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): July 9, 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 401 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 8.01. Other Events.

On July 9, 2024, Carisma Therapeutics Inc. (the "Company") will announce new analysis related to the Company's Phase 1 clinical trial of CT-0508, a human epidermal growth factor receptor 2 ("HER2") targeted chimeric antigen receptor macrophage for the treatment of HER2 overexpressing cancers, during a presentation at the Stifel Virtual Cell Therapy Forum. An excerpt from the presentation is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The Company is providing the following analysis related to its Phase 1 clinical trial of CT-0508:

The Company recently completed analysis of circulating tumor DNA ("ctDNA") from 13 patients enrolled in groups 1 and 2. Based on preliminary results assessed to date, the Company observed that 75% (n=6/8) of evaluable HER2 3+ patients experienced a ctDNA reduction, indicating direct tumor killing activity. Zero percent (n=0/5) of evaluable HER2 2+ patients experienced a ctDNA reduction. In the 6 patients that experienced a ctDNA reduction, the median decrease was 81% (range 33%-93% decrease in ctDNA 4-weeks post treatment with CT-0508).

While the results from this early clinical trial data are both preliminary and limited, the Company believes that repeat dosing of its follow-on product, CT-0525, in patients with HER2 overexpressing cancers could prolong pharmacologic efficacy and response.

Consistent with prior disclosure, enrollment of new patients in the Company's Phase 1 clinical trial of CT-0508 and its sub-study utilizing CT-0508 in combination with pembrolizumab was halted in April 2024 in connection with the implementation of the Company's revised operating plan. As of July 2024, all activities with respect to the patients enrolled in the Phase 1 clinical trial and sub-study have been completed. The Company only has preliminary results from the Phase 1 clinical trial and expects clinical data updates in the third quarter of 2024.

Item 9.01. Financial Statements and Exhibits.

Exhibit Number	Description
99.1	Excerpt from Company Presentation, dated July 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.

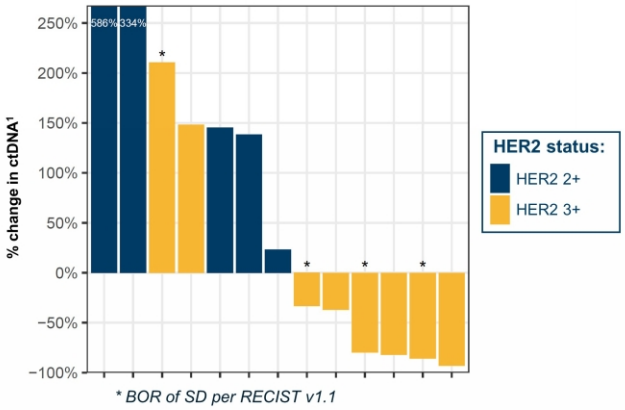
By: /s/ Steven Kelly
Steven Kelly
President and Chief Executive Officer

Date: July 9, 2024

Clinical Activity Observed in HER2 3+ Patients

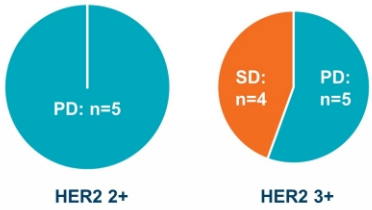
Correlation of target expression and clinical activity supports mechanism of action

Change in tumor ctDNA at week 4 based on HER2 status:



** BOR of SD per RECIST v1.1*

Correlation between HER2 status and Best Overall Response



KEY TAKEAWAYS

- Best Overall Response of Stable Disease was seen in HER2 3+ (n=4/9, 44% SD)
- All pts with HER2 2+ tumors had PD

