

**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): February 15, 2023

**GALERA THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

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

**001-39114**  
(Commission  
File Number)

**46-1454898**  
(I.R.S. Employer  
Identification No.)

**2 W Liberty Blvd #100**  
**Malvern, PA 19355**  
(Address of principal executive offices) (Zip Code)

**(610) 725-1500**  
(Registrant's telephone number, include area code)

N/A  
(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:

- 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<br>Symbol(s) | Name of each exchange<br>on which registered |
|---|----------------------|--|
| Common Stock, \$0.001 par value per share | GRTX                 | The Nasdaq Global Market                     |

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.**

### *Preliminary Financial Results – Cash Balance as of December 31, 2022*

Galera Therapeutics, Inc., or the Company, is currently finalizing its financial closing process for the year ended December 31, 2022. While complete financial information and operating data are not yet available, the Company expects to report that it had cash and cash equivalents and short-term investments of approximately \$31.6 million as of December 31, 2022.

The Company's audited financial results as of and for the year ended December 31, 2022 are not yet available. Upon completion of its financial closing procedures, the Company's audited financial results may differ materially from its preliminary estimates. The unaudited, preliminary consolidated financial data presented above as of December 31, 2022 is not a comprehensive statement of the Company's financial position, reflects the Company's preliminary estimates based on information available as of the date of this Current Report on Form 8-K, or the Form 8-K, and is subject to change. Accordingly, you should not place undue reliance upon these preliminary estimates. The unaudited, preliminary financial data included in this Form 8-K has been prepared by, and is the responsibility of, the Company's management. The Company's auditor has not audited, reviewed, compiled or applied agreed-upon procedures with respect to such preliminary financial data. Accordingly, the Company's auditor does not express an opinion or any other form of assurance with respect thereto.

The information contained in Item 2.02 of this Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly provided by specific reference in such a filing.

## **Item 8.01. Other Events.**

On February 15, 2023, the Company announced that the U.S. Food and Drug Administration, or the FDA, has accepted for priority review the Company's New Drug Application, or the NDA, for avasopasem manganese for radiotherapy-induced severe oral mucositis, or SOM, in patients with head and neck cancer undergoing standard-of-care treatment. The FDA has assigned a Prescription Drug User Fee Act, or PDUFA, target action date of August 9, 2023. At this time, the FDA is not planning to hold an advisory committee meeting to discuss the NDA. The Company believes that SOM represents a total market opportunity of more than \$1 billion in the United States.

The information contained in the first two paragraphs of Item 2.02 of this Form 8-K is incorporated by reference into this Item 8.01.

## **Forward-Looking Statements**

This Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Form 8-K that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding the Company's expected financial results as of and for the year ended December 31, 2022 and anticipated PDUFA target action date. These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, general business, financial and accounting risks and the other important factors discussed under the caption "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, and

Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, filed with the U.S. Securities and Exchange Commission, or the SEC, and the Company's other filings with the SEC, which could cause actual results to differ materially from those indicated by the forward-looking statements made in this Form 8-K. Any forward-looking statements speak only as of the date of this Form 8-K and are based on information available to the Company as of the date of this Form 8-K, and the Company assumes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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.

GALERA THERAPEUTICS, INC.

Date: February 15, 2023

By: /s/ J. Mel Sorensen, M.D.

J. Mel Sorensen, M.D.

President and Chief Executive Officer