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): November 14, 2023

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 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 November 14, 2023, Galera Therapeutics, Inc. announced its financial results for the quarter ended September 30, 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 November 14, 2023
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: November 14, 2023

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

Galera Reports Third Quarter 2023 Financial Results and Recent Corporate Updates

FDA confirms need for new trial for avasopasem; GRECO trials with rucosopasem to be discontinued

Company evaluating potential strategic options to optimize shareholder value

MALVERN, Pa. – November 14, 2023 – 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 third quarter ended September 30, 2023 and provided recent corporate updates.

“Given the considerable time and investment required for additional clinical trials, we find it prudent to explore strategic options,” said Mel Sorensen, M.D., Galera’s President and CEO. “We also made the difficult decision to discontinue our GRECO trials, which we believe is an appropriate step towards cash conservation and maximizing value for our shareholders. We extend our gratitude to all the patients, research teams, and dedicated employees who have contributed to the advances we have made.”

Recent Corporate Updates

Radiotherapy-Induced Severe Oral Mucositis (SOM)

- In August 2023, the Company announced that the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) for 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. 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, the Company held a Type A meeting 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 is exploring potential strategic alternatives, as it is not feasible to conduct an additional trial with the Company’s current resources.

Cisplatin-Related Chronic Kidney Disease (CKD)

- In November 2023, the cisplatin-related CKD data from the Phase 3 ROMAN trial was presented 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,” described significant

reduction in the incidence of CKD one year following treatment with cisplatin in the avasopasem arm, reducing CKD by 50% compared to placebo. This was a prospectively defined endpoint of the ROMAN trial, and the reduction was seen with both cisplatin dosing schedules and across all stages of CKD. The result paralleled improvements in preservation of kidney function across the entire population observed from three months through one year. Lower incidence of renal adverse events was also observed in the avasopasem arm compared to placebo during the treatment phase.

Locally Advanced Pancreatic Cancer (LAPC)

- In October 2023, the Company decided to halt the Phase 2b GRECO-2 trial of rucosopasem manganese (rucosopasem) in patients with LAPC, following a futility analysis of the trial. The analysis indicated that the trial was unlikely to succeed as designed. GRECO-2 is a randomized, double-blind, placebo-controlled trial evaluating rucosopasem or placebo in combination with stereotactic body radiation therapy (SBRT) in patients with LAPC. Overall survival was the trial's primary endpoint. The trial was designed to enroll 220 patients with final analysis at 120 events (deaths). The trial had enrolled 177 patients by the date of the decision to halt the trial, and the futility analysis was conducted based on 35 deaths with a data cutoff of October 9, 2023.

Non-Small Cell Lung Cancer (NSCLC)

- In October 2023, the Company decided to halt the randomized, placebo-controlled Phase 1/2 GRECO-1 trial of rucosopasem in patients with NCSLC, following the futility analysis of the GRECO-2 trial.
- In October 2023, a poster featuring rucosopasem preclinical data was presented at the 2023 American Society for Radiation Oncology (ASTRO) Annual Meeting, which took place October 1-3, 2023, in San Diego, CA. The poster, titled "Enhanced Peroxide Fluxes and Radiosensitization in Colorectal Tumors but Not Normal Enterocytes from the Combination of Superoxide Dismutase Mimetics and Pharmacological Ascorbate," noted that rucosopasem in combination with pharmacological ascorbate may sensitize tumors to clinically relevant radiotherapy doses while maintaining their normal tissue sparing effects.

General Corporate Updates

- In connection with the CRL announcement in August 2023, the Company further announced a reduction in force, which reduced the Company's workforce by 22 employees, or approximately 70%, as of August 9, 2023 ("Workforce Reduction"). The decision was based on cost-reduction initiatives intended to reduce operating expenses.
- To maximize value for shareholders, the Company engaged Stifel, Nicolaus & Company, Inc. to undertake a comprehensive review of strategic alternatives for both the Company and its portfolio of dismutase mimetics. These strategic alternatives may include, but are not limited to, mergers, asset sales, divestiture, licensing arrangements, or other strategic transactions. If the Company is unable to undertake any strategic alternative, it may be required to cease operations. The Company has not set a timetable for completion of this evaluation process and does not intend to disclose further updates unless and until it is determined that further disclosure is appropriate or necessary.

Third Quarter 2023 Financial Highlights

- Research and development expenses were $6.1 million in the third 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 reduced personnel-related expenses due to the Workforce Reduction, partially offset by an increase in rucosopasem development costs.
- General and administrative expenses were $5.0 million in the third quarter of 2023, compared to $4.9 million for the same period in 2022. The increase was primarily attributable to avasopasem commercial preparations and increased legal expenses, largely offset by reduced personnel-related expenses due to the Workforce Reduction and reduced insurance expense.
- 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 $(15.1) million, or $(0.33) per share, for the third quarter of 2023, compared to a net loss of $(16.0) million, or $(0.60) per share, for the same period in 2022.
- As of September 30, 2023, Galera had cash, cash equivalents and short-term investments of $28.4 million. Galera expects that its existing cash, cash equivalents and short-term investments, taking into account the discontinuation of the GRECO-1 and GRECO-2 trials, will enable Galera to fund its operating expenses and capital expenditure requirements into 2025.

About Galera Therapeutics

Galera Therapeutics, Inc. is a clinical-stage 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) is 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), is in clinical-stage 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: the expectations surrounding the continued advancement of Galera's product pipeline; the potential safety and efficacy of Galera's product candidates and their regulatory and clinical development; Galera's intention to pursue strategic alternatives and the ability of any such strategic alternative to provide shareholder value; the expected financial and operational impacts of Galera's decision to discontinue the Phase 2b GRECO-2 trial and the Phase 1/2 GRECO-1 trial; Galera's ability to fund its operating expenses and capital expenditure requirements into 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 Designation or Fast Track Designation 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's recent reduction in force undertaken to significantly reduce our ongoing operating expenses may not result in our intended outcomes and may yield unintended consequences and additional costs; 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, 2022 and Quarterly Report on Form 10-Q for the quarterly period ended September 30, 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 6,093	$ 8,105	$ 20,926	$ 22,848
General and administrative	4,994	4,853	20,849	15,193
Restructuring costs	2,309	—	2,309	—
Loss from operations	(13,396)	(12,958)	(44,084)	(38,041)
Other income (expense), net	(1,677)	(3,075)	(9,411)	(7,993)
Net loss	$ (15,073)	$ (16,033)	$ (53,495)	$ (46,034)
Net loss per share of common stock, basic and diluted	$ (0.33)	$ (0.60)	$ (1.30)	$ (1.72)
Weighted average common shares outstanding, basic and diluted	45,477,952	26,823,546	41,234,679	26,798,348

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

	September 30, 2023	December 31, 2022
Cash, cash equivalents, and short-term investments	$ 28,364	$ 31,597
Total assets	37,779	44,036
Total current liabilities	12,630	13,379
Total liabilities	164,332	153,217
Total stockholders' deficit	(126,553)	(109,181)

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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