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

May 9, 2024

Announced CT-0525 as lead product candidate for anti-HER2 program; initial data expected by year-end 2024

Presented preclinical proof of concept data in liver fibrosis at ASGCT; expects to nominate a development candidate in the first quarter of 2025

Presented Regimen Level 1 data from Phase 1 sub-study utilizing CT-0508 in combination with pembrolizumab at AACR; expects to report Regimen Level 2 data in second quarter of 2024

Cash and cash equivalents of $56.5 million expected to fund the Company into the third quarter of 2025

PHILADELPHIA, May 9, 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 March 31, 2024, and highlighted recent business updates.

"We enter the second quarter with a renewed focus on our programs that we believe exhibit the greatest potential and meaningful near-term milestones," said Steven Kelly, President and Chief Executive Officer of Carisma. "We are pleased by the continued clinical validation of our anti-HER2 CAR-M program as evidenced by the initial data from CT-0508 and are excited to shift our attention to the development of CT-0525, which we believe has the potential to significantly increase anti-tumor activity. The preclinical proof of concept data in liver fibrosis fuels our momentum to explore the potential of engineered macrophages beyond oncology. Carisma remains committed to advancing next-generation cell therapies that hold the potential to enhance treatment options for patients grappling with cancer and other serious disorders."

First Quarter 2024 Highlights and Upcoming Milestones

Ex Vivo Oncology

- **CT-0525 (Anti-HER2 chimeric antigen receptor monocyte (CAR-Monocyte))**
  - In late March 2024, Carisma made the decision to prioritize CT-0525 due to the potential for a CAR-Monocyte to have an approximately 2,000-fold increase in total exposure compared to a CAR-Macrophage. As a result, the Company believes that CT-0525 will be able to build on clinical anti-tumor activity observed in CT-0508, the Company's anti-HER2 CAR-Macrophage. CT-0525 is now Carisma's lead product candidate.
  - Carisma expects to treat the first patient in the CT-0525 Phase 1 clinical study in the second quarter of 2024 and to report initial data from the study by year-end 2024.
- **CT-0508 (Anti-HER2 CAR-Macrophage)**
  - Due to the prioritization of CT-0525, Carisma has ceased recruitment of new patients into Study 101 and its sub-studies. However, the Company will continue all study operations for enrolled subjects.
  - On April 10, 2024, during its presentation at the American Association for Cancer Research (AACR) 2024 Annual Meeting, Carisma reported Regimen Level 1 data (n=3 patients) from the open label Phase 1 (Study 101) sub-study utilizing CT-0508 in combination with pembrolizumab, a programmed cell death protein 1 (PD-1) checkpoint inhibitor. Based on preliminary results from these three patients, the combination therapy has been generally well-tolerated after infusion with no dose-limiting toxicities. Carisma observed a best overall response of progressive disease in the first two patients and stable disease in the third patient, per RECIST 1.1 criteria. The patient who achieved stable disease presented the greatest increase in peripheral blood T cell clonality seen across all 17 patients treated to date in Study 101 and had one out of two target lesions reduced by approximately 46%.
  - Carisma expects to report data from Regimen Level 2 in the Study 101 sub-study evaluating the co-administration of CT-0508 and pembrolizumab in the second quarter of 2024.
- **CT-1119 (Anti-Mesothelin CAR-Monocyte)**
  - In late March 2024, Carisma made the decision to pause further development of CT-1119, pending additional financing.

Fibrosis and Immunology

- **Fibrosis**
  - On May 8, 2024, during its presentation at the American Society of Gene and Cell Therapy (ASGCT) 2024 Annual Meeting, Carisma reported preclinical proof of concept data of its engineered macrophages for the treatment of liver fibrosis.
  - In the presentation titled "Genetically Engineered Macrophage Cell Therapy Reverses Liver and Lung Fibrosis in Preclinical Models," Carisma presented preclinical proof of concept data for engineered macrophage cell therapy in liver fibrosis. In a CCL4-induced liver fibrosis model, the data showed that a single dose of macrophages

co-expressing the anti-fibrotic factor relaxin and the anti-inflammatory cytokine IL10 significantly improved established fibrosis with a 116% reduction in fibrosis relative to untreated control. In addition, systemic administration of engineered macrophages co-expressing relaxin and IL10 significantly reduced liver fibrosis in a high fat diet metabolic dysfunction-associated steatohepatitis (MASH) model, with a 45% reduction in fibrosis relative to untreated control. In both models, the relaxin-IL10 macrophage treatment also resulted in a greater reduction in liver fibrosis compared to non-engineered macrophages.

- The presentation also included initial preclinical data for the use of engineered macrophages in pulmonary fibrosis. The data showed that a single dose of macrophages expressing a dominant negative TGFβ receptor, which nullified pro-fibrotic TGFβ signaling in the lung, prevented fibrosis in a bleomycin mouse model of pulmonary fibrosis, with a 90% reduction in fibrosis relative to untreated control.
- Carisma expects to nominate a development candidate for its liver fibrosis program in the first quarter of 2025.

