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): February 12, 2024

G1 THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38096**	**26-3648180**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

700 Park Offices Drive **Suite 200** **Research Triangle Park, NC**	**27709**
(Address of principal executive offices)	**(zip code)**

Registrant's telephone number, including area code: (919) 213-9835

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	Name of each exchange on which registered
Common stock, $0.0001 par value	**GTHX**	**The Nasdaq Stock Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 8.01 Other Events.

On February 12, 2024, G1 Therapeutics, Inc. issued a press release announcing that the independent Data Monitoring Committee recommended continuation of the pivotal Phase 3 trial (PRESERVE 2), evaluating trilaciclib in combination with gemcitabine and carboplatin for the first line treatment of metastatic triple negative breast cancer (mTNBC), to the final analysis. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated February 12, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 thereunto duly authorized.

G1 THERAPEUTICS, INC.

By: */s/ Monica Roberts Thomas*
Monica Roberts Thomas
General Counsel

Date: February 12, 2024

EXHIBIT 99.1

G1 Therapeutics to Continue Pivotal Phase 3 Trial of Trilaciclib in Metastatic Triple Negative Breast Cancer Following Interim Analysis by Independent Data Monitoring Committee

RESEARCH TRIANGLE PARK, N.C., February 12, 2024 – G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today announced that the independent Data Monitoring Committee (DMC) recommended continuation of the pivotal Phase 3 trial (PRESERVE 2), evaluating trilaciclib in combination with gemcitabine and carboplatin for the first line treatment of metastatic triple negative breast cancer (mTNBC), to the final analysis. This final analysis evaluating Overall Survival (OS) is estimated to occur in the third quarter of 2024 and will be conducted on the intent-to-treat (ITT) population. The DMC did not express any concerns regarding safety or recommend any other changes to the study. G1 remains blinded to all data as the early stopping criteria were not met during the interim analysis.

"We remain confident in the ability of trilaciclib to ultimately achieve the OS primary endpoint based on the robust survival benefit demonstrated in the prior randomized Phase 2 study, which continued to meaningfully increase over time as patients received subsequent therapies, as well as the increased statistical power for the final analysis of this pivotal study," said Jack Bailey, Chief Executive Officer at G1 Therapeutics. "While a positive interim analysis would have enabled us to bring this therapy to patients in need sooner, we look forward to completing the study and potentially making this meaningful new treatment option available to patients with this highly aggressive form of breast cancer as early as next year."

Trilaciclib, an IV-administered transient CDK4/6 inhibitor, is a first-in-class therapy designed to preserve bone marrow and immune system function during cytotoxic therapy to improve patient outcomes. PRESERVE 2 is a global, multi-center, randomized placebo-controlled, line extension pivotal Phase 3 trial of trilaciclib in patients with locally advanced unresectable or metastatic TNBC. Patients meeting eligibility requirements were randomized 1:1 to receive either trilaciclib or placebo administered prior to first-line gemcitabine and carboplatin (GCb). The regimen is given intravenously (IV) on Days 1 and 8 in 21-day cycles. Treatment is administered until disease progression.

About Triple Negative Breast Cancer (TNBC)

Breast cancer is the most commonly diagnosed cancer worldwide, with over 2.3 million new cases each year. According to the American Cancer Society, nearly 300,000 new cases of invasive breast cancer are diagnosed annually in the U.S. Triple negative breast cancer makes up approximately 15-20% of such diagnosed breast cancers. TNBC is cancer that tests negative for estrogen receptors, progesterone receptors, and excess HER2 protein. Because mTNBC cells lack key growth-signaling receptors, patients do not respond well to medications that block estrogen, progesterone, or HER2 receptors. Instead, treating mTNBC typically involves chemotherapy, radiation, and surgery. TNBC is considered to be more aggressive and have a poorer prognosis than other types of breast cancer. In general, survival rates tend to be lower with mTNBC compared to other forms of breast cancer, and mTNBC is also more likely than some other types of breast cancer to return after it has been treated, especially in the first few years after treatment. It also tends to be higher grade than other types of breast cancer.

About G1 Therapeutics

G1 Therapeutics, Inc. is a commercial-stage oncology biopharmaceutical company whose mission is to develop and deliver next-generation therapies that improve the lives of those affected by cancer, including the Company's first commercial product, COSELA® (trilaciclib). The Company is also evaluating

therapies in combination with cytotoxic therapies and/or immunotherapy in areas of high unmet need including triple-negative breast cancer and extensive stage small cell lung cancer. G1's goal is to provide innovative therapeutic advances for people living with cancer. G1 is based in Research Triangle Park, N.C. For additional information, please visit http://www.g1therapeutics.com and follow us on X (formerly known as Twitter) @G1Therapeutics and LinkedIn.

G1 Therapeutics® and the G1 Therapeutics logo and COSELA® and the COSELA logo are trademarks of G1 Therapeutics, Inc.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "could", "believe," "goal", "projections," "estimate," "intend," "indicate," "potential," "opportunity," "suggest," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Forward-looking statements in this press release include, but are not limited to, that the survival benefit observed in the Phase 2 trial appears to meaningfully increase over time as patients received subsequent therapies, and that completion of the trial will enable G1 to make this potentially meaningful new treatment available to patients living with mTNBC as early as next year, are based on the company's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Factors that may cause the company's actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in the company's filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" sections contained therein and include, but are not limited to, the Company's dependence on the commercial success of COSELA (trilaciclib); the development and commercialization of new drug products is highly competitive; the Company's ability to complete clinical trials for, obtain approvals for and commercialize any of its product candidates; the Company's initial success in ongoing clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials; the inherent uncertainties associated with developing new products or technologies and operating as a commercial-stage company; chemotherapy shortages and market conditions. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties. Except as required by law, the company assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

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