Carisma Therapeutics Reports Second Quarter 2024 Financial Results and Recent Business Highlights

August 8, 2024

Initial data for CT-0525, lead product candidate for anti-HER2 program, expected by year-end 2024

Nomination of a development candidate for liver fibrosis program expected in the first quarter of 2025

Nominated first in vivo CAR-M development candidate targeting Glypican-3 to treat hepatocellular carcinoma under the Moderna Collaboration in the second quarter of 2024

Cash and cash equivalents of $40.4 million and $2.0 million received in July under the Moderna Collaboration expected to fund the Company into the third quarter of 2025

PHILADELPHIA, Aug. 8, 2024 /PRNewswire/ -- Carisma Therapeutics Inc. (Nasdaq: CARM) ("Carisma" or the "Company"), a clinical-stage biopharmaceutical company focused on discovering and developing innovative immunotherapies, today reported financial results for the quarter ended June 30, 2024, and highlighted recent business updates.

"We've achieved considerable clinical and research advancements this year, and I'm excited about our strong momentum and clear focus for the next 12 months," said Steven Kelly, President and Chief Executive Officer of Carisma. "The CT-0508 program has provided us with invaluable insights. Looking ahead, we are dedicating our efforts to our lead asset, CT-0525, which is actively enrolling patients with initial data expected by the end of 2024. We have also made significant progress in our *in vivo* oncology and fibrosis programs. The nomination of a development candidate in collaboration with Moderna marks a significant step forward. We believe our robust development pipeline offers multiple potential value drivers in both the near and long term."

Second Quarter 2024 Highlights and Upcoming Milestones

Ex Vivo Oncology

- **CT-0525 (Anti-HER2 chimeric antigen receptor monocyte (CAR-Monocyte))**
  - On May 16, 2024, Carisma announced that the first patient was dosed in its Phase 1 clinical trial evaluating CT-0525, an *ex vivo* gene-modified autologous CAR-Monocyte cellular therapy, for the treatment of patients with solid tumors that overexpress human epidermal growth factor receptor 2 (HER2).
  - On June 25, 2024, Carisma announced the U.S. Food and Drug Administration granted Fast Track designation for CT-0525.
  - Carisma expects to report initial data from its Phase 1 clinical trial by year-end 2024.

- **CT-0508 (Anti-HER2 chimeric antigen receptor macrophage (CAR-Macrophage))**
  - As of July 2024, all clinical activities related to the clinical trial of CT-0508 and its sub-study utilizing CT-0508 in combination with pembrolizumab, have been completed.
  - On July 9, 2024, the Company announced a new analysis of circulating tumor DNA (ctDNA) from 13 patients enrolled in Groups 1 and 2 of the Phase 1 clinical trial of CT-0508. Although preliminary and limited, the data showed that 75% (n=6/8) of evaluable HER2 3+ patients experienced a decrease in ctDNA, indicating anti-tumor activity.
  - On August 8, 2024, Carisma updated the results of the open label Phase 1 sub-study evaluating the co-administration of CT-0508 and pembrolizumab, a programmed cell death protein 1 checkpoint inhibitor to include data from Regimen Level 2 (RL2) (n=3 patients). The study met its primary endpoints of safety, tolerability and manufacturing feasibility of CT-0508. The pembrolizumab sub-study data from Regimen Level 1 and RL2 (n=6 patients) demonstrate that the combination therapy was generally well-tolerated with no dose-limiting toxicities. The best overall response was stable disease (n=1/6 patients), with corticosteroid administration and / or loss of human leukocyte antigens (HLA) expression being key limitations to potential efficacy in three of the patients who experienced progressive disease. The correlative data concerning immune activation suggest a synergistic potential for the combination of CT-0508 with pembrolizumab based on increased peripheral blood T cell clonality, T cell activation, and frequency of effector memory CD8 T cells compared to CT-0508 alone. Supported by these safety and translational findings, as well as other results from the clinical trial of CT-0508, Carisma intends to explore the strategy of combining CAR-Monocyte with pembrolizumab or another checkpoint inhibitor in the CT-0525 program.

In Vivo Oncology

- **GPC3+ solid tumors (CAR-M + mRNA/LNP; Moderna Collaboration)**

- On June 27, 2024, Carisma announced the nomination of the first development candidate under its collaboration with ModernaTX Inc. ("Moderna"). The development candidate is an *in vivo* chimeric antigen receptor macrophage and monocyte, or CAR-M, targeting Glypican-3 and is designed to treat solid tumors, including hepatocellular carcinoma, the most prevalent type of liver cancer and the fastest-rising cause of cancer-related death in the United States. On July 3, 2024, the Company received the associated $2.0 million milestone payment from Moderna.
- The Company expects to present preclinical data from the development candidate at an upcoming medical meeting.

