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 16, 2022

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.)**

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 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 16, 2022, Galera Therapeutics, Inc. announced its financial results for the quarter ended March 31, 2022. 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 May 16, 2022
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 16, 2022

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

Galera Reports First Quarter 2022 Financial Results and Recent Corporate Updates

Company plans to submit a New Drug Application (NDA) for avasopasem for the treatment of radiotherapy-induced severe oral mucositis (SOM) by end of 2022

Data from its Phase 3 ROMAN trial of avasopasem for SOM will be presented in an oral presentation at the upcoming 2022 American Society of Clinical Oncology (ASCO) Annual Meeting

Reported positive topline results from its Phase 2a AESOP trial of avasopasem for chemoradiotherapy-induced esophagitis

MALVERN, Pa. – May 16, 2022 – Galera Therapeutics, Inc. (Nasdaq: GRTX), a clinical-stage biopharmaceutical company focused on developing and commercializing 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, 2022 and provided recent corporate updates.

"We are excited to announce our plan to submit an NDA for avasopasem by year end following discussions with the FDA," said Mel Sorensen, M.D., Galera's President and CEO. "Based on the positive data readout from our Phase 3 ROMAN trial, Galera continues to execute on its development strategy to advance its lead program, avasopasem, toward potential commercialization. To that end, we are delighted to attend the upcoming ASCO Annual Meeting where our ROMAN data will be highlighted in an oral presentation. In addition, we recently announced positive topline data from our Phase 2a AESOP study of avasopasem for chemoradiotherapy-induced esophagitis in patients with lung cancer. We are encouraged by these results, which further demonstrate avasopasem's ability to reduce radiation toxicity in high-risk patient populations."

Recent Corporate Updates

Radiotherapy-Induced Toxicity Programs:

Severe Oral Mucositis (SOM)

- The Company announced plans to submit a New Drug Application (NDA) for avasopasem, its lead product candidate, for the treatment of radiotherapy-induced SOM to the US Food and Drug Administration (FDA) by the end of 2022.
- An abstract on the Phase 3 ROMAN data of avasopasem for SOM was accepted for an oral presentation on June 3rd at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting.

Esophagitis

- The Company reported positive topline data from the Phase 2a AESOP trial of avasopasem evaluating its ability to reduce the incidence of severe acute radiation-induced esophagitis in patients with lung cancer receiving concurrent chemoradiotherapy. Overall, avasopasem was well tolerated and the incidence of Grade 3 esophagitis was substantially reduced in comparison to literature. No patients experienced Grade 4 or 5 esophagitis at any point during the trial.

Anti-Cancer Programs:

Locally Advanced Pancreatic Cancer (LAPC)

- Enrollment is ongoing in the Phase 2b, 160-patient randomized, multicenter, placebo-controlled GRECO-2 trial of rucosopasem, Galera's second dismutase mimetic product candidate, in combination with stereotactic body radiation therapy (SBRT) in patients with LAPC. The primary endpoint of the trial is overall survival.
- A Trials in Progress abstract on GRECO-2 was accepted for presentation at the upcoming 2022 ASCO Annual Meeting.

Non-Small Cell Lung Cancer (NSCLC)

- Enrollment is ongoing in the Phase 1/2 GRECO-1 trial of rucosopasem in combination with SBRT in patients with NSCLC. The Company expects to report initial data from this trial in the first half of 2022.

First Quarter 2022 Financial Highlights

- Research and development expenses were $8.1 million in the first quarter of 2022, compared to $12.4 million for the same period in 2021. The decrease was primarily attributable to a decrease in avasopasem development costs, partially offset by an increase in rucosopasem development costs.
- General and administrative expenses were $5.0 million in the first quarter of 2022, consistent with the first quarter of 2021.
- Galera reported a net loss of $(15.4) million, or $(0.58) per share, for the first quarter of 2022, compared to a net loss of $(18.7) million, or $(0.75) per share, for the same period in 2021.
- As of March 31, 2022, Galera had cash, cash equivalents and short-term investments of $60.9 million. Galera expects that its existing cash, cash equivalents and short-term investments will enable Galera to fund its operating expenses and capital expenditure requirements into the second half of 2023.

About Galera Therapeutics

Galera Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on developing and commercializing 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 (GC4419, also referred to as avasopasem) is being evaluated for radiotherapy-induced toxicities. The Company's second product candidate, rucosopasem manganese (GC4711, also referred to

as 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. Galera is headquartered in Malvern, PA. For more information, please visit **www.galeratx.com**.

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; the timing of the submission of an NDA for avasopasem for the treatment of radiotherapy-induced SOM in patients with locally advanced head and neck cancer with the FDA; the ability of the results of the Phase 2a AESOP trial of avasopasem evaluating its ability to reduce the incidence of esophagitis induced by radiotherapy in patients with lung cancer to demonstrate avasopasem's ability to reduce radiation toxicity in high-risk patient populations; the expectations surrounding the progress of the Phase 2b trial of rucosopasem in patients with LAPC; the expectations surrounding the progress of the Phase 1/2 trial of rucosopasem in patients with NSCLC and the timing of the release of initial data therefrom; the Company's ability to achieve its goal of transforming radiotherapy in cancer treatment with its selective dismutase mimetics; the potential of GC4711 to augment the anti-cancer efficacy of SBRT in patients with NSCLC and LAPC; and the Company's ability to fund its operating expenses and capital expenditure requirements into the second half of 2023. 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 and manage growth; 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; unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives; environmental, health and safety laws and regulations; the impact of the COVID-19 pandemic on Galera's business and operations, including preclinical studies and clinical trials, and general economic conditions; risks related to ownership of Galera's common stock; 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, 2021 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,	
	2022	2021
Operating expenses:		
Research and development	$ 8,107	$ 12,423
General and administrative	5,047	5,058
Loss from operations	(13,154)	(17,481)
Other income (expense), net	(2,289)	(1,234)
Net loss	$ (15,443)	$ (18,715)
Net loss per share of common stock, basic and diluted	$ (0.58)	$ (0.75)
Weighed average common shares outstanding, basic and diluted	26,749,379	24,988,198

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

	March 31, 2022	December 31, 2021
Cash, cash equivalents, and short-term investments	$ 60,947	$ 71,217
Total assets	71,099	83,311
Total current liabilities	10,931	12,935
Total liabilities	141,570	141,315
Total stockholders' deficit	(70,471)	(58,004)

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