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): December 12, 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 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 7.01 Regulation FD Disclosure.

On December 12, 2022, Galera Therapeutics, Inc. (the "Company") issued a press release announcing the submission of its New Drug Application for avasopasem for radiotherapy-induced severe oral mucositis in patients with head and neck cancer undergoing standard-of-care treatment to the U.S. Food and Drug Administration. A copy of the press release is attached to this Current Report on Form 8-K ("Form 8-K") as Exhibit 99.1.

The information contained in Item 7.01 of this 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

Exhibits 99.1 relating to Item 7.01 shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Press Release of Galera Therapeutics, Inc. issued December 12, 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: December 12, 2022

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

Exhibit 99.1

Galera Submits New Drug Application for Avasopasem for Severe Oral Mucositis

NDA based on two positive randomized, double-blinded, placebo-controlled trials which enrolled a total of 678 patients

MALVERN, Pa. – December 12, 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 the submission of its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for avasopasem for radiotherapy-induced severe oral mucositis (SOM) in patients with head and neck cancer (HNC) undergoing standard-of-care treatment. The FDA has granted Fast Track and Breakthrough Therapy designations to avasopasem for the reduction of SOM induced by radiotherapy. SOM is characterized by the inability to eat solid food or drink liquids and may require the surgical placement of feeding tubes to maintain nutrition and hydration. There are currently no FDA-approved drugs to reduce SOM for these patients.

"With submission of this NDA, we achieved an important milestone towards our goal of transforming radiotherapy, potentially bringing patients with HNC the first approved drug for SOM and relief from its tremendous burden," said Mel Sorensen, M.D., President and Chief Executive Officer of Galera Therapeutics. "Approximately 42,000 patients with HNC undergo standard-of-care radiotherapy every year in the U.S. and are at risk of developing SOM. Our two rigorous, placebo-controlled trials which enrolled nearly 700 patients give us confidence that avasopasem has the potential to provide meaningful clinical benefit for patients by reducing SOM incidence, days, and severity while also delaying its onset. We look forward to working closely with the FDA during the review process."

Dr. Sorensen continued, "Further, the reduction in cisplatin-related chronic kidney disease in patients treated with avasopasem reported in October may offer added clinical benefit to the large number of patients with HNC who receive cisplatin with their radiotherapy."

The NDA is supported by the randomized, double-blinded, placebo-controlled Phase 3 ROMAN and Phase 2b GT-201 trials which enrolled a total of 678 patients. Results from the 455-patient ROMAN trial demonstrated a clinically meaningful reduction in patients' SOM burden across multiple endpoints, with statistically significant reductions on the primary endpoint of incidence of SOM and the secondary endpoint of number of days of SOM, more than halving the median number of days a patient suffered SOM. Avasopasem also showed clinically meaningful reductions in severity of SOM (Grade 4 incidence) compared to placebo. Exploratory analyses, such as time to SOM onset and SOM incidence at various landmarks of radiotherapy delivered, further demonstrated the clinical benefit of avasopasem in reducing the burden of SOM. Avasopasem was generally well tolerated compared to placebo. Overall, the adverse event (AE) incidences noted in the clinical trials were consistent with the interpretation that avasopasem was not associated with a clinically meaningful increase in the AE profile expected for the target patient population receiving standard-of-care chemoradiation therapy. In addition, a prospectively defined exploratory analysis looking at renal function through 12 months follow-up showed that avasopasem reduced cisplatin-induced chronic kidney disease by 50%.

About the Phase 3 Roman Trial

The Phase 3 ROMAN trial (GTI-4419-301) was a randomized, double-blind, placebo-controlled trial in 455 patients designed to evaluate the ability of avasopasem to reduce radiation-induced SOM in patients with locally advanced HNC, receiving seven weeks of standard-of-care radiotherapy plus cisplatin. Patients were randomized to one of the two treatment groups (3:2) to receive 90 mg of avasopasem or placebo by infusion on the days they receive their radiation treatment.

