Galera Therapeutics completes acquisition of Nova Pharmaceuticals

Dec 31, 2024

Galera's development strategy shifts from toxicity reduction to anti-cancer therapeutics, with three trials in patients with highly resistant subsets of advanced breast cancer.

Lead program is Phase 1/2 trial of Nova Pharmaceutical's Clinical Stage Nitric Oxide Synthase (NOS) Inhibitor on top of standard-of-care nab-paclitaxel and alpelisib in metaplastic breast cancer.

Concurrent financing when added to Galera's existing cash balance, is anticipated to fund operations through data readout of its lead program and into 2026.

Galera intends to leverage NCI grants, academic partnerships and the I-SPY 2 network for efficient and cost-effective clinical dataset expansion.

MALVERN, Pa., Dec. 31, 2024 (GLOBE NEWSWIRE) -- Galera Therapeutics, Inc. (OTC: GRTX) announced today it has completed the acquisition of Nova Pharmaceuticals, Inc. ("Nova"), a privately held biotechnology company advancing a pan-NOS Inhibitor to treat patients with highly resistant forms of breast cancer, including metaplastic breast cancer and other refractory subsets of triple-negative breast cancer ("TNBC").

In support of the acquisition, a syndicate of investors led by Ikarian Capital has invested approximately $3 million to purchase Galera common stock. Galera's new lead program is the Investigator-sponsored Phase 1/2 trial of a pan-NOS Inhibitor on top of standard-of-care nab-paclitaxel and alpelisib in metaplastic breast cancer. The Company's cash balance at closing is anticipated to fund operations into 2026 and through data readout from its lead program in metaplastic breast cancer. A second trial is planned for this agent in TNBC in collaboration with the I-SPY 2 consortium. The Company intends to support a third trial of Avasopasem, one of its small molecule dismutase mimetics, in patients with hormone-receptor positive (HR+) advanced breast cancer who have become resistant to conventional therapy. This trial is expected to commence enrollment in the first half of 2025.

"Dismutase Mimetics and NOS inhibitors involve complementary pathways that play important roles in cancer, in the tumor microenvironment, in resistance to conventional chemoradiotherapy and in immuno-oncology," said Mel Sorensen, M.D., President & CEO of Galera. "Substantial mechanistic and preclinical rationale for both agents in solid tumors, especially in breast cancer, has been generated by the companies and their collaborators. Both product candidates are in clinical stage development, having been well-characterized in many patients both in oncologic and non-oncologic indications. Galera has decided to focus its near-term development on the hardest-to-treat subsets of advanced breast cancer."

The Company continues as Galera Therapeutics, Inc. (OTC:GRTX) and will be led by Dr. Sorensen, as President and Chief Executive Officer and Joel Sussman, as Chief Accounting Officer. A team of consultants comprising people from both Galera and Nova will manage the R&D of the company, in a capital efficient manner.

"I am excited about the ability to combine our technologies to address the unmet need of many breast cancer patients," said Par S Hyare CEO of Nova Pharmaceuticals. "This agreement allows Galera and our collaborators the opportunity to advance our product candidates to the next stage of clinical development. The investigators at Houston Methodist have presented data showing several responses in the ongoing trial and we look forward to the data readout in the next nine to fifteen months under the capable leadership of Galera's team."

About the Proposed Transactions

Under the terms of the merger agreement and the securities purchase agreement, Galera has issued approximately 21.1 million shares of common stock plus pre-funded warrants exercisable for approximately 23 million shares of common stock, and approximately 119,318 shares of Series B non-voting (1:1000) convertible preferred stock in a private placement. At the closing, Galera stockholders will own approximately 55.2% of the common shares (assuming that the pre-funded warrants are exercised in full). The shares of Series B non-voting convertible preferred stock will be convertible into shares of common stock, subject to stockholder approval at a subsequent meeting of the Company's stockholders. Following that approval, on an as-converted basis, the pre-acquisition Galera stockholders will own approximately 25% of the combined Company and the new investors and Nova stockholders will own approximately 75% of the combined Company (assuming that the pre-funded warrants are exercised in full).

The transaction was unanimously approved by the Board of Directors of both companies and by the stockholders of Nova.

The Board of Directors includes three current Galera board members, Mr. Larry Alleva and Mr. Kevin Lokay and Dr. Sorensen, and two additional board members selected by Nova, Mr. Michael Friedman and Dr. Nancy T. Chang. Mr. Friedman has an MBA from the University of Chicago and brings over 20 years' experience in investment banking, in finance and in the life science industry to the Board of Galera. Dr. Chang is a PhD biochemist who has spent her career in leadership roles in academia, in large and small pharma companies and in the venture capital world and she has extensive experience in biopharma boards.

Stifel, Nicolaus & Company served as the financial advisor to Galera. Lucid Capital Markets, LLC has provided a fairness opinion to Galera's Board of

Directors. Sidley Austin LLP is serving as legal counsel to Galera. Cooley LLP is serving as legal counsel to Nova.

About Galera Therapeutics

Galera Therapeutics, Inc. is a biopharmaceutical company with a portfolio of small molecule superoxide dismutase mimetics. It was historically focused on developing these agents in combination with chemoradiotherapy to reduce the toxicities of the conventional regimens in patients with head and neck cancer. The FDA has granted Fast Track and Breakthrough Therapy designations to avasopasem for the reduction of severe oral mucositis induced by radiotherapy and has demonstrated toxicity reduction in phase 2 and 3 trials. Dismutase mimetics also have a well-developed mechanistic role in anti-cancer therapeutics in preclinical studies, and Galera completed a pilot of avasopasem combined with stereotactic radiotherapy (SBRT) in patients with locally advanced pancreatic cancer (Taniguchi, Cullen M et al. The Lancet Oncology, Volume 24, Issue 12, 1387 – 1398).

About Nova Pharmaceuticals

Nova Pharmaceuticals is a clinical stage biotechnology company focused on targeting the molecular mechanisms driving resistance to current treatments in triple negative and metaplastic breast cancer and improving outcomes for patients. Nova Pharmaceuticals' pan-nitric oxide synthase (NOS) inhibitor is currently being studied in a Phase 1/2 study at Houston Methodist Hospital and has completed a Phase 1/2 study in triple negative breast cancer patients.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements concerning expectations regarding our cash runway, and data from current and future clinical trials.

These forward-looking statements relate to us, our business prospects and our results of operations and are subject to certain risks and uncertainties posed by many factors and events that could cause our actual business, prospects and results of operations to differ materially from those anticipated by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those described under the heading "Risk Factors" included in Galera's annual report on Form 10-K for the year ended December 31, 2023, and Quarterly Reports on Form 10-Q for the quarters ended March 31, June 30 and September 30, 2024. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. In some cases, you can identify forward-looking statements by the following words: "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "aim," "may," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. We undertake no obligation to revise any forward-looking statements in order to reflect events or circumstances that might subsequently arise.

These forward-looking statements are based upon our current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including, without limitation:

- Changes in capital resource requirements;
- Risks related to our inability to obtain sufficient additional capital to continue to advance our product candidates;
- Our and our collaborator's ability to execute clinical programs for our product candidates;
- Results of clinical trials with our product candidates; and
- Our ability to obtain and maintain intellectual property rights and regulatory exclusivities.

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