash and Cash Equivalents – Beginning of Year	-	-
Cash and Cash Equivalents – End of Year	$ 112	$ -
Supplemental Disclosures of Cash Flow Information and Non-cash Activities:		
IPR&D Milestones included in License Payable	$ 28,400,000	$ -
Capital Contribution of due to related party by parent	$ 33,180,961	$ -
Prepaid Manufacturing transferred to Inventory	$ 6,134,895	$ -

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