Carisma Therapeutics Reports Second Quarter 2023 Financial Results and Recent Business Highlights

August 10, 2023

Dosed first patient in Phase 1 clinical trial of CT-0508 in combination with KEYTRUDA® (pembrolizumab) in patients with HER2-overexpressing solid tumors

Nominated additional oncology target as part of the Company's collaboration with Moderna to develop in-vivo targeted CAR-M therapies

Cash, cash equivalents and marketable securities of $117.1 million expected to fund company through 2024

PHILADELPHIA, Aug. 10, 2023 /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, 2023, and highlighted recent business updates.

"In the second quarter, the Carisma team successfully achieved the important clinical milestone of dosing the first patient in the Phase 1 clinical trial of CT-0508 in combination with KEYTRUDA, which represents the next step in our progression of engineering macrophages for the treatment of solid tumors," said Steven Kelly, President and Chief Executive Officer of Carisma. "We continue to execute on our overall strategic plan and we are excited to use this momentum to reach our upcoming potential value inflection points within our HER2 franchise and across our pipeline. We believe we are well-positioned to drive innovation as the leader in engineered macrophages and deliver value to our stakeholders."

Pipeline Updates

- **CT-0508**
  - Announced the first patient has been dosed in the Company's Phase I clinical trial that will test the safety and tolerability of the Company's lead candidate, CT-0508, a human epidermal growth factor receptor 2 (HER2) targeted chimeric antigen receptor macrophage (CAR-M) in combination with Merck's anti-PD1 therapy KEYTRUDA® (pembrolizumab) for the treatment of HER2 overexpressing solid tumors.
- **In Vivo Oncology Program (Moderna Collaboration)**
  - Nominated and initiated research on an additional oncology target under the Moderna research collaboration to develop in-vivo targeted CAR-M therapies. The goal of the program, which now has five nominated targets, is to create novel in vivo CAR-M therapies with an approach that uses Moderna's mRNA/LNP technology together with Carisma's CAR-M platform technology.

Recent Business Highlights

- **Expanded Leadership Team to support legal and human resources functions.** The Company appointed Eric Siegel as General Counsel and Corporate Secretary and Terry Shields as Senior Vice President of Human Resources. Mr. Siegel and Ms. Shields each bring to Carisma more than 25 years of experience in their respective fields.
- **Added to the Russell 2000, Russell 3000, and Russell Microcap Indexes.** Following the conclusion of the 2023 Russell indexes annual reconstitution, the Company joined three Russell indexes that capture the 4,000 largest U.S. stocks as of April 28, 2023, ranked by total market capitalization.

Anticipated Upcoming Milestones

- Data from Group 2 of Phase 1 clinical trial of CT-0508 expected in the second half of 2023
- Initial data from Phase 1 clinical trial of CT-0508 in combination with KEYTRUDA® (pembrolizumab) expected in the second half of 2023
- Submission of Investigational New Drug (IND) application to the U.S. Food and Drug Administration for CT-0525, Carisma's first anti-HER2 CAR-Monocyte product candidate, expected in the second half of 2023
- Selection of next-generation candidate for CT-1119 expected in the first half of 2024
- Proof-of-concept data for the Company's initial non-oncology program expected in the first half of 2024

Second Quarter 2023 Financial Results

- Cash, cash equivalents and marketable securities as of June 30, 2023 were $117.1 million, compared to $139.0 million as of March 31, 2023.
- Research & development expenses were $18.5 million for the second quarter of 2023, compared to $14.2 million for the same period in 2022. The increase of $4.3 million was primarily due to a $1.5 million increase in direct costs associated with the preclinical development of CT-0525, a $1.3 million increase in direct costs associated with CT-0508, a $1.0 million increase in personnel costs due to growth in research and development employee headcount, a $0.5 million increase in direct costs related to CT-1119, and a $0.2 million increase in facilities and other expenses due to an increase in rent expense, partially offset by a $0.2 million decrease of other clinical and pre-clinical development expenses associated with tracking CT-0525 and CT-1119 separately.
- General & administrative expenses were $6.0 million for the second quarter of 2023, compared to $2.4 million for the same period in 2022. The increase of $3.6 million was attributable to $1.9 million increase in legal and professional fees in support of our expanding infrastructure and patent portfolio, a $1.5 million increase of higher personnel costs as a result of an increase in headcount, as well as a $0.3 million increase in other expenses due to an increase in travel and other administrative costs, partially offset by a $0.1 million decrease in facilities and supplies due to a decline in office expenditures.
- Net loss was $19.9 million for the second quarter of 2023, compared to net loss of $14.8 million for the same period in 2022, primarily due to increased research and development expenses to support CT-0508 and CT-0525 as well as increase in expanding headcount and infrastructure, which was partially offset by Moderna collaboration revenue.

