

**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 30, 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.)

**45 Liberty Blvd #230
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 Symbol(s)	Name of each exchange 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 8.01 Other Events

On May 30, 2023, Galera Therapeutics, Inc. (the “Company”) filed a lawsuit in the Court of Common Pleas in Chester County, Pennsylvania against Alira Health Clinical, LLC and IQVIA Biotech, LLC (the “CROs”) alleging breach of contract and negligence specifically related to an error by the CROs in 2021 in the statistical program for the Phase 3 ROMAN trial of avasopasem for the reduction of severe oral mucositis (“SOM”) induced by radiotherapy in patients with locally advanced head and neck cancer (the “Phase 3 ROMAN trial”) and seeking damages. In December 2021, the Company announced that the error in the statistical program for the Phase 3 ROMAN trial had been detected and that correction of this error yielded the correct, statistically significant p-values for the primary endpoint and a key secondary endpoint of the Phase 3 ROMAN trial.

This litigation is in its early stages, and the Company is unable to predict the outcome at this time.

As previously disclosed by the Company, in February 2023, the U.S. Food and Drug Administration accepted and granted Priority Review designation to the Company’s New Drug Application (“NDA”) for avasopasem for the reduction of SOM induced by radiotherapy. The Prescription Drug User Fee Act (PDUFA) target date for the NDA is August 9, 2023.

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: May 30, 2023

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

J. Mel Sorensen, M.D.

President and Chief Executive Officer