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): March 28, 2024

GALERA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-39114**	**46-1454898**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(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 March 28, 2024, Galera Therapeutics, Inc. announced its financial results for the quarter and year ended December 31, 2023. 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:

Exhibit No.	Description
99.1	Press Release of Galera Therapeutics, Inc. issued March 28, 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: March 28, 2024

By: /s/ J. Mel Sorensen, M.D.
J. Mel Sorensen, M.D.
President and Chief Executive Officer

Galera Reports Fourth Quarter and Full Year 2023 Financial Results and Recent Corporate Updates

Company continues to evaluate strategic options to maximize shareholder value

MALVERN, Pa. – March 28, 2024 – Galera Therapeutics, Inc. (Nasdaq: GRTX), a 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 fourth quarter and year ended December 31, 2023 and provided recent corporate updates.

"As a result of last year's FDA request for a second Phase 3 trial to support the avasopasem NDA, we have implemented key measures to extend our cash runway and assess strategic alternatives," said Mel Sorensen, M.D., Galera's President and CEO. "Among these measures, we recognize that the decision to discontinue our GRECO trials was challenging for our team and our clinical investigators, but we believe it was the appropriate decision, following the negative futility analysis in the pancreatic trial. We are continuing to explore strategic options to maximize value to our shareholders, including a potential development path for avasopasem. This process could ultimately result in the dissolution of the Company."

Recent Corporate Updates

General Corporate Updates

- In August 2023, the Company announced a reduction in force, which reduced the Company's workforce by approximately 70%, as of August 9, 2023 (Workforce Reduction). The decision was made to reduce operational costs as part of broader cost-saving measures.
- In October 2023, the Company announced it had engaged Stifel, Nicolaus & Company, Inc., as its financial advisor, to assist in reviewing strategic alternatives with the goal of maximizing value for its stockholders.

Radiotherapy-Induced Severe Oral Mucositis (SOM)

- In February 2023, the Company announced that the U.S. Food and Drug Administration (FDA) accepted for filing and granted priority review to the New Drug Application (NDA) for avasopasem manganese (avasopasem) for radiotherapy-induced SOM in patients with head and neck cancer (HNC) undergoing standard-of-care treatment. The Prescription Drug User Fee Act (PDUFA) target date assigned by the FDA for the NDA was August 9, 2023.
- In August 2023, the FDA issued a Complete Response Letter (CRL) for the NDA for avasopasem. In the CRL, the FDA communicated that the data from the Phase 2b GT-201 and Phase 3 ROMAN trials were not sufficient for approval and that an additional clinical trial will be required for an NDA resubmission.

- In September 2023, a Type A meeting was held with the FDA to understand the FDA's rationale for its decision and discuss next steps to support an NDA resubmission.
- In October 2023, the Company received official meeting minutes from the Type A meeting in which the FDA reiterated the need for an additional Phase 3 trial to support resubmission. The Company continues to explore potential options for the development of avasopasem.

Cisplatin-Related Chronic Kidney Disease (CKD)

- In November 2023, the Company presented the prospectively collected cisplatin-related CKD data from the Phase 3 ROMAN trial at the American Society of Nephrology (ASN) Kidney Week 2023 meeting, which took place November 2-5 in Philadelphia, PA. The oral presentation, titled "Effects of Avasopasem on Rates of Cisplatin-Induced Acute Kidney Injury and Chronic Kidney Disease," reported significant preservation of kidney function across cisplatin dosing schedules, including a 50% reduction in the avasopasem arm in the incidence of CKD one year following treatment with cisplatin compared to placebo. During the treatment phase, lower incidences of acute renal adverse events were also observed in the avasopasem arm compared to placebo.

Locally Advanced Pancreatic Cancer (LAPC)

- In May 2023, the FDA granted Orphan Drug Designation for rucosopasem for the treatment of pancreatic cancer.
- In October 2023, the Company decided to halt the Phase 2b GRECO-2 trial of rucosopasem manganese (rucosopasem) in patients with LAPC, following an early futility analysis of the trial which indicated that the trial was unlikely to succeed as designed.

