Carisma Therapeutics Reports Fiscal 2022 Financial Results and Recent Business Highlights

April 4, 2023

Closed merger with Sesen Bio and commenced trading on Nasdaq under ticker symbol "CARM"

Cash position as of the closing of the merger with Sesen Bio provides anticipated operating runway through 2024

PHILADELPHIA, April 4, 2023 /PRNewswire/ -- Carisma Therapeutics Inc. (Nasdaq: CARM), a clinical-stage biopharmaceutical company focused on discovering and developing innovative immunotherapies, today reported financial results for the year ended December 31, 2022 and highlighted recent business updates.

"2022 was a transformational year for Carisma as we made meaningful progress across all areas of our business, including entering a development collaboration with Moderna, advancing our lead program CT-0508 in HER2+ solid tumors, and announcing our merger with Sesen Bio," said Steven Kelly, President and Chief Executive Officer of Carisma. "The successful close of the merger and concurrent financing has further strengthened our foundation, enabling us to continue to advance our pipeline of important therapies. We look forward to the multiple potential value inflection points over the next 18 months, including the completion of our Phase 1 study of CT-0508, as well as data from clinical trial sub-study of CT-0508 in combination with pembrolizumab."

Recent Business Highlights

- **Completed merger transaction with Sesen Bio in March 2023.** Carisma Therapeutics and Sesen Bio closed the previously announced merger, pursuant to which the combined company changed its name to "Carisma Therapeutics Inc." and commenced trading on The Nasdaq Global Market under the symbol "CARM." The combined company will focus on the development of Carisma's chimeric antigen receptor macrophage (CAR-M) therapies, which are believed to be the only therapies of their kind with demonstrated proof of mechanism and safety data in clinical trials. At the closing of the merger, taking into account the reverse stock split of shares of common stock of Sesen Bio prior to the closing, the combined company had approximately 40.3 million outstanding shares of common stock.
- **Received $105.3 million of proceeds as a result of completing the merger transaction, which includes $74.7 million from Sesen Bio and $30.6 million from a concurrent financing.** The $30.6 million financing was from a syndicate of investors, including HealthCap, AbbVie, Wellington Partners, SymBiosis, Penn Medicine, TPG Biotech, MRL Ventures Fund, the therapeutics-focused corporate venture arm of Merck & Co., Agent Capital, Solasta, Livzon, Pictet Alternative Advisors and 4Bio.
- **Expanded Scientific Advisory Board (SAB) with additional expertise in solid tumor immunotherapy development capabilities.** The Company appointed leading solid tumor immunotherapy expert Padmanee Sharma, MD, PhD to Carisma's SAB in January 2023. Dr. Sharma is a nationally regarded cancer immunologist and professor in the departments of Genitourinary Medical Oncology and Immunology, Associate VP of Immunobiology and the T.C. and Jeanette D. Hsu Endowed Chair in Cell Biology at The University of Texas MD Anderson Cancer Center. Additionally, the Company appointed Moderna CSO of External Research Ventures, Lin Guey, PhD to Carisma's SAB in February 2023. Dr. Guey is a leading expert in mRNA therapeutics and oversees Moderna's partnership with Carisma to develop in vivo CAR-M therapies.
- **Presented new data from Phase 1 clinical trial of CT-0508 at the Society for Immunotherapy of Cancer (SITC) Annual Meeting in November 2022.** Additional findings from the CT-0508 CAR-M clinical trial for patients with advanced metastatic human epidermal growth factor receptor 2 (HER2) overexpressing solid tumors, supported a favorable safety profile and demonstrate that CT-0508 has been successfully manufactured using macrophages obtained from heavily pre-treated, advanced solid tumor patients and has shown high CAR expression, viability, and purity.

Anticipated Upcoming Milestones

- Additional data from Group 2 of Carisma's Phase 1 CT-0508 study expected in the second half of 2023
- Initial data from clinical trial sub-study of CT-0508 in combination with KEYTRUDA® (pembrolizumab) expected in the second half of 2023
- Submission of IND application to the FDA for CT-0525, Carisma's first anti-HER2 CAR-Mono product candidate, expected in the second half of 2023
- Nomination of additional targets(s) under the Moderna development collaboration expected in 2023

Fiscal 2022 Financial Results

- Cash, cash equivalents and marketable securities as of December 31, 2022 were $52.0 million, compared to $28.6 million as of December 31, 2021, and is not inclusive of proceeds from the merger transaction with Sesen Bio and concurrent financing, which were completed in March of 2023.
- Moderna collaboration revenues were $9.8 million for the year ended December 31, 2022. The Company began its collaboration with Moderna in January 2022 and deferred $47.5 million in revenue from the Moderna collaboration agreement, which will be recognized in future periods.
- Research & development expenses were $56.6 million for the year ended December 31, 2022, compared to $34.4 million in 2021. The increase was primarily due to costs associated with growth and expansion of Carisma's clinical and pre-clinical activities to support advancing CT-0508 in clinical development and expand research for the Company's Moderna in vivo research.
- General & administrative expenses were $9.4 million for the year ended December 31, 2022, compared to $6.4 million in 2021, primarily due to costs associated with the expanded patent portfolio and preparing to operate as a public company.
- Net loss was $61.2 million for the year ended December 31, 2022, compared to net loss of $40.8 million in 2021, primarily due to increased research and development expenses, which was partially offset by Moderna collaboration revenue.

