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): April 1, 2024

Carisma Therapeutics Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-36296**	**26-2025616**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
3675 Market Street, Suite 200 Philadelphia, PA		**19104**
(Address of Principal Executive Offices)		**(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:

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

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 April 1, 2024, Carisma Therapeutics Inc. (the "Company") announced its financial results for the quarter and year ended December 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.

Exhibit Number	Description
99.1	Press Release issued by Carisma Therapeutics Inc. on April 1, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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.

By: /s/ Steven Kelly
Steven Kelly
President and Chief Executive Officer

Date: April 1, 2024

Exhibit 99.1

Carisma Therapeutics Provides Business Update and Reports Fourth Quarter and Full Year 2023 Financial Results

Company to prioritize CT-0525 as its anti-HER2 CAR-M product candidate and will cease further development of CT-0508

Other prioritized pipeline programs include the Company's in vivo CAR-M collaboration with Moderna, and research programs including fibrosis

Cash and cash equivalents of $77.6 million as of December 31, 2023, combined with a restructuring of operations, including pausing development of CT-1119, expected to fund the Company into the third quarter of 2025

PHILADELPHIA – April 1, 2024 – 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 fourth quarter, and full year ended December 31, 2023, and provided a business update.

"Clinical data generated with CT-0508 in Study 101 has shown that CAR-M is well-tolerated, feasible to manufacture and biologically active in HER2 positive solid tumors. Combining this data set with the multiple potential advantages we've seen preclinically around a monocyte-based approach gives us confidence that CT-0525 may be a significant advancement in CAR-M treatment," said Steven Kelly, President and Chief Executive Officer of Carisma. "We have therefore made the decision to focus our resources on the clinical development of the product we believe is best suited to deliver benefit to patients with significant unmet need."

Mr. Kelly continued, "We have also undertaken a careful review of our business and prioritized our other pipeline programs on those with the greatest overall potential and near-term milestones. This prioritization enables us to reduce expenses and streamline operations, including a restructuring of our workforce. I want to express my sincere gratitude to those impacted by the workforce reduction for their invaluable contributions to our mission and their dedication to helping patients."

Reprioritization Plan, Pipeline Updates, and Upcoming Milestones:

Ex Vivo Oncology

- **Anti-human epidermal growth factor receptor 2 (Anti-HER2) Program**
    - The Company's goal to identify a registrational profile for the product candidate in its anti-HER2 program in 2025 remains unchanged.
    - In Study 101, CT-0508, a chimeric antigen receptor macrophage (CAR-Macrophage), was well-tolerated, remodeled the tumor microenvironment (TME), and induced anti-tumor T cell immunity in patients with HER2 3+ tumors that achieved stable disease, despite suboptimal dose and a patient population with exhausted T cells.
    - In late March 2024, Carisma made the decision to prioritize CT-0525, a chimeric antigen receptor monocyte (CAR-Monocyte), as the development candidate in its anti-HER2 program 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 CT-0508's observed clinical anti-tumor activity.
- **CT-0525 (Anti-HER2 CAR-Monocyte)**
    - In November 2023, Carisma announced the clearance of its Investigational New Drug application (IND) by the U.S. Food and Drug Administration (FDA) for CT-0525.
    - The Company 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)**
    - In September 2023, the Company reported preliminary data from 14 patients in the open label Phase 1 clinical study of CT-0508 (Study 101) designed to evaluate the safety, tolerability and manufacturing feasibility of CT-0508 along with several customary secondary endpoints.
    - The Company has also enrolled six patients in a Study 101 substudy evaluating the co-administration of CT-0508 and pembrolizumab, a programmed cell death protein 1 (PD-1) checkpoint inhibitor, evaluating the safety and tolerability of the co-administration, along with several customary secondary endpoints.
    - While the Company will continue all study operations for subjects enrolled in Study 101, it plans to stop recruitment of new patients into the study and its substudies, and expects to report data from the substudy evaluating the co-administration of CT-0508 and pembrolizumab in the second quarter of 2024.
- **CT-1119 (Anti-Mesothelin CAR-Monocyte)**
    - The Company has elected to pause further development of CT-1119 as part of its reprioritization plan, pending additional financing.

In Vivo Oncology

- **Oncology (CAR-M + mRNA/LNP; Moderna Collaboration)**
    - In November 2023, Carisma presented pre-clinical data from its *in vivo* program demonstrating that chimeric antigen receptor macrophages and monocytes (CAR-M) can be directly produced *in vivo*, successfully redirecting endogenous myeloid cells against tumor-associated antigens using mRNA/LNP. The data demonstrated feasibility, tolerability, and efficacy of *in vivo* CAR-M against metastatic solid tumors.
    - In December 2023, the Company announced the nomination of the first lead candidate in its collaboration with Moderna Tx, Inc., which will target an antigen present on a solid tumor with significant unmet medical need.

Fibrosis and Immunology

- **Liver Fibrosis**
    - Pre-clinical proof of concept data from the fibrosis program is targeted for the second quarter of 2024.

Corporate Updates

- As a result of the pipeline reprioritization and corporate restructuring, Carisma plans to reduce 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.

Fourth Quarter and Full Year 2023 Financial Results

- **Cash and Cash Equivalents:** As of December 31, 2023, Carisma had cash and cash equivalents of $77.6 million.

