
**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): March 10, 2020

GALERA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

001-39114
(Commission
File Number)

46-1454898
(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 March 10, 2020, Galera Therapeutics, Inc. announced its financial results for the quarter and year ended December 31, 2019. 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 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:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued on March 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: March 10, 2020

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

J. Mel Sorensen, M.D.

President and Chief Executive Officer



Galera Therapeutics Reports Fourth Quarter and Full Year 2019 Financial Results and Recent Accomplishments

- *Expanded Lead Product Candidate Avasopasem Manganese into Second Radiation Toxicity Indication -*

- *Presented Data Demonstrating Avasopasem Manganese Maintained Anti-Cancer Benefit of Chemoradiotherapy for Head and Neck Cancer While Substantially Reducing Radiation-Induced Severe Oral Mucositis at 2020 Multidisciplinary Head and Neck Cancers Symposium -*

MALVERN, Pennsylvania, March 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 fourth quarter and year ended December 31, 2019, and highlighted recent corporate accomplishments.

“Galera capped off a strong 2019 with the closing of an IPO for total gross proceeds of approximately \$65 million, which positions us for growth and the continued advancement of our pipeline in 2020,” said Mel Sorensen, M.D., President and CEO of Galera. “We kicked off 2020 by taking a critical step toward broadening our understanding of the breadth of our lead candidate avasopasem manganese’s (GC4419) utility in addressing radiation toxicities with the initiation of a Phase 2a trial in a second radiation toxicity, esophagitis, in patients with lung cancer. We also presented data showing that avasopasem manganese maintained tumor outcomes, and remain on track to read out data from our ongoing pilot Phase 1b/2a safety and anti-cancer trial in patients with locally advanced pancreatic cancer in the second half of this year. The Phase 3 ROMAN trial continues to progress, and we look forward to reporting topline data in the first half of next year.”

Recent Corporate Highlights

- In February 2020, presented full tumor outcomes results from the two-year follow-up of patients with head and neck cancer treated with avasopasem manganese (GC4419) for severe oral mucositis (SOM) in a Phase 2b clinical trial in a late-breaking oral presentation at the 2020 Multidisciplinary Head and Neck Cancers Symposium. At the final two-year mark, tumor outcomes were maintained in both avasopasem manganese dose groups (30 mg and 90 mg) compared to placebo. Specifically, outcomes for the 90 mg dose group, the dose currently being evaluated in the ongoing Phase 3 ROMAN trial, were comparable to placebo across all four measures – overall survival, progression-free survival, locoregional control and metastasis-free survival.

- In February 2020, received a \$20.0 million payment from Clarus, investment funds managed by Blackstone Life Sciences, for achievement of the third specified clinical milestone in our Phase 3 ROMAN trial under our royalty purchase agreement with Clarus.
- In January 2020, announced the first patient dosed in a Phase 2a clinical trial of avasopasem manganese to evaluate its ability to reduce the incidence of radiation-induced esophagitis in patients with lung cancer. Esophagitis, or mucositis of the esophagus, is a common and painful complication of radiation therapy for lung cancer. Symptoms can be life-threatening and include an inability to swallow, severe pain, ulceration, infection, bleeding and weight loss, and may require hospitalization.
- In the fourth quarter of 2019, completed an initial public offering of common stock and raised net proceeds of \$58.0 million.
- Continued enrollment in two ongoing clinical trials evaluating avasopasem manganese. Enrollment in the Phase 3 ROMAN clinical trial of avasopasem manganese for the treatment of SOM in patients with locally advanced head and neck cancer receiving radiotherapy is on track to be completed in the second half of 2020, with topline data anticipated in the first half of 2021. Topline data from the pilot Phase 1b/2a safety and anti-cancer efficacy clinical trial of avasopasem manganese in patients with locally advanced pancreatic cancer are expected in the second half of 2020.

