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 11, 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, including 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 May 11, 2021, Galera Therapeutics, Inc. announced its financial results for the quarter ended March 31, 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

The following Exhibit 99.1 relating to Item 2.02 shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Press Release issued on May 11, 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: May 11, 2021

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

Exhibit 99.1

Galera Reports First Quarter 2021 Financial Results and Recent Accomplishments

Phase 3 ROMAN trial in severe oral mucositis expected to complete enrollment in 1H21; topline data expected in 2H21

Recently announced near doubling of median overall survival observed in placebo-controlled pancreatic cancer trial

Phase 2b pancreatic cancer trial, GRECO-2, expected to commence enrollment in 1H21

MALVERN, Pa. – May 11, 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 first quarter ended March 31, 2021, and highlighted recent corporate accomplishments.

"Galera is off to a strong start in 2021, as we continue to progress our clinical oncology programs in radiation-induced severe oral mucositis (SOM), locally advanced pancreatic cancer (LAPC) and non-small cell lung cancer (NSCLC) with our dismutase mimetics," said Mel Sorensen, M.D., President and CEO of Galera. "We recently reported updated data from our placebo-controlled Phase 1/2 pilot trial, in which a near doubling of median overall survival was observed in patients with pancreatic cancer. Building on the positive results from this trial, we anticipate initiating a Phase 2b trial in the first half of 2021 in patients with LAPC, with overall survival as the primary endpoint. Importantly, we look forward to announcing topline data in the pivotal Phase 3 trial in SOM and potential regulatory approval and commercialization of avasopasem, our lead dismutase mimetic product candidate."

Recent Corporate Highlights

Severe Oral Mucositis (SOM)

- Continued enrollment in the pivotal Phase 3 ROMAN trial of avasopasem for the treatment of SOM in patients with locally advanced head and neck cancer (HNC) undergoing standard-of-care radiotherapy. The Company remains on track to report topline data in the second half of 2021.
- 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 second half of 2021.

Locally Advanced Pancreatic Cancer (LAPC)

- Reported updated data from the placebo-controlled Phase 1/2 pilot trial of Galera's dismutase mimetic in patients with LAPC who are also undergoing stereotactic body radiation therapy (SBRT). As of the data analysis, median overall survival (OS) in the treatment arm (20.1 months) was nearly twice as long as observed in the placebo arm (10.9 months); 29% of patients in the treatment arm achieved a partial response compared to 11% of patients in the placebo arm; and positive results were also observed in local tumor control, time to metastases and progression-free survival. The Company expects to report final results from the trial with at least one year of follow-up on all patients in the second half of 2021.

Non-Small Cell Lung Cancer (NSCLC)

- Continued enrollment in the Phase 1/2 GRECO-1 trial of GC4711, Galera's second dismutase mimetic product candidate, in combination with SBRT in patients with NSCLC. The Company remains on track to report initial data in the first half of 2022.

Esophagitis

- Continued enrollment 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.

First Quarter 2021 Financial Highlights

- Research and development expenses were $12.4 million in the first quarter of 2021, compared to $14.3 million for the same period in 2020. The decrease was primarily attributable to avasopasem development costs, due to decreased expenses related to the ROMAN trial and a decrease in preclinical expenses.
- General and administrative expenses were $5.1 million in the first quarter of 2021, compared to $3.6 million for the same period in 2020. The increase was primarily attributable to employee-related costs from increased headcount and share-based compensation expense, and increased expenses related to pre-commercial activities for avasopasem.
- Galera reported a net loss of $(18.7) million, or $(0.75) per share, for the first quarter of 2021, compared to a net loss of $(18.4) million, or $(0.74) per share, for the same period in 2020.
- As of March 31, 2021, Galera had cash, cash equivalents and short-term investments of $57.5 million. Galera expects that its existing cash, cash equivalents and short-term investments, together with the expected payments from Blackstone in the amount of $57.5 million upon the achievement of certain clinical enrollment milestones in the ROMAN trial and the anti-cancer program in combination with SBRT under the amended royalty agreement, will enable Galera to fund its operating expenses and capital expenditure requirements into the second half of 2022. The Company expects to achieve these clinical enrollment milestones in the first half of 2021.

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 lead product candidate is avasopasem manganese (GC4419,

also referred to as avasopasem), a selective small molecule dismutase mimetic initially being developed for the reduction of radiation-induced severe oral mucositis (SOM). Avasopasem is being studied in the Phase 3 ROMAN trial to assess its ability to reduce the incidence and severity of SOM induced by radiotherapy in patients with locally advanced head and neck cancer (HNC), its lead indication. It is also being studied in the EUSOM Phase 2a multi-center trial in Europe assessing the safety of avasopasem in patients with HNC undergoing standard-of-care radiotherapy, the AESOP Phase 2a trial to assess its ability to reduce the incidence of esophagitis induced by radiotherapy in patients with lung cancer, and a Phase 2 trial in hospitalized patients who are critically ill with COVID-19. A pilot Phase 1/2 trial of avasopasem in combination with stereotactic body radiation therapy (SBRT) in patients with locally advanced pancreatic cancer (LAPC) has completed enrollment and reported updated results, with follow-up ongoing. The FDA granted Fast Track and Breakthrough Therapy designations to avasopasem for the reduction of SOM induced by radiotherapy, with or without systemic therapy. Galera's second dismutase mimetic product candidate, GC4711, is being developed specifically to augment the anti-cancer efficacy of SBRT, and is currently being studied in the GRECO-1 Phase 1/2 trial in combination with SBRT in patients with non-small cell lung cancer. Galera also intends to initiate the GRECO-2 Phase 2b trial of GC4711 in combination with SBRT in patients with LAPC. 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 our growth and the continued advancement of our product pipeline, including plans for the commercial launch of avasopasem; the potential, safety, efficacy, and regulatory and clinical development of Galera's product candidates; plans and timing for the commencement of and the release of data from Galera's clinical trials; expected payments from Blackstone; and the sufficiency of Galera's cash, cash equivalents and short-term investments. 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 March 31,	
	2021	2020
Operating expenses:		
Research and development	$ 12,423	$ 14,252
General and administrative	5,058	3,566
Loss from operations	(17,481)	(17,818)
Other income (expense), net	(1,234)	(599)
Net loss	$ (18,715)	$ (18,417)
Net loss per share of common stock, basic and diluted	$ (0.75)	$ (0.74)
Weighed average common shares outstanding, basic and diluted	24,988,198	24,815,024

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

	March 31, 2021	December 31, 2020
Cash, cash equivalents, and short-term investments	$ 57,520	$ 72,776
Total assets	70,486	84,098
Total current liabilities	15,855	13,968
Total liabilities	81,059	77,980
Total stockholders’ equity (deficit)	(10,573)	6,118

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