Galera Reports Fourth Quarter and Full Year 2022 Financial Results and Recent Corporate Updates

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Avasopasem NDA granted FDA priority review for radiotherapy-induced severe oral mucositis (SOM); PDUFA target date of August 9, 2023

Company raised $30 million in gross proceeds from registered direct offering

MALVERN, Pa., March 08, 2023 (GLOBE NEWSWIRE) -- 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, 2022 and provided recent corporate updates.

“2023 is a pivotal year for Galera, as we received Priority Review designation for our NDA for avasopasem, and we look forward to continuing productive discussions with the FDA over the coming months,” said Mel Sorensen, M.D., Galera’s President and CEO. “Avasopasem has the potential to be the first FDA-approved drug to reduce SOM, a debilitating radiotherapy-induced toxicity, in head and neck cancer patients undergoing standard-of-care treatment. Each year approximately 43,500 U.S. patients with HNC are at high risk of developing SOM as a result of their cancer treatment. Following our recent financing, we believe that we are well-equipped to build out our operations and expand our commercial leadership team in preparation for potential approval of avasopasem in the second half of the year.”

Recent Corporate Updates

Radiotherapy-Induced Toxicity Programs:

Severe Oral Mucositis (SOM)

- In December 2022, the Company submitted its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for avasopasem manganese (avasopasem) for radiotherapy-induced SOM in patients with head and neck cancer (HNC) undergoing standard-of-care treatment. There are currently no FDA-approved drugs to reduce SOM for these patients.
- On February 15, 2023, the Company announced that the FDA accepted for filing and granted priority review to the NDA for avasopasem. With Priority Review designation, the Prescription Drug User Fee Act (PDUFA) target date assigned by the FDA for the NDA is August 9, 2023. The FDA indicated in its acceptance of filing letter that it is not planning to hold an advisory committee meeting on the application.
- Data from the Phase 3 ROMAN trial is scheduled to be presented by Dr. Carryn Anderson, MD, Clinical Associate Professor of Radiation Oncology at the University of Iowa, at the European Congress on Head and Neck Oncology (ECHNO), taking place March 8-11, 2023, in Lisbon, Portugal. The presentation will include a generalized pairwise comparisons (GPC) analysis, a statistical method to assess the net treatment benefit of avasopasem compared to placebo.

Esophagitis

- In May 2022, the Company announced topline results from the open-label, single-arm Phase 2a AESOP trial evaluating avasopasem for its potential to reduce the incidence of

radiotherapy-induced esophagitis in patients with lung cancer. The results demonstrated that avasopasem was generally well tolerated and substantially reduced the incidence of severe esophagitis in patients with lung cancer receiving chemoradiotherapy compared to expectations based on review of historical data in the literature. Based on these data, Galera intends to pursue a strategy for avasopasem, if approved for the reduction of SOM, to support the use of avasopasem to reduce radiotherapy-induced esophagitis in patients with lung cancer as a medically accepted indication in published drug compendia.

Anti-Cancer Programs:

Locally Advanced Pancreatic Cancer (LAPC)

- Enrollment is ongoing in the randomized, placebo-controlled Phase 2b GRECO-2 trial of rucosopasem in combination with stereotactic body radiation therapy (SBRT) in patients with LAPC. The primary endpoint of the trial is overall survival. The Company continues to anticipate completion of enrollment in the second half of 2023.

Non-Small Cell Lung Cancer (NSCLC)

- Enrollment is ongoing in the randomized, placebo-controlled Phase 2 stage of the GRECO-1 trial of rucosopasem in combination with SBRT in patients with NSCLC. The Company continues to anticipate completion of enrollment in the second half of 2023.

General Corporate Updates

- On February 17, 2023, the Company completed a registered direct offering, which resulted in the issuance and sale of 14,320,000 shares of common stock and warrants to purchase up to 14,320,000 shares of common stock at a combined offering price of $2.095 per share and accompanying warrant, generating gross proceeds of $30 million. The warrants have an exercise price of $1.97 per share of common stock, are exercisable immediately following their issuance and will expire five years from the date of issuance. The Company received net proceeds of approximately $27.7 million from this offering, after deducting placement agent fees and offering expenses.