- **R&D Expenses:** Research and development (R&D) expenses were $19.4 million and $74.1 million for the fourth quarter and full year ended December 31, 2023, respectively, compared to $18.1 million and $56.6 million for the fourth quarter and full year ended December 31, 2022, respectively. The increase of $17.5 million year-over-year was primarily due to a $8.4 million increase in direct costs associated with pre-clinical development of CT-0525, a $4.4 million increase in personnel costs due to growth in research and development employee headcount, a $2.7 million increase in the Company's facilities and other expenses resulting from increased laboratory space and laboratory supplies from expanded clinical and pre-clinical work, a $1.3 million increase due to costs associated with growth and expansion of pre-clinical activities towards submission of an IND for CT-0525, and a $0.9 million increase in direct costs associated with the pre-clinical development related to CT-1119, partially offset by a $0.2 million decrease in direct costs associated with CT-0508. The Company expects its research and development expenses to decrease in 2024 as it implements the revised operating plan, including a reduction in workforce, prioritization of CT-0525 and a pause in development of CT-1119. The Company expects that its expenses will increase again in future years as it continues to advance its clinical trials and potentially progress additional product candidates.

- **G&A Expenses:** General and administrative (G&A) expenses were $7.3 million and $29.5 million for the fourth quarter and full year ended December 31, 2023, respectively, compared to $1.0 million and $9.4 million for the fourth quarter and full year ended December 31, 2022, respectively. The increase of $20.1 million year-over-year was primarily attributable to a $9.2 million increase in personnel costs and a $7.5 million increase in professional fees. The increase in personnel costs was primarily due to non-recurring severance and other costs associated with the merger with Sesen Bio, Inc. on March 7, 2023 ("Merger") of $4.6 million, and higher personnel costs as a result of an increase in headcount to support operating as a public company of $4.6 million. The increase in professional fees primarily consisted of $5.3 million in costs associated with activities to support the transitioning to and operating as a public company and protecting the Company's IP portfolio, along with $2.2 million in legal fees and communication fees associated with the Merger. Insurance and taxes increased $2.1 million as a result of costs associated with operating as a public company, such as director and officer insurance. Facilities and supplies increased $0.8 million due to office expenditures resulting from an increased footprint, and other expenses increased $0.5 million. The Company expects that its general and administrative expenses will decrease in 2024 as its 2023 expenses included a significant amount of non-recurring costs related to the Merger and as it implements its revised operating plan, including reducing its workforce and decreasing expenses related to non-essential activities.

- **Net Loss:** Net loss was $86.9 million and $61.2 million for the years ended December 31, 2023, and 2022, respectively.

Outlook

Carisma anticipates that its cash and cash equivalents of $77.6 million as of December 31, 2023, 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

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 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 and with its current financial and human resources; (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 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.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31,	
	2023	**2022**
Assets		
Current assets:		
Cash and cash equivalents	$ 77,605	$ 24,194
Marketable securities	-	27,802
Prepaid expenses and other assets	2,866	2,596
Total current assets	80,471	54,592
Property and equipment, net	6,764	8,628
Right of use assets – operating leases	2,173	4,822
Deferred financing costs	146	4,111
Total assets	$ 89,554	$ 72,153
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 3,933	$ 1,728
Accrued expenses	7,662	10,361
Deferred revenue	1,413	2,459
Operating lease liabilities	1,391	3,437
Finance lease liabilities	544	1,162
Other current liabilities	965	523
Total current liabilities	15,908	19,670
Deferred revenue	45,000	45,000
Convertible promissory note	-	33,717
Derivative liability	-	5,739
Operating lease liabilities	860	976
Finance lease liabilities	328	872
Other long-term liabilities	926	1,041
Total liabilities	63,022	107,015
Convertible preferred stock	-	107,808
Stockholders' equity (deficit):		
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, 40,609,915 and 2,217,737 shares issued and outstanding at December 31, 2023 and 2022, respectively	40	2
Additional paid-in capital	271,594	1,197
Accumulated other comprehensive loss	-	(41)
Accumulated deficit	(245,102)	(158,223)
Total Carisma Therapeutics Inc. stockholders' equity (deficit)	26,532	(157,065)
Noncontrolling interests	-	14,395
Total stockholders' equity (deficit)	26,532	(142,670)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 89,554	$ 72,153

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

	Three Months Ended December 31,		Year Ended December 31,	
	2023	**2022**	**2023**	**2022**
Collaboration revenues	$ 4,289	$ 3,731	$ 14,919	$ 9,834
Operating expenses:				
Research and development	19,415	18,082	74,125	56,618
General and administrative	7,324	971	29,525	9,378
Total operating expenses	26,739	19,053	103,650	65,996
Operating loss	(22,450)	(15,322)	(88,731)	(56,162)
Change in fair value of derivative liability	—	(550)	(84)	(1,919)
Interest income (expense), net	1,295	(867)	1,936	(3,145)
Pre-tax loss	(21,155)	(16,739)	(86,879)	(61,226)
Income tax provision	197	—	—	—
Net loss	$ (20,958)	$ (16,739)	$ (86,879)	$ (61,226)
Share information:				
Net loss per share of common stock, basic and diluted	$ (0.52)	$ (7.61)	$ (2.59)	$ (28.77)
Weighted-average shares of common stock outstanding, basic and diluted	40,391,608	2,198,748	33,524,197	2,128,069
Comprehensive loss				
Net loss	$ (20,958)	$ (16,739)	$ (86,879)	$ (61,226)
Unrealized gain (loss) on marketable securities	26	119	440	(41)
Less: reclassification to net loss of previous unrealized gain on marketable securities	(399)	—	(399)	—
Comprehensive loss	$ (21,331)	$ (16,620)	$ (86,838)	$ (61,267)