Corporate Updates

- On May 2, 2024, Carisma announced the appointment of Eugene P. Kennedy, M.D., F.A.C.S. as the Company's Chief Medical Officer. Dr. Kennedy brings over 15 years of clinical and industry experience, including cross-functional leadership driving clinical development and regulatory strategies for oncology and immuno-oncology focused organizations.
- On April 1, 2024, Carisma announced a pipeline reprioritization and corporate restructuring. The pipeline reprioritization includes stopping recruitment of new patients in the Phase 1 clinical study of CT-0508 (Study 101) to focus the Company's efforts and resources on CT-0525 as its lead anti-HER2 product candidate, as well as pausing development of CT-1119 pending additional financing. As a result of the pipeline reprioritization and corporate restructuring, Carisma reduced its workforce by approximately 37% in the second quarter of 2024.
- On April 1, 2024, Carisma announced the appointment of John Hohneker, M.D. to the Board of Directors of the Company, effective April 1, 2024. Dr. Hohneker brings over 30 years of extensive experience in drug development and leadership across the biotech and pharmaceutical sectors. The Company concurrently announced the resignation of Chidozie Ugwumba from Carisma's Board of Directors, also effective April 1, 2024.

First Quarter 2024 Financial Results

- Cash and cash equivalents as of March 31, 2024 were $56.5 million, compared to $77.6 million as of December 31, 2023.
- Research and development expenses for the three months ended March 31, 2024 were $17.5 million, compared to $16.6 million for the three months ended March 31, 2023. The increase of $0.8 million was primarily due to a $0.9 million increase in personnel costs due to increased stock-based compensation and payroll, $0.7 million increase in direct costs associated with pre-clinical development of CT-0525, a $0.4 million increase in direct costs associated with the pre-clinical development related to CT-1119, partially offset by a $0.7 million decrease in direct costs associated with CT-0508, a $0.4 million decrease in our facilities and other expenses associated with a decrease in sponsored research agreement fees, and a $0.1 million decrease in costs associated with a reduction in pass through studies.
- General and administrative expenses for the three months ended March 31, 2024 were $5.4 million, compared to $9.6 million for the three months ended March 31, 2023. The decrease of $4.1 million was attributable to a $3.5 million decrease in personnel costs including severance and related costs resulting from the Merger offset by an increase in salaries and stock-based compensation, and a $0.7 million decrease in professional fees as a result of non-recurring legal costs associated with the Merger.
- Net loss was $19.0 million for the first quarter of 2024, compared to a $24.6 million net loss for the same period in 2023.

Outlook

Carisma anticipates that its cash and cash equivalents of $56.5 million as of March 31, 2024, combined with the expected cost savings from implementing the revised operating plan, are sufficient to sustain its planned operations into 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 CT-0508.

About CT-0508

CT-0508 is an *ex vivo* gene-modified autologous chimeric antigen receptor-macrophage (CAR-Macrophage) cellular therapy intended to treat solid tumors that overexpress HER2. It is being evaluated in a Phase 1 multi-center clinical trial that focuses on patients with recurrent or metastatic HER2-overexpressing solid tumors whose cancers do not have approved HER2-targeted therapies or who do not respond to treatment. The Phase 1 clinical trial marks the first time that engineered macrophages are being studied in humans.

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, 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 per share data)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 56,515	$ 77,605
Prepaid expenses and other assets	4,438	2,866
Total current assets	60,953	80,471
Property and equipment, net	7,550	6,764
Right of use assets – operating leases	5,150	2,173
Deferred financing costs	142	146
Total assets	$ 73,795	$ 89,554
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,166	$ 3,933
Accrued expenses	4,729	7,662
Deferred revenue	1,189	1,413
Operating lease liabilities	2,474	1,391
Finance lease liabilities	1,390	544
Other current liabilities	1,193	965

Total current liabilities	13,141	15,908
Deferred revenue	45,000	45,000
Operating lease liabilities	2,759	860
Finance lease liabilities	869	328
Other long-term liabilities	1,131	926
Total liabilities	62,900	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, 41,542,744 and 40,609,915 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	41	40
Additional paid-in capital	274,934	271,594
Accumulated deficit	(264,080)	(245,102)
Total stockholders' equity	10,895	26,532
Total liabilities and stockholders' equity	$ 73,795	$ 89,554

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

	Three Months Ended March 31,	
	2024	**2023**
Collaboration revenues	$ 3,397	$ 3,243
Operating expenses:		
Research and development	17,462	16,641
General and administrative	5,445	9,574
Total operating expenses	22,907	26,215
Operating loss	(19,510)	(22,972)
Change in fair value of derivative liability	—	(84)
Interest income (expense), net	532	(1,477)
Pre-tax loss	(18,978)	(24,533)
Income tax expense	—	(109)
Net loss	$ (18,978)	$ (24,642)
Share information:		
Net loss per share of common stock, basic and diluted	$ (0.46)	$ (1.93)
Weighted-average shares of common stock outstanding, basic and diluted	40,938,464	12,783,523
Comprehensive loss		
Net loss	$ (18,978)	$ (24,642)
Unrealized gain on marketable securities	—	177
Comprehensive loss	$ (18,978)	$ (24,465)

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