# 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): June 27, 2024 Carisma Therapeutics Inc. (Exact Name of Registrant as Specified in its Charter) 001-36296 26-2025616 Delaware (State or other jurisdiction (Commission (IRS Employer File Number) Identification No.) of incorporation) 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): П 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: Trading Name of exchange Title of each class Symbol(s) 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  $\square$ 

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 June 27, 2024, Carisma Therapeutics Inc. (the "Company") announced that it received notice from ModernaTX, Inc. ("Moderna") that Moderna had nominated the first development candidate (the "Development Candidate") under the Collaboration and License Agreement, dated January 7, 2022, by and between the Company and Moderna. The Development Candidate is an *in vivo* chimeric antigen receptor macrophage targeting Glypican-3 and is designed to treat solid tumors, including hepatocellular carcinoma, the most prevalent type of liver cancer and the fastest-rising cause of cancer-related death in the United States. The nomination triggers a \$2 million milestone payment to the Company.

A copy of the Company's press release announcing the nomination of the Development Candidate is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

### Item 9.01. Financial Statements and Exhibits.

<u>Exhibit</u> <u>Number</u>	<b>Description</b>
<u>99.1</u>	Press Release issued by Carisma Therapeutics Inc. on June 27, 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: June 27, 2024



# Carisma Therapeutics Announces Nomination of First In Vivo CAR-M Development Candidate for Hepatocellular Carcinoma Under Collaboration with Moderna

Development Candidate targets Glypican-3 for the treatment of solid tumors, including hepatocellular carcinoma

Nomination triggers a \$2 million milestone payment to Carisma

PHILADELPHIA, PA – June 27, 2024 – <u>Carisma Therapeutics Inc.</u> (Nasdaq: CARM) ("Carisma" or the "Company"), a clinical stage biopharmaceutical company focused on discovering and developing innovative immunotherapies, today announced the nomination of the first development candidate ("Development Candidate"), under its collaboration with Moderna, Inc. The Development Candidate is an *in vivo* CAR-M targeting Glypican-3 ("GPC3") and is designed to treat solid tumors, including hepatocellular carcinoma ("HCC"), the most prevalent type of liver cancer and the fastest-rising cause of cancer-related death in the U.S. This nomination triggers a \$2 million milestone payment to Carisma.

The nomination of this Development Candidate leverages Carisma's expertise in engineering chimeric antigen receptor monocytes and macrophages ("CAR-M") with Moderna's mRNA and lipid nanoparticle platform to create a novel *in vivo* cell therapy for oncology. Pre-clinical data demonstrated that the Development Candidate can successfully create CAR-M directly *in vivo*, redirecting endogenous myeloid cells to attack cancer cells.

"The nomination of the first Development Candidate underscores our productive collaboration with Moderna to develop mRNA-based *in vivo* CAR-M cell therapies," said Michael Klichinsky, PharmD, PhD, Co-Founder and Chief Scientific Officer at Carisma. "The Development Candidate targets GPC3, a tumor antigen that is highly expressed in HCC. This milestone represents a significant step forward in the development of immunotherapies for solid tumors, and an advance for the *in vivo* cell therapy field."

Lin Guey, PhD, Chief Scientific Officer of Therapeutics Research Ventures and Biotherapeutics at Moderna, stated, "We are thrilled with the significant progress we've made in advancing *in vivo* CAR-M therapies alongside Carisma. We eagerly anticipate further development of the nominated candidate for patients with solid tumors, and we look forward to continued success as we develop additional *in vivo* CAR-M together to bring new therapies to patients with HCC and other cancers."

The *in vivo* CAR-M program targeting GPC3 is being developed under the 2022 strategic collaboration agreement between Carisma and Moderna to discover, develop, and commercialize *in vivo* engineered CAR-M therapeutics for the treatment of cancer. In addition to this program, Moderna has nominated four undisclosed oncology research targets under the collaboration. Carisma is responsible for the discovery and optimization of development candidates, while Moderna will lead the development and commercialization of resulting therapeutics.

#### **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. Carisma is headquartered in Philadelphia, PA. For more information, please visit <a href="www.carismatx.com">www.carismatx.com</a>.

### **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 realize the anticipated benefits of its pipeline reprioritization and corporate restructuring, (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 and with its current financial and human resources; (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 related to its product candidates; (vii) changes to clinical trial designs and regulatory pathways; (viii) risks associated with Carisma's ability to manage expenses; (ix) changes in capital resource requirements; (x) risks related to the inability of Carisma to obtain sufficient additional capital to continue to advance its product candidates and its preclinical programs; and (xi) 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, its Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, 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.

### **Investors:**

Shveta Dighe Head of Investor Relations <u>investors@carismatx.com</u>

# **Media Contact:**

Julia Stern (763) 350-5223 jstern@realchemistry.com