

**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 13, 2024

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 Stock Market LLC (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.

On May 13, 2024, Galera Therapeutics, Inc. announced its financial results for the quarter ended March 31, 2024. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 2.02 of this Current Report on Form 8-K (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 under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly provided by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit 99.1 relating to Item 2.02 shall be deemed to be furnished, and not filed:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Galera Therapeutics, Inc. issued May 13, 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.

GALERA THERAPEUTICS, INC.

Date: May 13, 2024

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

J. Mel Sorensen, M.D.

President and Chief Executive Officer



Galera Reports First Quarter 2024 Financial Results and Recent Corporate Updates

Company's evaluation of potential strategic alternatives progresses with goal to maximize stockholder value

MALVERN, Pa. – May 13, 2024 – Galera Therapeutics, Inc. (Nasdaq: GRTX), a clinical-stage biopharmaceutical company focused on developing a pipeline of novel, proprietary therapeutics that have the potential to transform radiotherapy in cancer, today announced financial results for the first quarter ended March 31, 2024, and provided recent corporate updates.

“Our review of strategic options continues, as we strive to maximize value for our stockholders,” said Mel Sorensen, M.D., Galera’s President and CEO. “Potential options may include mergers, asset sales, divestiture, licensing arrangements, or other strategic transactions and may encompass a potential development path for avasopasem. The process could ultimately culminate in the dissolution of the Company.”

General Corporate Updates

- Galera remains actively engaged with Stifel, Nicolaus & Company, Inc. to undertake a comprehensive review of strategic alternatives for both the Company and its portfolio of dismutase mimetics. The Company has not set a fixed timeline for completing this evaluation process and does not intend to disclose further updates unless and until it is determined that further disclosure is appropriate or necessary.
- On May 3, 2024, the Company announced that its Board of Directors (the “Board”) unanimously resolved to adopt a limited duration stockholder rights agreement (the “Rights Agreement”) to protect stockholder interests. The Board resolved to adopt the Rights Agreement in response to recent accumulations of the Company’s common stock, and the Rights Agreement is intended to enable all Galera stockholders to realize the full potential value of their investment in Galera and to protect the interests of the Company and its stockholders by reducing the likelihood that any person or group gains control of Galera without paying an appropriate control premium. In addition, the Rights Agreement provides the Board with time to make informed decisions that are in the best long-term interests of Galera and its stockholders. It does not deter the Board from considering any offer or proposal that is fair and otherwise in the best interest of Galera stockholders.

First Quarter 2024 Financial Highlights

- Research and development expenses were \$1.5 million in the first quarter of 2024, compared to \$7.3 million for the same period in 2023. The decrease was primarily attributable to a decrease in avasopasem and rucosopasem development costs. The Company has ceased all clinical trial activity and suspended the clinical development of its product candidates as it explores potential strategic alternatives.

- General and administrative expenses were \$3.1 million in the first quarter of 2024, compared to \$6.6 million for the same period in 2023. The decrease was primarily attributable to the cessation of avasopasem commercial preparations and medical affairs activities and reduced personnel-related expenses due to the workforce reduction announced in August 2023.
- Galera reported a net loss of \$(4.4) million, or \$(0.08) per share, for the first quarter of 2024, compared to a net loss of \$(17.7) million, or \$(0.50) per share, for the same period in 2023.
- As of March 31, 2024, Galera had cash and cash equivalents of \$13.5 million. Galera expects that its existing cash and cash equivalents will enable Galera to fund its operating expenses and capital expenditure requirements into the third quarter of 2025.

About Galera Therapeutics

Galera Therapeutics, Inc. is a biopharmaceutical company that was historically focused on developing a pipeline of novel, proprietary therapeutic candidates that have the potential to transform radiotherapy in cancer. Galera's selective dismutase mimetic product candidate avasopasem manganese (avasopasem) was being developed for radiation-induced and cisplatin-related toxicities. The FDA has granted Fast Track and Breakthrough Therapy designations to avasopasem for the reduction of severe oral mucositis induced by radiotherapy. The Company's second product candidate, rucosopasem manganese (rucosopasem), was being developed to augment the anti-cancer efficacy of stereotactic body radiation therapy in patients with non-small cell lung cancer and locally advanced pancreatic cancer. Rucosopasem has been granted orphan drug designation and orphan medicinal product designation by the FDA and EMA, respectively, for the treatment of pancreatic cancer. Galera is headquartered in Malvern, PA.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding: Galera's pursuit of strategic alternatives and the ability of any such strategic alternative to provide stockholder value, including a potential development path for avasopasem; the potential safety and efficacy of Galera's product candidates and their regulatory and clinical development; Galera's ability to fund its operating expenses and capital expenditure requirements into the third quarter of 2025; and Galera's ability to achieve its goal of transforming radiotherapy in cancer treatment with its selective dismutase mimetics. 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 Galera'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, the following: Galera's limited operating history; anticipating continued losses for the foreseeable future; needing substantial funding and the ability to raise capital; Galera's dependence on avasopasem manganese (GC4419); uncertainties inherent in the conduct of clinical trials; difficulties or delays enrolling patients in clinical trials; the FDA's acceptance of data from clinical trials outside the United States; undesirable side effects from Galera's product candidates; risks relating to the regulatory approval process; failure to capitalize on more profitable product candidates or indications; ability to receive or maintain Breakthrough Therapy, Orphan Drug or Fast Track Designations for product candidates; failure to obtain regulatory approval of product candidates in the United States or other

jurisdictions; ongoing regulatory obligations and continued regulatory review; risks related to commercialization; risks related to competition; ability to retain key employees; risks related to intellectual property; inability to maintain collaborations or the failure of these collaborations; Galera's reliance on third parties; the possibility of system failures or security breaches; liability related to the privacy of health information obtained from clinical trials and product liability lawsuits; environmental, health and safety laws and regulations; Galera may not be able to enter into any desired strategic alternative or partnership on a timely basis, on acceptable terms, or at all; if Galera is unable to secure additional funding or enter into any desired strategic alternative or partnership, it may need to cease operations; risks related to ownership of Galera's common stock; the possibility of Galera's common stock being delisted from The Nasdaq Global Market; and significant costs as a result of operating as a public company. These and other important factors discussed under the caption "Risk Factors" in Galera's Annual Report on Form 10-K for the year ended December 31, 2023 filed with the U.S. Securities and Exchange Commission (SEC) and Galera's other filings with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any forward-looking statements speak only as of the date of this press release and are based on information available to Galera as of the date of this release, and Galera assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

Galera Therapeutics, Inc.
Consolidated Statements of Operations
(unaudited, in thousands except share and per share data)

	Three Months Ended March 31,	
	2024	2023
Operating expenses:		
Research and development	\$ 1,488	\$ 7,272
General and administrative	3,089	6,609
Loss from operations	(4,577)	(13,881)
Other income (expense), net	196	(3,829)
Net loss	\$ (4,381)	\$ (17,710)
Net loss per share of common stock, basic and diluted	\$ (0.08)	\$ (0.50)
Weighted average common shares outstanding, basic and diluted	54,392,170	35,196,134

Galera Therapeutics, Inc.
Selected Consolidated Balance Sheet Data
(unaudited, in thousands)

	March 31,	December 31,
	2024	2023
Cash and cash equivalents	\$ 13,466	\$ 18,257
Total assets	19,651	26,141
Total current liabilities	2,013	4,957
Total liabilities	154,342	157,326
Total stockholders' deficit	(134,691)	(131,185)

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