Non-Small Cell Lung Cancer (NSCLC)

- In October 2023, following the futility analysis of the GRECO-2 trial, the Company decided to halt the randomized, placebo-controlled Phase 1/2 GRECO-1 trial of rucosopasem in patients with NCSLC.

Fourth Quarter 2023 Financial Highlights

- Research and development expenses were $3.2 million in the fourth quarter of 2023, compared to $8.1 million for the same period in 2022. The decrease was primarily attributable to a decrease in avasopasem development costs and lower personnel-related expenses due to the Workforce Reduction.
- General and administrative expenses were $2.0 million in the fourth quarter of 2023, compared to $5.0 million for the same period in 2022. The decrease was primarily attributable to lower personnel-related expenses due to the Workforce Reduction and the halting of avasopasem commercial preparation efforts following the receipt of the CRL from the FDA for the avasopasem NDA for radiotherapy-induced SOM in August 2023.
- Galera reported a net loss of $(5.6) million, or $(0.10) per share, for the fourth quarter of 2023, compared to a net loss of $(16.2) million, or $(0.58) per share, for the same period in 2022.
- As of December 31, 2023, Galera had cash and cash equivalents of $18.3 million. Galera expects that its existing cash and cash equivalents will enable Galera to fund its operating expenses and capital expenditure requirements into the second quarter of 2025.

Full Year 2023 Financial Highlights

- Research and development expenses were $24.1 million for the year ended December 31, 2023, compared to $31.0 million for the year ended December 31, 2022. The decrease was primarily attributable to a decrease in avasopasem development costs and lower personnel-related expenses due to the Workforce Reduction, partially offset by an increase in rucosopasem development costs.
- General and administrative expenses were $22.8 million for the year ended December 31, 2023, compared to $20.2 million for the year ended December 31, 2022. The increase was primarily attributable to avasopasem commercial preparations in 2023, partially offset by a decrease in personnel-related expenses driven by the Workforce Reduction.
- As a result of the Workforce Reduction, the Company incurred restructuring-related charges of $2.3 million in the third quarter of 2023, primarily consisting of severance payments, employee benefits and related costs.
- Galera reported a net loss of $(59.1) million, or $(1.33) per share, for the year ended December 31, 2023, compared to a net loss of $(62.2) million, or $(2.30) per share, for the year ended December 31, 2022.

About Galera Therapeutics

Galera Therapeutics, Inc. is a biopharmaceutical company 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) has been developing 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), has been in development 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 shareholder 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 second quarter 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
(in thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 3,189	$ 8,137	$ 24,115	$ 31,012
General and administrative	1,987	5,021	22,836	20,214
Restructuring costs	—	—	2,309	—
Loss from operations	(5,176)	(13,158)	(49,260)	(51,226)
Other income (expense), net	(411)	(3,100)	(9,822)	(11,066)
Loss before income tax benefit	(5,587)	(16,258)	(59,082)	(62,292)
Income tax benefit	—	70	—	70
Net Loss	$ (5,587)	$ (16,188)	$ (59,082)	$ (62,222)
Net loss per share of common stock, basic and diluted	$ (0.10)	$ (0.58)	$ (1.33)	$ (2.30)
Weighted average common shares outstanding, basic and diluted	54,385,017	27,942,210	44,549,285	27,086,664

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

	December 31, 2023	December 31, 2022
Cash, cash equivalents, and short-term investments	$ 18,257	$ 31,597
Total assets	26,141	44,036
Total current liabilities	4,957	13,379
Total liabilities	157,326	153,217
Total stockholders' deficit	(131,185)	(109,181)

###

Investor Contacts:

Christopher Degnan
Galera Therapeutics, Inc.
610-725-1500
cdegnan@galeratx.com

William Windham
Solebury Strategic Communications
646-378-2946
wwindham@soleburystrat.com

Media Contact:

Timothy Biba
Solebury Strategic Communications
646-378-2927
tbiba@soleburystrat.com