Outlook

Carisma believes that its cash, cash equivalents and marketable securities of $52.0 million as of December 31, 2022, in combination with the net proceeds of $105.3 million from the completion of the merger with Sesen Bio and concurrent financing, 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. We are 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 our 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 Therapeutics

Carisma Therapeutics Inc. is a biopharmaceutical company dedicated to developing a differentiated and proprietary cell therapy platform focused on engineered macrophages, cells that play a crucial role in both the innate and adaptive immune response. The first applications of the platform, developed in collaboration with the University of Pennsylvania, are autologous chimeric antigen receptor (CAR)-macrophages for the treatment of solid tumors. 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 and future operations, the sufficiency of its cash resources, 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) risks associated with the possible failure to realize certain anticipated benefits of the merger, including with respect to future financial and operating results; (ii) the effect of the completion of the merger on Carisma's business relationships, operating results and business generally; (iii) the outcome of any legal proceedings related to the merger agreement or the transactions contemplated thereby; (iv) Carisma's ability to obtain, maintain and protect its intellectual property rights related to its product candidates; (v) Carisma's ability to advance the development of its product candidates under the timelines it anticipates in planned and future clinical trials; (vi) Carisma's ability to replicate in later clinical trials positive results found in preclinical studies and early-stage clinical trials of its product candidates; (vii) 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; (viii) 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; (ix) changes to clinical trial designs and regulatory pathways; (x) risks associated with Carisma's ability to manage expenses; (xii) changes in capital resource requirements; (xii) risks related to the inability of Carisma to obtain sufficient additional capital to continue to advance its product candidates and its preclinical programs; and (xiii) legislative, regulatory, political and economic developments. For a discussion of other risks and uncertainties, and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, see the "Risk Factors" set forth in Exhibit 99.3 to

Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 8, 2023, as well as discussions of potential risks, uncertainties, and other important factors in the Company's most 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.
Consolidated Balance Sheets
(in thousands, except share data)

	December 31,	
Assets	**2022**	**2021**
Current assets:		
Cash and cash equivalents	$ 24,194	$ 28,551
Marketable securities	27,802	—
Prepaid expenses and other assets	2,596	1,235
Total current assets	54,592	29,786
Property and equipment, net	8,628	3,084
Right of use assets – operating leases	4,822	2,579
Deferred financing costs	4,111	—
Total assets	$ 72,153	$ 35,449
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 1,728	$ 2,322
Accrued expenses	10,361	4,471
Deferred revenue	2,459	—
Operating lease liabilities	3,437	898
Finance lease liabilities	1,162	—
Other current liabilities	523	—
Total current liabilities	19,670	7,691
Deferred revenues	45,000	—
Convertible promissory note	33,717	—
Derivative liability	5,739	—
Operating lease liabilities	976	1,734
Finance lease liabilities	872	—
Other long-term liabilities	1,041	—
Total liabilities	107,015	9,425
Total convertible preferred stock	107,808	107,808
Stockholders' deficit:		
Common stock $0.0001 par value, 14,910,158 shares authorized, 1,167,602 and 1,084,082 shares issued and outstanding at December 31, 2022 and 2021, respectively	—	—
Additional paid-in capital	1,199	818
Accumulated other comprehensive loss	(41)	—
Accumulated deficit	(158,223)	(96,997)
Total Carisma Therapeutics Inc. stockholders' deficit	(157,065)	(96,179)
Noncontrolling interests	14,395	14,395
Total stockholders' deficit	(142,670)	(81,784)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 72,153	$ 35,449

CARISMA THERAPEUTICS INC.
Consolidated Statements of Operations

(in thousands, except share and per share data)

	Year Ended December 31,	
	2022	**2021**
Collaboration revenues	$ 9,834	$ —
Operating expenses:		
Research and development	56,618	34,387
General and administrative	9,378	6,407
Total operating expenses	65,996	40,794
Operating loss	(56,162)	(40,794)
Change in fair value of derivative liability	(1,919)	—
Interest (expense) income, net	(3,145)	10
Net loss	$ (61,226)	$ (40,784)
Share information:		
Net loss per share of common stock, basic and diluted	$ (54.65)	$ (37.62)
Weighted-average shares of common stock outstanding, basic and diluted	1,120,390	1,084,082

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