

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 8-K**

**CURRENT REPORT**  
**Pursuant to Section 13 or 15(d)**  
**of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): May 11, 2023**

**Carisma Therapeutics Inc.**  
(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-36296**  
(Commission  
File Number)

**26-2025616**  
(IRS Employer  
Identification No.)

**3675 Market Street, Suite 200**  
**Philadelphia, PA**  
(Address of Principal Executive Offices)

**19104**  
( Zip Code)

**Registrant's telephone number, including area code: (267) 491-6422**

**(Former Name or Former Address, if Changed Since Last Report)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2 below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)  
 Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)  
 Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))  
 Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of exchange on which registered</b>
<b>Common Stock, \$0.001 par value</b>	<b>CARM</b>	<b>The Nasdaq Stock Market LLC</b>

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 2.02. Results of Operations and Financial Condition.**

On May 11, 2023, Carisma Therapeutics Inc. (the “Company”) announced its financial results for the quarter ended March 31, 2023. The full text of the press release issued in connection with the announcement is being furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 2.02, including Exhibit 99.1 attached hereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 9.01. Financial Statements and Exhibits.**

<u>Exhibit Number</u>	<u>Description</u>
99.1 104	<a href="#">Press Release issued by Carisma Therapeutics Inc. on May 11, 2023.</a> Cover Page Interactive Data File (embedded within the Inline XBRL document).

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## **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

### **CARISMA THERAPEUTICS INC.**

Date: May 12, 2023

By: /s/ Steven Kelly

Steven Kelly

President and Chief Executive Officer

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## **Carisma Therapeutics Reports First Quarter 2023 Financial Results and Provides Business Highlights**

*Initiated a Phase 1 Sub-Study of CT-0508 in combination with KEYTRUDA® (pembrolizumab) in patients with HER2-overexpressing solid tumors*

*Expanded clinical manufacturing capacity through successful technology transfer of CT-0508*

*Closed merger with Sesen Bio and commenced trading on Nasdaq under ticker symbol “CARM”*

PHILADELPHIA, PA – May 11, 2023 – 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 first quarter ended March 31, 2023 and provided business highlights.

“In the first quarter, we closed our merger with Sesen Bio, Inc., which further strengthened our foundation to advance our pipeline through the end of 2024,” said Steven Kelly, President and Chief Executive Officer of Carisma. “With multiple potential value inflection points on the horizon, including the completion of our Phase 1 clinical trial of CT-0508 and the upcoming data from the clinical trial sub-study of CT-0508 in combination with KEYTRUDA®, we believe we are well positioned to continue driving innovation and delivering value to our stakeholders. We remain committed to advancing our pipeline and leveraging our expertise in chimeric antigen receptor (CAR)-macrophages to bring transformative therapies to patients in need.”

### **Pipeline Updates**

- **CT-0508**

- Initiated a sub-study in the Company’s Phase 1 clinical trial that will test the safety and tolerability of Carisma’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 cancers.
- Presented a trial-in-progress poster at The American Association for Cancer Research (AACR) Annual Meeting in April 2023 that provided an overview of Carisma’s Phase 1, first-in-human study of CT-0508.
- Increased clinical manufacturing capacity by successfully completing a technology transfer of CT-0508 manufacturing to Novartis, including the first manufacturing run for a clinical trial patient.

- **CT-1119**

- Presented pre-clinical data at the AACR Annual Meeting demonstrating that CT-1119, an autologous human anti-mesothelin CAR-M, can phagocytose, eradicate, and induce an inflammatory response against mesothelin overexpressing solid tumors. The results show that CAR-M is potentially a feasible approach for the treatment of mesothelin overexpressing solid tumors.

## **Business Highlights**

- **Completed merger with Sesen Bio and concurrent financing in March 2023.** The Company closed its previously announced merger with Sesen Bio, Inc. (Sesen Bio), 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.” 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. The net assets acquired by the Company in the merger with Sesen Bio was \$80.3 million. In addition, the Company raised \$30.6 million from a concurrent financing.
- **Expanded Scientific Advisory Board (SAB) with additional expertise in solid tumor immunotherapy development capabilities.** The Company appointed leading solid tumor immunotherapy expert Padmanee Sharma, M.D., Ph.D. 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 V.P. 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 Inc. (Moderna) CSO of External Research Ventures, Lin Guey, Ph.D. to Carisma’s SAB in February 2023. Dr. Guey is a leading expert in mRNA therapeutics and oversees Moderna’s collaboration with Carisma to develop *in vivo* CAR-M therapies.

## **Anticipated Upcoming Milestones**

- Additional data from Group 2 of Carisma’s Phase 1 clinical trial of CT-0508 expected in the second half of 2023.
- Initial data from clinical trial sub-study of CT-0508 in combination with KEYTRUDA® expected in the second half of 2023.
- Submission of Investigational New Drug 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.
- Nomination of additional target(s) under the Moderna development collaboration expected in 2023.

