Galera Reports Second Quarter 2023 Financial Results and Recent Corporate Updates

Aug 14, 2023

Company received Complete Response Letter from FDA for avasopasem and intends to request Type A meeting with FDA to discuss potential next steps

Cash runway extended into Q2 2024 in connection with reduction in workforce

FDA granted orphan drug designation to rucosopasem for the treatment of pancreatic cancer

Enrollment in GRECO trials with rucosopasem remains ongoing

MALVERN, Pa., Aug. 14, 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 second quarter ended June 30, 2023, and provided recent corporate updates.

"Following the FDA's decision on the avasopasem NDA, we have taken decisive steps to extend our cash runway as we seek a Type A meeting with the FDA to discuss the potential path forward for approval," said Mel Sorensen, M.D., Galera's President and CEO. "In parallel, enrollment continues in the ongoing GRECO trials of rucosopasem, our anti-cancer candidate, as we investigate the novel compound's potential to enhance stereotactic body (high daily dose) radiotherapy and extend the lives of patients with deadly cancers."

Radiotherapy-Induced Severe Oral Mucositis (SOM)

- In August 2023, the Company announced that the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) for the New Drug Application (NDA) for avasopasem for radiotherapy-induced SOM in patients with head and neck cancer (HNC) undergoing standard-of-care treatment. In the CRL, the FDA communicated that the results from the Phase 3 ROMAN trial together with the supporting data from the GT-201 trial are not sufficiently persuasive to establish substantial evidence of avasopasem's effectiveness and safety for reducing SOM in patients with HNC. FDA stated that results from an additional clinical trial will be required for resubmission. The Company intends to request a Type A meeting with the FDA to understand the FDA's rationale for its decision and discuss next steps to support an NDA resubmission seeking approval of avasopasem.

Cisplatin-Related Chronic Kidney Disease

- In June 2023, Galera presented an abstract featuring avasopasem, as part of the Head and Neck Cancer session at the American Society of Clinical Oncology (ASCO) Annual Meeting, which took place June 2-6, 2023, in Chicago, IL. The abstract, titled "One-year reductions in cisplatin-related chronic kidney disease (CKD) in patients with head and neck cancer (HNC) treated with avasopasem manganese: A prespecified analysis from the Phase 3 ROMAN trial," noted significant improvements in preservation of kidney function compared to placebo based on mean change in estimated Glomerular Filtration Rate, beginning by 3 months through one-year end of follow-up. Reductions in CKD were consistent across cisplatin dosing schedules.

Locally Advanced Pancreatic Cancer (LAPC)

- Enrollment is ongoing in the randomized, placebo-controlled Phase 2b GRECO-2 trial of rucosopasem in combination with SBRT in patients with LAPC. The primary endpoint of the trial is overall survival. Completion of enrollment continues to be anticipated in the first half of 2024, and topline data readout is expected by the end of 2024.
- In May 2023, the FDA granted Orphan Drug Designation for rucosopasem for the treatment of pancreatic cancer.

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. Completion of enrollment continues to be anticipated in the second half of 2023, and topline data readout is expected in the second half of 2024.

General Corporate Updates

- In connection with the CRL announcement, on August 9, 2023, the Company further announced it will focus resources on defining the path forward for avasopasem, progressing the ongoing clinical trials for rucosopasem, and concurrently evaluating strategic alternatives, including partnering, for the continued development of avasopasem and rucosopasem. As a result, the Company reduced its workforce by approximately 70%. The plan includes a wind-down of commercial readiness efforts and headcount reductions across several departments.

Second Quarter 2023 Financial Highlights

- Research and development expenses were $7.6 million in the second quarter of 2023, compared to $6.6 million for the same period in 2022. The increase was primarily attributable to an increase in rucosopasem development costs, partially offset by a decrease in avasopasem development costs.
- General and administrative expenses were $9.2 million in the second quarter of 2023, compared to $5.3 million for the same period in 2022. The increase was primarily attributable to avasopasem commercial preparations.
- Galera reported a net loss of $(20.7) million, or $(0.48) per share, for the second quarter of 2023, compared to a net loss of $(14.6) million, or $(0.54) per share, for the same period in 2022.
- As of June 30, 2023, Galera had cash, cash equivalents and short-term investments of $38.8 million. Galera expects that its existing cash, cash equivalents and short-term investments, taking into account the implementation of the reduction in workforce announced in August 2023, will enable Galera to fund its operating expenses and capital expenditure requirements into the second quarter of 2024.

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) is being developed for radiation-induced toxicities. The FDA has granted Fast Track and Breakthrough Therapy designations to avasopasem for the reduction of severe oral mucositis induced by radiotherapy. The Company's second product candidate, rucosopasem manganese (rucosopasem), 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. Rucosopasem was granted Orphan Drug Designation by the FDA for the treatment of 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 Company's intention to request and hold a Type A meeting with the FDA in order to understand the FDA's rationale for its decision and discuss next steps to support an NDA resubmission seeking approval of avasopasem; the Company's ability to resubmit the NDA; the Company's plans to take actions, and the potential for those actions, to extend its cash runway; the Company's intention to pursue strategic alternatives; 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 and topline data readout therefrom; 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 and topline data readout therefrom; the expected financial and operational impacts of Galera's recent reduction in force; Galera's ability to fund its operating expenses and capital expenditures into the second quarter of 2024; and Galera'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; 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; Galera's recent reduction in force undertaken to significantly reduce our ongoing operating expenses may not result in our intended outcomes and may yield unintended consequences and additional costs; Galera may not be able to enter into any desired strategic alternative or partnership on a timely basis, on acceptable terms, or at all; if Galera is unable to secure additional funding or enter into any desired strategic alternative or partnership, it may need to cease operations; 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
(unaudited, in thousands except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 7,561	$ 6,636	$ 14,833	$ 14,743
General and administrative	9,246	5,293	15,855	10,340
Loss from operations	(16,807)	(11,929)	(30,688)	(25,083)
Other income (expense), net	(3,905)	(2,629)	(7,734)	(4,918)
Net loss	$ (20,712)	$ (14,558)	$ (38,422)	$ (30,001)
Net loss per share of common stock, basic and diluted	$ (0.48)	$ (0.54)	$ (0.98)	$ (1.12)
Weighted average common shares outstanding, basic and diluted	42,916,962	26,821,303	39,077,876	26,785,540

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

	June 30, 2023	December 31, 2022
Cash, cash equivalents, and short-term investments	$ 38,755	$ 31,597
Total assets	48,276	44,036
Total current liabilities	13,622	13,379
Total liabilities	163,275	153,217
Total stockholders' deficit	(114,999)	(109,181)

Investor Contacts:
Christopher Degnan
Galera Therapeutics, Inc.
610-725-1500
cdegnan@galeratx.com

William Windham
Solebury Strategic Communications
646-378-2946
wwindham@soleburystrat.com

Media Contact:
Timothy Biba
Solebury Strategic Communications
646-378-2927
tbiba@soleburystrat.com