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): August 10, 2020

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 2.02. Results of Operations and Financial Condition.

On August 10, 2020, Galera Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended June 30, 2020. 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 relating to Item 2.02 shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Press Release issued on August 10, 2020

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: August 10, 2020

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

Exhibit 99.1

Galera Therapeutics Reports Second Quarter 2020 Financial Results and Provides Business Updates

Completed Enrollment of Randomized, Blinded, Placebo-controlled Trial of GC4419 in Combination with Radiotherapy in Locally Advanced Pancreatic Cancer; Topline Data Readout Expected in 2H20

Phase 3 ROMAN Trial Remains on Track for Completion of Enrollment in 1H21

MALVERN, Pennsylvania, August 10, 2020 – 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 second quarter ended June 30, 2020, and provided business updates.

"During the second quarter, we continued to advance the development of our small molecule superoxide dismutase mimetics in clinical trials evaluating their ability to address radiation toxicities and augment the anti-cancer efficacy of radiation," said Mel Sorensen, M.D., President and CEO of Galera. "We were pleased to announce the completion of enrollment in our randomized, blinded, placebo-controlled, adaptive Phase 1b/2a trial of avasopasem manganese (GC4419) in combination with stereotactic body radiation therapy (SBRT) for patients with locally advanced pancreatic cancer (LAPC). We expect to report topline data from that trial as well as initiate a Phase 1b/2a trial of GC4711 with SBRT in non-small cell lung cancer in the second half of this year. We also remain on track to complete enrollment of the Phase 3 ROMAN trial of avasopasem in the first half of next year and to report topline data from the ROMAN trial in the second half of 2021."

Second Quarter 2020 and Recent Corporate Highlights

- In July, announced the completion of patient enrollment in the randomized, blinded, placebo-controlled, adaptive Phase 1b/2a clinical trial of avasopasem in combination with SBRT in patients with LAPC. Topline data from this trial are expected in the second half of this year.
- In June, dosed the first patient in a Phase 2a multi-center trial in Europe assessing the safety of avasopasem in patients with head and neck cancer (HNC) undergoing standard-of-care radiotherapy.
- Continued enrollment in the Phase 2a clinical trial of avasopasem to evaluate its ability to reduce the incidence of radiation-induced esophagitis in patients with lung cancer.
- In May, presented new data at the American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program, which demonstrated statistically significant reductions by avasopasem on markers of chronic kidney disease due to concurrent cisplatin chemoradiation in a retrospective

analysis of the completed Phase 2b trial for the reduction of severe oral mucositis in patients with HNC. As a result, the assessment of these markers has been incorporated into the ROMAN Phase 3 trial.

- In May, entered into an amendment to the royalty purchase agreement with Blackstone Life Sciences (Blackstone), which adds $37.5 million in additional funding to the existing $80 million royalty financing commitment that Blackstone (formerly Clarus Ventures) made in 2018. Under the updated agreement terms, Galera agreed to pay Blackstone up to a high single-digit percentage of future commercial royalties from the sales of avasopasem and GC4711 until the total royalty amount achieves an unchanged fixed single-digit multiple of the aggregate financing sum received, upon which the royalty terminates. As partial consideration for the amendment, Galera issued two warrants to Blackstone to purchase an aggregate of 550,661 shares of its common stock at an exercise price of $13.62 per share, each of which will become exercisable upon the receipt by Galera of the applicable specified milestone payment.
- In April, announced the appointment of Linda B. West to its Board of Directors. Ms. West most recently served as Vice President for DuPont Corporate Planning & Analyses, where she led the execution of transformational transactions.

Second Quarter 2020 Financial Highlights

- Research and development expenses were $13.8 million in the second quarter of 2020, compared to $9.5 million for the same period in 2019. The increase was primarily attributable to avasopasem development costs due to increased expenses in the Phase 3 ROMAN trial, additional clinical trials including the Phase 2a trial for the treatment of esophagitis in patients with lung cancer and the Phase 2a multi-center trial in Europe assessing the safety of avasopasem in patients with HNC, and costs associated with manufacturing scale-up activities. Employee-related costs also increased due to increased headcount and share-based compensation expense.
- General and administrative expenses were $3.9 million in the second quarter of 2020, compared to $1.8 million for the same period in 2019. The increase was primarily the result of employee-related costs from increased headcount and share-based compensation expense, and increased insurance, professional fees and other operating costs as a result of becoming a public company.
- Galera reported a net loss of $(18.7) million, or $(0.75) per share, for the second quarter of 2020, compared to a net loss of $(11.6) million, or $(45.30) per share, for the same period in 2019.
- As of June 30, 2020, Galera had cash, cash equivalents and short-term investments of $104.4 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.

About Galera Therapeutics

Galera Therapeutics, Inc. is 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. Galera's lead product candidate is avasopasem manganese (GC4419), a highly selective small molecule superoxide dismutase (SOD) mimetic initially being developed for the reduction of radiation-induced severe oral mucositis (SOM). Avasopasem is being studied in the Phase 3 ROMAN trial for 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 a Phase 2a multi-center trial in Europe assessing the safety of avasopasem in patients with HNC undergoing standard-of-care radiotherapy, a Phase 2a trial for its ability to reduce the incidence of esophagitis induced by radiotherapy in patients with lung cancer and in a randomized Phase 1/2 trial in combination with stereotactic body radiation therapy (SBRT) in patients with locally advanced pancreatic cancer. The FDA granted Fast Track and Breakthrough Therapy designations to avasopasem for the reduction of SOM induced by radiotherapy. Galera is developing a second product candidate, GC4711, specifically for use in combination with SBRT, which successfully completed Phase 1 trials in healthy volunteers. 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, the potential, 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 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 Quarterly Report on Form 10-Q for the quarterly

period ended June 30, 2020 filed with the U.S. Securities and Exchange Commission (SEC), Annual Report on Form 10-K for the year ended December 31, 2019 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 13,839	$ 9,515	$ 28,092	$ 18,017
General and administrative	3,874	1,756	7,439	3,650
Loss from operations	(17,713)	(11,271)	(35,531)	(21,667)
Other income (expense), net	(944)	(287)	(1,543)	(240)
Net Loss	(18,657)	(11,558)	(37,074)	(21,907)
Accretion of redeemable convertible preferred stock to redemption value	—	(2,060)	—	(4,071)
Net loss attributable to common stockholders	$ (18,657)	$ (13,618)	$ (37,074)	$ (25,978)
Net loss per share of common stock, basic and diluted	$ (0.75)	$ (45.30)	$ (1.49)	$ (86.42)
Weighed average common shares outstanding, basic and diluted	24,832,264	300,597	24,823,644	300,597

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

	June 30, 2020	December 31, 2019
Cash, cash equivalents, and short-term investments	$104,409	$ 112,290
Total assets	114,295	123,376
Total current liabilities	12,402	9,694
Total liabilities	74,058	53,768
Total stockholders' equity	40,237	69,608

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