Fourth Quarter 2022 Financial Highlights

- Research and development expenses were $8.1 million in the fourth quarter of 2022, compared to $9.2 million for the same period in 2021. The decrease was primarily attributable to a decrease in avasopasem development costs, partially offset by an increase in rucosopasem development costs.
- General and administrative expenses were $5.0 million in the fourth quarter of 2022, compared to $5.3 million for the same period in 2021. The decrease was primarily attributable to the timing of spend for avasopasem commercial preparations.
- Galera reported a net loss of $(16.2) million, or $(0.58) per share, for the fourth quarter of 2022, compared to a net loss of $(16.8) million, or $(0.64) per share, for the same period in 2021.
- As of December 31, 2022, Galera had cash, cash equivalents and short-term investments of $31.6 million. Galera expects that its existing cash, cash equivalents and short-term investments, together with the net proceeds from its February 2023 registered direct offering, will enable Galera to fund its operating expenses and capital expenditure requirements into the fourth quarter of 2023.

Full Year 2022 Financial Highlights

- Research and development expenses were $31.0 million for the year ended December 31, 2022, compared to $52.4 million for the year ended December 31, 2021. The decrease was primarily attributable to a decrease in avasopasem development costs and decreased manufacturing expenses, partially offset by an increase in rucosopasem development costs.
- General and administrative expenses were $20.2 million for the year ended December 31, 2022, compared to $21.0 million for the year ended December 31, 2021. The decrease was primarily attributable to the timing of spend for avasopasem commercial preparations.
- Galera reported a net loss of $(62.2) million, or $(2.30) per share, for the year ended December 31, 2022, compared to a net loss of $(80.5) million, or $(3.12) per share, for the year ended December 31, 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 selective dismutase mimetic product candidate avasopasem manganese (avasopasem, or GC4419) is being developed for radiation-induced toxicities. A New Drug Application (NDA) for avasopasem is currently under priority review by the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee (PDUFA) date of August 9, 2023 for radiotherapy-induced severe oral mucositis in patients with head and neck cancer undergoing standard-of-care treatment. The Company's second product candidate, rucosopasem manganese (rucosopasem, or GC4711), 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.

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: the expectations surrounding the continued advancement of Galera's product pipeline; the potential safety and efficacy of Galera's product candidates and their regulatory and clinical development; the potential to obtain approval by the U.S. Food and Drug Administration for avasopasem for the treatment of radiotherapy-induced severe oral mucositis (SOM) in patients with locally advanced head and neck cancer at any time, including the anticipated PDUFA target date of August 9, 2023; the potential for avasopasem to be the first FDA-approved drug to reduce SOM in head and neck cancer patients undergoing standard-of-care treatment; the Company's ability to be well-equipped to build out its operations and expand its commercial leadership team in preparation for potential approval of avasopasem; the Company's intention to pursue a strategy for avasopasem, if approved for the reduction of SOM, to support the use of avasopasem to reduce radiotherapy-induced esophagitis in patients with lung cancer as a medically accepted indication in published drug compendia; the ability of avasopasem to reduce radiotherapy-induced esophagitis; the expectations surrounding the progress of the randomized, placebo-controlled Phase 2b GRECO-2 trial of rucosopasem in combination with stereotactic body radiation therapy (SBRT) in patients with LAPC and the timing of completion of enrollment of the trial; the expectations surrounding the randomized, placebo-controlled Phase 2 stage of the GRECO-1 trial of rucosopasem in combination with SBRT in patients with NSCLC and the timing of completion of enrollment of the trial; upcoming events and presentations; the Company's ability to fund its operating expenses and capital expenditures into the fourth quarter of 2023; and the Company's ability to achieve its goal of transforming radiotherapy in cancer treatment with its selective dismutase mimetics. 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; substantial doubt regarding Galera's ability to continue as a going concern; 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, 2022 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)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 8,137	$ 9,215	$ 31,012	$ 52,417
General and administrative	5,021	5,284	20,214	20,951
Loss from operations	(13,158)	(14,499)	(51,226)	(73,368)
Other income (expense), net	(3,100)	(2,307)	(11,066)	(7,166)

Loss before income tax benefit	(16,258)	(16,806)	(62,292)	(80,534)
Income tax benefit	70	-	70	-
Net Loss	$ (16,188)	$ (16,806)	$ (62,222)	$ (80,534)
Net loss per share of common stock, basic and diluted	$ (0.58)	$ (0.64)	$ (2.30)	$ (3.12)
Weighted average common shares outstanding, basic and diluted	27,942,210	26,442,028	27,086,664	25,789,458

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

	December 31, 2022	December 31, 2021
Cash, cash equivalents, and short-term investments	$ 31,597	$ 71,217
Total assets	44,036	83,311
Total current liabilities	13,379	12,935
Total liabilities	153,217	141,315
Total stockholders' deficit	(109,181)	(58,004)

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