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 10, 2019

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 December 10, 2019, Galera Therapeutics, Inc. announced its financial results for the quarter ended September 30, 2019. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report and on Form 8-K.

The information contained in Item 2.02 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

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 December 10, 2019

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 10, 2019

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

Exhibit 99.1

Galera Therapeutics Reports Third Quarter 2019 Financial Results and Provides Business Update

- Completed Initial Public Offering of Common Stock That Raised Approximately $58 Million in Net Proceeds -

- Progressed Pivotal Clinical Trial of GC4419 in Head & Neck Cancer with Topline Data Expected in 1H 2021 -

MALVERN, Penn., December 10, 2019 – 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, 2019, and highlighted recent corporate accomplishments.

"2019 has been a momentous year for Galera, culminating in the closing of our IPO last month," said Mel Sorensen, M.D., President and CEO of Galera. "We look forward to continuing to advance our clinical development of GC4419 and GC4711, which we believe could change the management of radiation therapy by both protecting normal tissue and improving the effectiveness of radiation."

Third Quarter 2019 and Recent Corporate Highlights

- In November 2019, completed an initial public offering of common stock and raised net proceeds of approximately $58.1 million, after deducting the underwriting discounts and other offering expenses, through the sale of 5,445,690 common shares, including shares sold pursuant to the partial exercise of the underwriters' option to purchase additional shares in December 2019, at a public offering price of $12.00 per share.
- Continued enrollment in the Phase 3 ROMAN clinical trial of GC4419 for the treatment of severe oral mucositis (SOM) in patients with locally advanced head and neck cancer receiving radiotherapy with enrollment expected to be completed by the second half of 2020. Galera anticipates reporting topline data in the first half of 2021.
- Continued enrollment in the pilot Phase 1b/2a safety and anti-cancer efficacy clinical trial of GC4419 in patients with locally advanced pancreatic cancer with topline data expected in the second half of 2020.
- In December 2019, full results from the 223-patient randomized, double-blind Phase 2b clinical trial of GC4419 for the treatment of SOM in patients with locally advanced head and neck cancer receiving radiotherapy were published in the *Journal of Clinical Oncology*, a journal of the American Society of Clinical Oncology (ASCO). The paper, titled, "Phase IIb, Randomized, Double-Blind Trial of GC4419 Versus Placebo to Reduce Severe Oral Mucositis Due to Concurrent Radiotherapy and Cisplatin For Head and Neck Cancer," reinforces the potential of GC4419 to address a serious unmet need for a therapy to reduce the incidence and severity of radiation-induced SOM, for which there is currently no FDA-approved drug.

- In October 2019, announced final data from the two-year tumor outcomes follow up of patients enrolled in the Phase 2b clinical trial of GC4419 for the treatment of SOM in patients with locally advanced head and neck cancer receiving radiotherapy. At both the one-year interim assessment and final two-year mark, tumor outcomes were maintained across all four measures – overall survival, progression-free survival, locoregional control and metastasis-free survival – in both GC4419 dose groups (30 mg and 90 mg) compared to placebo.
- In October 2019, strengthened Galera's leadership team with the appointment of Christopher Degnan as Chief Financial Officer.

Third Quarter Financial Highlights

- Research and development expenses were $11.0 million in the third quarter of 2019, compared to $4.2 million for the same period in 2018. The increase was primarily attributable to GC4419 and GC4711 development costs. Galera initiated the Phase 3 ROMAN trial in October 2018, began chronic toxicology studies of GC4419 to support registration, and initiated a Phase 1 clinical trial and additional toxicology studies of GC4711.
- General and administrative expenses were $1.8 million in the third quarter of 2019, compared to $1.2 million for the same period in 2018. The increase was primarily the result of employee-related costs from increased headcount.
- Galera reported a net loss of $(13.4) million, or $(51.43) per share, for the third quarter of 2019, compared to a net loss of $(5.2) million, or $(22.35) per share, for the same period in 2018.
- As of September 30, 2019, Galera had cash, cash equivalents, and short-term investments of $67.9 million. Galera expects that its existing cash, cash equivalents and short-term investments, together with the net proceeds from the IPO and assumed payments from Clarus in the amount of $40 million upon the achievement of the two remaining specified clinical milestones in the ROMAN trial, will enable Galera to fund its operating expenses and capital expenditure requirements into 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 GC4419 (avasopasem manganese), a potent and highly selective small molecule dismutase mimetic being developed for the reduction of severe oral mucositis (SOM). GC4419 is being studied in the Phase 3 ROMAN trial for its ability to reduce the incidence, severity and duration of SOM in patients with locally advanced head and neck cancer, its lead indication. The FDA granted Fast Track and Breakthrough Therapy designations to GC4419 for the reduction of the duration, incidence and severity of SOM induced by radiotherapy. 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 potential, efficacy, and regulatory and clinical development of Galera's product candidates, plans and timing for the release of data from Galera's clinical trials, 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 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; 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 quarter ended September 30, 2019 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,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 11,040	$ 4,162	$ 29,057	$ 11,551
General and administrative	1,816	1,245	5,466	3,846
Loss from operations	(12,856)	(5,407)	(34,523)	(15,397)
Other income (expense)	(495)	106	(735)	143
Loss before income tax benefit	(13,351)	(5,301)	(35,258)	(15,254)
Income tax benefit	—	52	—	141
Net loss	(13,351)	(5,249)	(35,258)	(15,113)
Accretion of redeemable convertible preferred stock to redemption value	(2,108)	(1,468)	(6,178)	(3,879)
Net loss attributable to common stockholders	$ (15,459)	$ (6,717)	$ (41,436)	$ (18,992)
Net loss per share of common stock, basic and diluted	$ (51.43)	$ (22.35)	$ (137.85)	$ (63.18)
Weighed average common shares outstanding, basis and diluted	300,597	300,597	300,597	300,597

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

	September 30, 2019	December 31, 2018
Cash, cash equivalents, and short-term investments	$ 67,945	$ 81,517
Total assets	79,758	88,056
Total current liabilities	9,083	6,444
Total liabilities	52,298	26,974
Redeemable convertible preferred stock	172,080	165,902
Total stockholders' deficit	(144,620)	(104,820)

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