Fourth Quarter 2019 Financial Highlights

- Research and development expenses were \$13.3 million in the fourth quarter of 2019, compared to \$7.1 million for the same period in 2018. The increase was primarily attributable to avasopasem manganese and GC4711 development costs. Galera initiated the Phase 3 ROMAN clinical trial in October 2018, progressed chronic toxicology studies of avasopasem manganese to support registration, and progressed a Phase 1 clinical trial and additional toxicology studies of GC4711.
- General and administrative expenses were \$2.9 million in the fourth quarter of 2019, compared to \$1.7 million for the same period in 2018. The increase was primarily the result of employee-related costs from increased headcount and increased insurance, professional fees and other operating costs as a result of becoming a public company.
- Galera reported a net loss of \$(16.7) million, or \$(1.31) per share, for the fourth quarter of 2019, compared to a net loss of \$(8.6) million, or \$(35.24) per share, for the same period in 2018.
- As of December 31, 2019, Galera had cash, cash equivalents and short-term investments of \$112.3 million. Galera expects that its existing cash, cash equivalents and short-term investments, including the \$20.0 million payment received from Clarus in February 2020 for the achievement of the third clinical milestone in the Phase 3 ROMAN clinical trial, together with the \$20.0 million payment from Clarus expected to be received upon the achievement of the remaining specified clinical milestone in the ROMAN trial, will enable Galera to fund its operating expenses and capital expenditure requirements into 2022.

Full Year 2019 Financial Highlights

- Research and development expenses were \$42.3 million for the year ended December 31, 2019, compared to \$18.7 million for the year ended December 31, 2018. The increase was primarily attributable to avasopasem manganese and GC4711 development costs. Galera initiated the Phase 3 ROMAN clinical trial in October 2018, began chronic toxicology studies of avasopasem manganese to support registration, and initiated a Phase 1 clinical trial and additional toxicology studies of GC4711.
- General and administrative expenses were \$8.4 million for the year ended December 31, 2019, compared to \$5.6 million for the year ended December 31, 2018. The increase was primarily the result of employee-related costs from increased headcount and increased insurance, professional fees and other operating costs as a result of becoming a public company.
- Galera reported a net loss of \$(51.9) million, or \$(16.31) per share, for the year ended December 31, 2019, compared to a net loss of \$(23.7) million, or \$(9.42) per share, for the year ended December 31, 2018.

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 manganese 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, its lead indication, and in the Phase 2a trial for its ability to reduce the incidence of esophagitis induced by radiotherapy in patients with lung cancer. The FDA granted Fast Track and Breakthrough Therapy designations to avasopasem manganese for the reduction of SOM induced by radiotherapy. Galera is developing a second product candidate, GC4711, which successfully completed a Phase 1 trial 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 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 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; 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, 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
(in thousands, except share and per share data)

	<u>Three Months Ended December 31,</u>		<u>Year Ended December 31,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Operating expenses:				
Research and development	\$ 13,276	\$ 7,112	\$ 42,333	\$ 18,663
General and administrative	2,892	1,746	8,358	5,592
Loss from operations	(16,168)	(8,858)	(50,691)	(24,255)
Other income (expense)	(513)	213	(1,248)	356
Loss before income tax benefit	(16,681)	(8,645)	(51,939)	(23,899)
Income tax benefit	9	82	9	223
Net loss	(16,672)	(8,563)	(51,930)	(23,676)
Accretion of redeemable convertible preferred stock to redemption value	(998)	(2,031)	(7,176)	(5,910)
Net loss attributable to common stockholders	<u>\$ (17,670)</u>	<u>\$ (10,594)</u>	<u>\$ (59,106)</u>	<u>\$ (29,586)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (1.31)</u>	<u>\$ (35.24)</u>	<u>\$ (16.31)</u>	<u>\$ (98.42)</u>
Weighted average common shares outstanding, basis and diluted	<u>13,489,826</u>	<u>300,597</u>	<u>3,625,005</u>	<u>300,597</u>

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

	<u>December 31,</u>	
	<u>2019</u>	<u>2018</u>
Cash, cash equivalents, and short-term investments	\$ 112,290	\$ 81,517
Total assets	123,376	88,056
Total current liabilities	9,694	6,444
Total liabilities	53,768	26,974
Redeemable convertible preferred stock	—	165,902
Total stockholders' equity (deficit)	69,608	(104,820)

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