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 10, 2021

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 November 10, 2021, Galera Therapeutics, Inc. announced its financial results for the quarter ended September 30, 2021. 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 issued November 10, 2021
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 10, 2021

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

J. Mel Sorensen, M.D.

President and Chief Executive Officer

Galera Reports Third Quarter 2021 Financial Results and Recent Corporate Updates

Recently announced topline results of Phase 3 ROMAN trial of avasopasem for radiotherapy-induced severe oral mucositis

Enrollment ongoing in GRECO-1 and GRECO-2 trials of rucosopasem (GC4711) in combination with SBRT in patients with NSCLC and Pancreatic Cancer; initial data from GRECO-1 expected in 1H2022

Strong cash position of $89M with expected cash runway into 2023

MALVERN, Pa. – November 10, 2021 – 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 third quarter ended September 30, 2021 and provided recent corporate updates.

“We are well-positioned financially to continue advancing our dismutase mimetic candidate rucosopasem (GC4711) in combination with stereotactic body radiation therapy (SBRT) in our randomized Phase 2 GRECO trials, with the goal of increasing the anti-cancer effectiveness of SBRT in patients with lung and pancreatic cancer,” said Mel Sorensen, M.D., President and CEO. “We have already observed improved tumor outcomes and survival when combining one of our dismutase mimetics with SBRT in our randomized, placebo-controlled, proof-of-concept trial in patients with locally advanced pancreatic cancer, reported in September. We look forward to reporting initial data evaluating rucosopasem in lung cancer in the first half of next year.”

Dr. Sorensen continued: “Following the recent announcement of topline results of the Phase 3 ROMAN trial, we are continuing to analyze the data and evaluating next steps for avasopasem. While ROMAN did not achieve statistical significance in the primary endpoint of reducing SOM incidence, avasopasem was generally well tolerated and more than halved the number of days patients experienced this severe side effect resulting from radiation therapy.”

Recent Corporate Updates

Anti-Cancer Programs:

Locally Advanced Pancreatic Cancer (LAPC)

- The Company reported final data from the Phase 1/2 pilot trial of avasopasem in combination with SBRT in patients with unresectable or borderline resectable LAPC. In this proof-of-concept trial, relative improvements were observed in overall survival, progression-free survival, local

tumor control and time to distant metastases. 46% of patients in the active arm were alive at last follow-up (11 out of 24) compared to 33% in the placebo arm (6 out of 18).

- 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 SBRT in patients with LAPC. The primary endpoint of the trial is overall survival.

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.

Radiotherapy-Induced Toxicity Programs:

Severe Oral Mucositis (SOM)

- The Company reported topline data from the Phase 3 ROMAN trial of avasopasem for the reduction of SOM in patients with locally advanced head and neck cancer (HNC) undergoing standard-of-care radiotherapy. The Company announced that the trial did not meet its primary endpoint of reduction in the incidence of SOM. Consistent with the Phase 2b trial, the data showed relative reduction across all key SOM endpoints, including more than halving the median duration of SOM.

- The Company expects to report topline data from the Phase 2a EUSOM multi-center trial of avasopasem in Europe in patients with HNC undergoing standard-of-care radiotherapy in the fourth quarter of 2021.

Esophagitis

- Enrollment is ongoing in the Phase 2a AESOP trial of avasopasem evaluating its ability to reduce the incidence of esophagitis induced by radiotherapy in patients with lung cancer. The Company expects to report topline data in the first half of 2022.

Third Quarter 2021 Financial Highlights

- Research and development expenses were $14.8 million in the third quarter of 2021, compared to $12.1 million for the same period in 2020. The increase was primarily attributable to rucosopasem development costs and an increase in contractor and consultant expense associated with the avasopasem SOM program.

- General and administrative expenses were $5.5 million in the third quarter of 2021, compared to $3.9 million for the same period in 2020. The increase was primarily attributable to employee-related costs from increased headcount and share-based compensation expense, increased expenses related to preparation for potential commercialization of avasopasem, and increased insurance expense and professional fees.

- Galera reported a net loss of $(22.6) million, or $(0.86) per share, for the third quarter of 2021, compared to a net loss of $(17.1) million, or $(0.69) per share, for the same period in 2020.

- As of September 30, 2021, Galera had cash, cash equivalents and short-term investments of $88.7 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 2023, assuming limited future development and commercial activities for avasopasem during this period. These assumptions may change as a result of many factors currently unknown to the Company, including without limitation the results of further analyses of data from the ROMAN trial and potential next steps for the Company's radiotherapy-induced toxicity programs.

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 technology consists of selective small molecule dismutase mimetics that are in late-stage development in patients with cancer. Avasopasem manganese (GC4419, also referred to as avasopasem) is in development for radiotherapy-induced toxicities, including SOM in patients with head and neck cancer and esophagitis in patients with lung cancer. Avasopasem has been granted FDA Fast Track and Breakthrough Therapy designations for the reduction of SOM induced by radiotherapy, with or without systemic therapy. Galera's second dismutase mimetic 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: expectations surrounding the continued advancement of our product pipeline; the potential safety and efficacy of Galera's product candidates and their regulatory and clinical development, including the interpretation of the safety and efficacy results from the Phase 3 ROMAN trial, expectations surrounding the progress of the Phase 2b trial of GC4711 in patients with LAPC, the expectations surrounding the progress of the Phase 1/2 trial of GC4711 in patients with NSCLC and the timing of the release of initial data therefrom, the timing of reporting topline data from the Phase 2a EUSOM multi-center trial of avasopasem in Europe in patients with HNC undergoing standard-of-care radiotherapy, the expectations surrounding the progress 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 and the timing of the release of topline 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 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, 2020 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,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 14,813	$ 12,133	$ 43,203	$ 40,225
General and administrative	5,487	3,945	15,667	11,384
Loss from operations	(20,300)	(16,078)	(58,870)	(51,609)
Other income (expense), net	(2,326)	(1,000)	(4,857)	(2,543)
Net loss	$ (22,626)	$ (17,078)	$ (63,727)	$ (54,152)
Net loss per share of common stock, basic and diluted	$ (0.86)	$ (0.69)	$ (2.49)	$ (2.18)
Weighted average common shares outstanding, basic and diluted	26,304,920	24,874,805	25,569,545	24,840,822

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

	September 30, 2021	December 31, 2020
Cash, cash equivalents, and short-term investments	$ 88,705	$ 72,776
Total assets	98,765	84,098
Total current liabilities	15,724	13,968
Total liabilities	141,932	77,980
Total stockholders' equity (deficit)	(43,167)	6,118

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