Results from the 455-patient ROMAN trial demonstrated a meaningful reduction in patients' SOM burden across multiple endpoints, with statistically significant reductions on the primary endpoint of incidence of SOM and the secondary endpoint of number of days of SOM, more than halving the median number of days a patient suffered SOM. Meaningful reduction in the number of patients who developed the most severe form of SOM (Grade 4) was also observed. Exploratory analyses, such as time to SOM onset and SOM incidence at various landmarks of radiotherapy delivered, also demonstrated the clinical benefit of avasopasem in reducing the burden of SOM, along with a reduction in long-term loss of kidney function associated with concurrent cisplatin. Avasopasem was generally well tolerated compared to placebo.

About the Phase 2b GT-201 Trial

The GT-201 trial (GTI-4419-201) was a randomized, double-blind, placebo-controlled trial in 223 patients designed to evaluate the ability of avasopasem to reduce radiation-induced SOM in patients with locally advanced HNC, receiving seven weeks of standard-of-care radiotherapy plus cisplatin. Patients were randomized to one of the three treatment groups (1:1:1) to receive either 30 mg or 90 mg of avasopasem or placebo by infusion on the days they receive their radiation treatment.

Results from the 223-patient Phase 2b trial demonstrated a meaningful reduction in patients' SOM burden across multiple endpoints, with a statistically significant reduction on the primary endpoint of number of days of SOM in the 90 mg avasopasem arm compared to placebo. Avasopasem also resulted in clinically meaningful reductions in the incidence, severity (Grade 4 incidence), and onset of SOM compared to placebo. Avasopasem was generally well tolerated compared to placebo. The FDA granted Breakthrough Therapy designation to avasopasem for the reduction of SOM induced by radiotherapy, based on the positive results of the GT-201 trial.

About Severe Oral Mucositis (SOM)

Approximately 42,000 patients with head and neck cancer undergo standard-of-care radiotherapy every year in the U.S. and are at risk of experiencing SOM. In patients with head and neck cancer, radiotherapy is a mainstay of treatment. Approximately 70 percent of patients receiving radiotherapy for head and neck cancer develop SOM, defined by the inability to eat solid food or drink liquids. The impact on patients who develop SOM is substantial, particularly when hospitalization and/or surgical placement of feeding (PEG) tubes to maintain nutrition and hydration are required. SOM can adversely affect cancer treatment outcomes by causing interruptions in radiotherapy, which may compromise the otherwise good prognosis for tumor control in many of these patients. There is currently no drug approved to prevent or treat SOM for these patients.

About Avasopasem

Avasopasem manganese 90 mg (avasopasem, or GC4419) is a selective small molecule dismutase mimetic in development for the reduction of radiotherapy-induced severe oral mucositis (SOM) in patients with locally advanced head and neck cancer (HNC) and for the reduction of radiotherapy-induced esophagitis in patients with lung cancer. The FDA has granted Fast Track and Breakthrough Therapy designations to avasopasem for the reduction of SOM induced by radiotherapy.

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 (avasopasem, or GC4419) is being evaluated for radiotherapy-induced toxicities. The Company's second product candidate, rucosopasem manganese (rucosopasem, or GC4711), 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 potential to obtain approval by the U.S. Food and Drug Administration for avasopasem for the treatment of radiotherapy-induced severe oral mucositis (SOM) in patients with locally advanced head and neck cancer; the ability of avasopasem to provide meaningful clinical benefit to patients by reducing the number who develop SOM and how long they are afflicted with it; the ability of avasopasem to delay onset of SOM and decrease the number of patients who develop the most severe form of SOM; the potential of avasopasem to offer clinical benefit to a large number of patients with HNC who receive cisplatin; the clinical benefit in reducing the burden of SOM along with reduction in long-term loss of kidney function associated with concurrent cisplatin; and the Company'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 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; 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, 2021 filed with the U.S. Securities and Exchange Commission (SEC), Galera's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2022, 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.

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