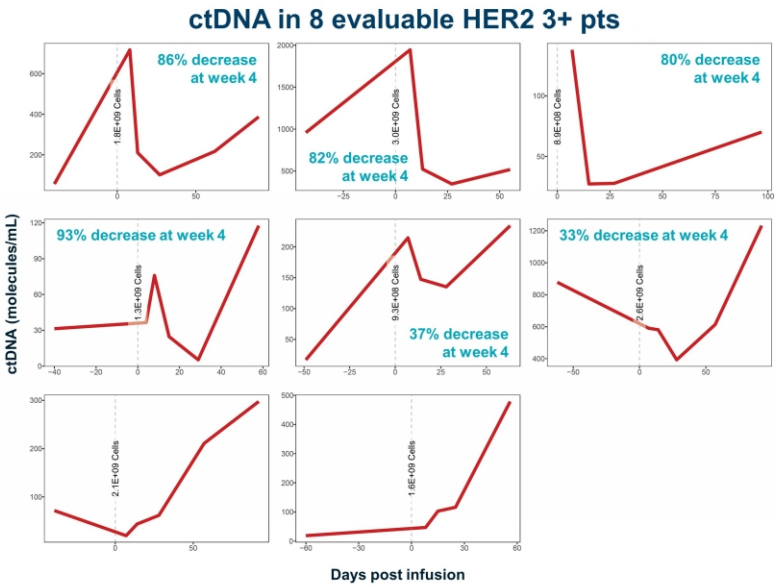
Clinical activity as measured by imaging or ctDNA correlates with HER2 expression

carisma THERAPEUTICS

ctDNA: Circulating Tumor DNA; PFS: Progression-Free Survival; Signatera assay used for CtDNA; ¹ From day 8 to week 4

ctDNA Reduction Observed in 75% of HER2 3+ Patients

ctDNA reductions are clear evidence of clinical activity



KEY TAKEAWAYS

- **75% (6/8) of HER2 3+ patients** exhibited a decrease in ctDNA, indicating direct tumor killing activity
- **Up to 93% decrease in ctDNA levels**
- **Decreases were observed in multiple tumor** types
- **Peak response occurred ~4 weeks** post CT-0508 infusion, suggesting potential timing for redosing
- **Consistent with clinical assessments,** no decreases in ctDNA were observed in HER2 2+ patients

carisma THERAPEUTICS

ctDNA: Circulating Tumor DNA; ctDNA is a biomarker of tumor burden; dotted grey line is infusion of CT-0508

Operating Plan and Corporate Milestones

Capital efficient R&D program designed to reach significant value inflection points

THERAPEUTIC AREA	PRODUCT CANDIDATE	PLATFORM	RECENT AND ANTICIPATED MILESTONES		
***Ex Vivo* Oncology**					
HER2+ solid tumors	CT-0525	CAR-Monocyte *(1st Gen CAR)*	**4Q'23**	IND cleared	✓
			2Q'24	Treat first patient	✓
			4Q'24	Report initial data from Phase 1 study	☐
	CT-0508*	CAR-Macrophage *(1st Gen CAR)*	**3Q'24**	Report data from Phase 1 combination sub-study	☐
***In Vivo* Oncology**					
GPC3+ solid tumors	TBD	CAR-Macrophage + mRNA/LNP	**4Q'23**	Nominate first *in vivo* CAR-M lead candidate	✓
			2Q'24	Development Candidate nominated	✓
			TBD	IND submission	☐
Oncology	4 Additional Targets[2]	CAR-Macrophage + mRNA/LNP	**4Q'23**	Report proof of concept data for *in vivo* CAR-M (SITC 2023)	✓
Fibrosis and Immunology					
Liver Fibrosis	TBD	Engineered macrophage	**2Q'24**	Report preclinical proof of concept data (ASGCT 2024)	✓
			1Q'25	Nominate Development Candidate	☐

carisma THERAPEUTICS

* In late March 2024, Carisma made the decision to cease further development of CT-0508, including monotherapy and in combination with pembrolizumab
1. Target undisclosed; 2. Moderna collaboration has identified 5 total oncology targets, with the option to identify an additional 7 oncology targets