Outlook

Carisma believes that its cash, cash equivalents and marketable securities of $117.1 million as of June 30, 2023, are sufficient to sustain Carisma's planned operations through the end of 2024.

About CT-0508

CT-0508 is a human epidermal growth factor receptor 2 (HER2) targeted chimeric antigen receptor macrophage (CAR-M). It is being evaluated in a landmark 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. Carisma is selecting participants who have tumors of any anatomical origin, but with the commonality of overexpressing the HER2 receptor on the cell surface, which is the target for its CAR-M. The Phase 1 clinical trial is first-of-its-kind, marking the first time that engineered macrophages are being studied in humans. The trial continues to enroll patients at seven clinical sites in the U.S., including (i) the University of Pennsylvania Abramson Cancer Center, (ii) the University of North Carolina Lineberger Comprehensive Cancer Center, (iii) the City of Hope National Medical Center, (iv) the MD Anderson Cancer Center, (v) the Sarah Cannon Cancer Research Institute, (vi) Oregon Health & Science University and (vii) Fred Hutchinson Cancer Center.

About Carisma

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 Therapeutics' 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 obtain, maintain and protect its intellectual property rights related to its product candidates; (ii) Carisma's ability to advance the development of its product candidates under the timelines it anticipates in planned and future clinical trials; (iii) Carisma's ability to replicate in later clinical trials positive results found in preclinical studies and early-stage clinical trials of its product candidates; (iv) 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; (v) 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; (vi) changes to clinical trial designs and regulatory pathways; (vii) risks associated with Carisma's ability to manage expenses; (viii) changes in capital resource requirements; (ix) risks related to the inability of Carisma to obtain sufficient additional capital to continue to advance its product candidates and its preclinical programs; and (x) 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 10, 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)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 76,353	$ 24,194
Marketable securities	40,725	27,802
Prepaid expenses and other assets	5,122	2,596
Total current assets	122,200	54,592
Property and equipment, net	7,590	8,628
Right of use assets – operating leases	3,047	4,822
Restricted cash	30	—
Deferred financing costs	146	4,111
Total assets	$ 133,013	$ 72,153
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,487	$ 1,728
Accrued expenses	9,614	10,361
Deferred revenue	1,416	2,459
Operating lease liabilities	2,486	3,437
Finance lease liabilities	1,215	1,162
Other current liabilities	755	523
Total current liabilities	17,973	19,670
Deferred revenue	45,000	45,000
Convertible promissory note	—	33,717
Derivative liability	—	5,739
Operating lease liabilities	920	976
Finance lease liabilities	606	872
Other long-term liabilities	1,809	1,041
Total liabilities	66,308	107,015
Convertible preferred stock	—	107,808
Stockholders' equity (deficit):		
Common stock $0.001 par value, 350,000,000 shares authorized, 40,269,576 and 2,217,737 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	40	2
Additional paid-in capital	269,141	1,197
Accumulated other comprehensive income (loss)	265	(41)
Accumulated deficit	(202,741)	(158,223)
Total Carisma Therapeutics Inc. stockholders' equity (deficit)	66,705	(157,065)
Noncontrolling interests	—	14,395
Total stockholders' equity (deficit)	66,705	(142,670)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 133,013	$ 72,153

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

	Three Months Ended June 30,

	2023	2022
Collaboration revenues	$ 3,560	$ 2,703
Operating expenses:		
Research and development	18,518	14,212
General and administrative	6,007	2,424
Total operating expenses	24,525	16,636
Operating loss	(20,965)	(13,933)
Change in fair value of derivative liability	—	(144)
Interest income (expense), net	1,177	(771)
Pre-tax loss	(19,788)	(14,848)
Income tax expense	(88)	—
Net loss	$ (19,876)	$ (14,848)
Share information:		
Net loss per share of common stock, basic and diluted	$ (0.49)	$ (7.20)
Weighted-average shares of common stock outstanding, basic and diluted	40,258,107	2,061,643
Comprehensive loss		
Net loss	$ (19,876)	$ (14,848)
Unrealized gain (loss) on marketable securities	129	(39)
Comprehensive loss	$ (19,747)	$ (14,887)

SOURCE Carisma Therapeutics Inc.