## **First Quarter 2023 Financial Results<sup>(1)</sup>**

- Cash, cash equivalents and marketable securities as of March 31, 2023 were \$139.0 million, compared to \$52.0 million as of December 31, 2022.
- Research & development expenses were \$16.6 million for the first quarter of 2023, compared to \$8.8 million in 2022. The increase was primarily due to an increase in lab space and lab supplies, personnel costs due to growth in employee headcount, pre-clinical activities towards submission of an IND for CT-0525, and pre-clinical development expenses associated with the Moderna collaboration, partially offset by a \$0.5 million decrease in direct costs associated with CT-0508.

- General & administrative expenses were \$9.6 million for the first quarter of 2023, compared to \$2.2 million in 2022. The increase was primarily attributable to severance and payroll costs associated with the Sesen Bio merger, an increase in headcount, costs associated with Carisma's patent portfolio, costs associated with expanding infrastructure in preparation of operating as a public company and public relation expenditures.
- Net loss was \$24.6 million for the first quarter of 2023, compared to net loss of \$11.3 million for the same period in 2022, primarily due to increased research and development expenses, which was partially offset by Moderna collaboration revenue.

<sup>(1)</sup> All prior year comparisons are relative to CTx Operations, Inc. (formerly CARISMA Therapeutics Inc.), which merged with and into a subsidiary of the Company in connection with the closing of the merger with Sesen Bio, surviving as a wholly owned subsidiary of the Company. Following the completion of the merger, the business conducted by the Company became primarily the business conducted by Carisma.

## Outlook

Carisma believes that its cash, cash equivalents and marketable securities of \$139.0 million as of March 31, 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 are not eligible for treatment with currently available 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 genetically 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 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. 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](http://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, 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) risks associated with the possible failure to realize certain anticipated benefits of the merger, including with respect to future financial and operating results; (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; (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; (vii) changes to clinical trial designs and regulatory pathways; (viii) Carisma's commercialization and manufacturing capabilities and strategy; (ix) risks associated with Carisma's ability to manage expenses; (x) Carisma's competitive position; (xi) 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 Carisma'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 (SEC) on March 8, 2023, Carisma's Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on February 28, 2023 and Carisma's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 to be filed with the SEC on May 11, 2023, as well as discussions of potential risks, uncertainties, and other important factors in Carisma'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.**  
**Unaudited Consolidated Balance Sheets**  
(in thousands, except share and per share data)

	<b>March 31, 2023</b>	<b>December 31, 2022</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 62,777	\$ 24,194
Marketable securities	76,190	27,802
Prepaid expenses and other assets	5,535	2,596
Total current assets	<u>144,502</u>	<u>54,592</u>
Property and equipment, net	8,107	8,628
Right of use assets – operating leases	3,493	4,822
Restricted cash	30	—
Deferred financing costs	—	4,111
Total assets	<u>\$ 156,132</u>	<u>\$ 72,153</u>
<b>Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)</b>		
Current liabilities:		
Accounts payable	\$ 4,614	\$ 1,728
Accrued expenses	10,187	10,361
Deferred revenue	2,136	2,459
Operating lease liabilities	2,597	3,437
Finance lease liabilities	1,188	1,162
Other current liabilities	755	523
Total current liabilities	<u>21,477</u>	<u>19,670</u>
Deferred revenues	45,000	45,000
Convertible promissory note	—	33,717
Derivative liability	—	5,739
Operating lease liabilities	948	976
Finance lease liabilities	740	872
Other long-term liabilities	1,897	1,041
Total liabilities	<u>70,062</u>	<u>107,015</u>
Convertible preferred stock	—	107,808
Stockholders' equity (deficit):		
Common stock \$0.001 par value, 100,000,000 shares authorized, 40,254,666 and 2,217,708 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	40	2
Additional paid-in capital	268,759	1,197
Accumulated other comprehensive income (loss)	136	(41)
Accumulated deficit	(182,865)	(158,223)
Total Carisma Therapeutics Inc. stockholders' equity (deficit)	<u>86,070</u>	<u>(157,065)</u>
Noncontrolling interests	—	14,395
Total stockholders' equity deficit	<u>86,070</u>	<u>(142,670)</u>
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	<u>\$ 156,132</u>	<u>\$ 72,153</u>

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

	Three Months Ended March 31,	
	2023	2022
Collaboration revenues	\$ 3,243	\$ 822
Operating expenses:		
Research and development	16,641	8,767
General and administrative	9,574	2,211
Total operating expenses	<u>26,215</u>	<u>10,978</u>
Operating loss	(22,972)	(10,156)
Change in fair value of derivative liability	(84)	(557)
Interest (expense) income, net	(1,477)	(599)
Pre-tax loss	<u>(24,533)</u>	<u>(11,312)</u>
Income tax expense	(109)	-
Net loss	<u><u>\$ (24,642)</u></u>	<u><u>\$ (11,312)</u></u>
Share information:		
Net loss per share of common stock, basic and diluted	\$ (1.93)	\$ (5.49)
Weighted-average shares of common stock outstanding, basic and diluted	<u>12,783,523</u>	<u>2,059,986</u>
Comprehensive loss		
Net loss	\$ (24,642)	\$ (11,312)
Unrealized gain (loss) on marketable securities	177	(158)
Comprehensive loss	<u><u>\$ (24,465)</u></u>	<u><u>\$ (11,470)</u></u>