Fibrosis and Immunology

- **Fibrosis**
  - On August 6, 2024, Carisma announced that additional preclinical data for liver fibrosis will be highlighted in a poster presentation at the American Association for the Study of Liver Diseases The Liver Meeting 2024, being held November 15-19, 2024, in San Diego, CA.
  - Carisma expects to nominate a development candidate for its liver fibrosis program in the first quarter of 2025.

Corporate Updates

- On July 1, 2024, Carisma announced the appointment of David Scadden, M.D., and Marella Thorell to the Company's Board of Directors, effective June 30, 2024. David Scadden, M.D., is a renowned physician and medical researcher with extensive clinical and medical research experience. Marella Thorell brings more than 25 years of extensive experience in finance and operations across both public and private biotech companies. The Company concurrently announced the resignation of Regina Hodits and Björn Odlander from Carisma's Board of Directors, also effective June 30, 2024.
- On August 6, 2024, Carisma announced the appointment of Scott Friedman, M.D. and Ira Tabas, M.D., Ph.D. to its Scientific Advisory Board. Dr. Friedman and Dr. Tabas bring extensive expertise and pioneering contributions in liver fibrosis, which will be instrumental as Carisma continues its program to develop transformative treatments for patients.

Second Quarter 2024 Financial Results

- Cash and cash equivalents as of June 30, 2024, were $40.4 million, compared to $56.5 million as of March 31, 2024.
- Research and development expenses for the three months ended June 30, 2024 were $15.3 million, compared to $18.5 million for the three months ended June 30, 2023. The decrease of $3.2 million was primarily due to a $2.9 million decrease in our facilities and other expenses associated with a decrease in sponsored research agreement fees, a $1.7 million decrease in direct costs associated with CT-0508, a $0.2 million decrease in direct costs associated with the pre-clinical development related to CT-1119, a $0.1 million decrease in costs associated with a reduction in pass through studies, partially offset by a $1.2 million increase in direct costs associated with pre-clinical development of CT-0525 and a $0.5 million increase in personnel costs due to severance costs related to the revised operating plan.
- General and administrative expenses for the three months ended June 30, 2024 were $5.6 million, compared to $6.0 million for the three months ended June 30, 2023. The decrease of $0.4 million was attributable to a $1.2 million decrease in professional fees as a result of non-recurring legal costs associated with the merger with Sesen Bio, Inc. in 2023, and a $0.4 million decrease in insurance costs, partially offset by a $0.7 million increase in facilities and supplies due to a rise in office expenditures, and a $0.5 million increase in personnel costs which includes an increase in personnel costs which includes a raise in salaries and headcount, stock-based compensation, and severance costs related to the revised operating plan.
- Net loss was $11.2 million for the second quarter of 2024, compared to a $19.9 million net loss for the same period in 2023.

Outlook

Carisma anticipates that its cash and cash equivalents of $40.4 million as of June 30, 2024 are sufficient to sustain its planned operations into the third quarter of 2025. The Company's cash forecast contains estimates and assumptions, and management cannot predict the timing of all cash receipts and expenditures with certainty. Variances from management's estimates and assumptions could impact the Company's liquidity prior to the third quarter of 2025.

About CT-0525

CT-0525 is a first-in-class, *ex vivo* gene-modified autologous chimeric antigen receptor-monocyte (CAR-Monocyte) cellular therapy intended to treat solid tumors that overexpress human epidermal growth factor receptor 2 (HER2). It is being studied in a multi-center, open label, Phase 1 clinical trial for patients with advanced/metastatic HER2-overexpressing solid tumors that have progressed on available therapies. The CAR-Monocyte approach has the potential to address some of the challenges of treating solid tumors with cell therapies, including tumor infiltration, immunosuppression within the tumor microenvironment, and antigen heterogeneity. CT-0525 has the potential to enable significant dose escalation, enhance tumor infiltration, increase persistence, and reduce manufacturing time compared to macrophage therapy.

About Carisma Therapeutics

Carisma Therapeutics Inc. is a clinical-stage biopharmaceutical company focused on utilizing our proprietary macrophage and monocyte cell engineering platform to develop transformative immunotherapies to treat cancer and other serious diseases. We have created a comprehensive,

differentiated proprietary cell therapy platform focused on engineered macrophages and monocytes, cells that play a crucial role in both the innate and adaptive immune response. Carisma is headquartered in Philadelphia, PA. For more information, please visit www.carismatx.com.

Cautionary Note on Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements relating to Carisma's business, strategy, future operations, cash runway, the advancement of Carisma's product candidates and product pipeline, and clinical development of Carisma's product candidates, including expectations regarding timing of initiation and results of clinical trials. The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "goals," "intend," "may," "might," "outlook," "plan," "project," "potential," "predict," "target," "possible," "will," "would," "could," "should," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in, or implied by, such forward-looking statements. These risks and uncertainties include, but are not limited to, (i) Carisma's ability to realize the anticipated benefits of its pipeline reprioritization and corporate restructuring, (ii) Carisma's ability to obtain, maintain and protect its intellectual property rights related to its product candidates; (iii) Carisma's ability to advance the development of its product candidates under the timelines it anticipates in planned and future clinical trials and with its current financial and human resources; (iv) Carisma's ability to replicate in later clinical trials positive results found in preclinical studies and early-stage clinical trials of its product candidates; (v) Carisma's ability to realize the anticipated benefits of its research and development programs, strategic partnerships, research and licensing programs and academic and other collaborations; (vi) regulatory requirements or developments and Carisma's ability to obtain and maintain necessary approvals from the U.S. Food and Drug Administration and other regulatory authorities related to its product candidates; (vii) changes to clinical trial designs and regulatory pathways; (viii) risks associated with Carisma's ability to manage expenses; (ix) changes in capital resource requirements; (x) risks related to the inability of Carisma to obtain sufficient additional capital to continue to advance its product candidates and its preclinical programs; and (xi) legislative, regulatory, political and economic developments.

For a discussion of these risks and uncertainties, and other important factors, any of which could cause Carisma's actual results to differ from those contained in the forward-looking statements, see the "Risk Factors" set forth in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, its Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, as well as discussions of potential risks, uncertainties, and other important factors in Carisma's other recent filings with the Securities and Exchange Commission. Any forward-looking statements that are made in this press release speak as of the date of this press release. Carisma undertakes no obligation to revise the forward-looking statements or to update them to reflect events or circumstances occurring after the date of this press release, whether as a result of new information, future developments or otherwise, except as required by the federal securities laws.

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CARISMA THERAPEUTICS INC.
Unaudited Consolidated Balance Sheets
(in thousands, except share and par value)

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 40,362	$ 77,605
Prepaid expenses and other assets	10,359	2,866
Total current assets	50,721	80,471
Property and equipment, net	6,531	6,764
Right of use assets – operating leases	1,945	2,173
Deferred financing costs	142	146
Total assets	$ 59,339	$ 89,554
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,033	$ 3,933
Accrued expenses	9,241	7,662
Deferred revenue	659	1,413
Operating lease liabilities	1,179	1,391
Finance lease liabilities	1,283	544
Other current liabilities	1,222	965

Total current liabilities	15,617	15,908
Deferred revenue	41,250	45,000
Operating lease liabilities	795	860
Finance lease liabilities	502	328
Other long-term liabilities	815	926
Total liabilities	58,979	63,022
Stockholders' equity:		
Preferred stock $0.001 par value, 5,000,000 shares authorized, none issued or outstanding	—	—
Common stock $0.001 par value, 350,000,000 shares authorized, 41,544,975 and 40,609,915 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	41	40
Additional paid-in capital	275,561	271,594
Accumulated deficit	(275,242)	(245,102)
Total stockholders' equity	360	26,532
Total liabilities and stockholders' equity	$ 59,339	$ 89,554

CARISMA THERAPEUTICS INC.
Unaudited Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Three Months Ended June 30,	
	2024	**2023**
Collaboration revenues	$ 9,197	$ 3,560
Operating expenses:		
Research and development	15,307	18,518
General and administrative	5,560	6,007
Total operating expenses	20,867	24,525
Operating loss	(11,670)	(20,965)
Interest income (expense), net	508	1,177
Pre-tax loss	(11,162)	(19,788)
Income tax expense	—	(88)
Net loss	$ (11,162)	$ (19,876)
Share information:		
Net loss per share of common stock, basic and diluted	$ (0.27)	$ (0.49)
Weighted-average shares of common stock outstanding, basic and diluted	41,543,553	40,258,107
Comprehensive loss		
Net loss	$ (11,162)	$ (19,876)
Unrealized gain on marketable securities	—	129
Comprehensive loss	$ (11,162)	$ (19,747)

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