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): June 18, 2019

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.)**

79 T.W. Alexander Drive **4501 Research Commons, Suite 100** **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(s)	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 June 18, 2019, G1 Therapeutics, Inc. (the "Company") issued a press release announcing topline data demonstrating trilaciclib in combination with chemotherapy improves overall survival in women with metastatic triple-negative breast cancer. A copy of the press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated June 18, 2019

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/ Mark A. Velleca*
Mark A. Velleca, M.D., Ph.D.
President and Chief Executive Officer

Date: June 18, 2019

G1 Therapeutics Announces Updated Results from Phase 2 Trial of Trilaciclib in Combination with Chemotherapy Showed Statistically Significant Improvement in Overall Survival in Women with Metastatic Triple-Negative Breast Cancer

- Detailed data from this trial will be presented at a medical meeting later this year -

RESEARCH TRIANGLE PARK, N.C., June 18, 2019 – G1 Therapeutics, Inc. (Nasdaq: GTHX), a clinical-stage oncology company, today announced preliminary overall survival (OS) results from a randomized Phase 2 trial which demonstrated that women with metastatic triple-negative breast cancer (mTNBC) lived significantly longer when receiving trilaciclib and chemotherapy compared with women receiving chemotherapy alone. Detailed data from this trial will be presented at a medical meeting later this year.

Myelopreservation results, objective response rate (ORR), progression-free survival (PFS) and safety data from this trial were presented at the 2018 San Antonio Breast Cancer Symposium (SABCS). Updated anti-tumor efficacy results demonstrated that women receiving trilaciclib and a chemotherapy regimen of gemcitabine/carboplatin had a statistically significant improvement in OS compared with those receiving gemcitabine/carboplatin alone.

“Triple-negative breast cancer is the most aggressive type of breast cancer, and women diagnosed with metastatic TNBC need new treatment options. We look forward to sharing these data with regulators, as well as presenting findings from this trial at a medical meeting later this year,” said Mark Velleca, M.D., Ph.D., Chief Executive Officer. “As a company committed to improving the lives, treatment options and outcomes of those living with cancer, we’re proud to have a pipeline that now includes three investigational therapies with the potential to become new standards of care for those with breast cancer and benefit women at the earliest stages of their disease.”

About the Study

This randomized, open-label Phase 2 clinical trial (NCT02978716) enrolled 102 patients with mTNBC who had received 0-2 prior lines of therapy in the recurrent/metastatic setting. In this three-arm trial, all patients received a chemotherapy regimen of gemcitabine/carboplatin (GC). Patients were randomized to receive GC only or GC plus one of two dosing schedules of trilaciclib: trilaciclib administered on the day of chemotherapy or trilaciclib administered the day prior to and the day of chemotherapy. Primary endpoints for the trial included myelopreservation measures; secondary endpoints included additional myelopreservation measures and anti-tumor efficacy measures of ORR, PFS and OS.

Topline OS improvements were statistically significant in both trilaciclib arms compared with the control arm. ORR and PFS data were consistent with results presented at SABCS 2018. The safety and tolerability of trilaciclib were consistent with previously reported data and there have been no serious adverse events attributed to treatment with trilaciclib in this trial.

About Trilaciclib

Trilaciclib is a first-in-class myelopreservation agent designed to protect the bone marrow from damage by chemotherapy and improve patient outcomes. G1 expects to submit marketing applications in the U.S. and Europe for myelopreservation in small cell lung cancer in 2020. In a randomized trial of women with metastatic triple-negative breast cancer, trilaciclib improved overall survival when administered in combination with chemotherapy compared with chemotherapy alone. The company plans to initiate additional randomized trials to evaluate the myelopreservation and survival benefits of trilaciclib in other tumor types and chemotherapy regimens.

About G1 Therapeutics

G1 Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the discovery, development and delivery of innovative therapies that improve the lives of those affected by cancer. The company is advancing three clinical-stage programs. Trilaciclib is a first-in-class myelopreservation agent designed to improve outcomes for patients being treated with chemotherapy. Lerociclib is a differentiated oral CDK4/6 inhibitor designed to enable more effective combination treatment strategies. G1T48 is a potential best-in-class oral selective estrogen receptor degrader (SERD) for the treatment of ER+ breast cancer. G1 also has an active discovery program focused on cyclin-dependent kinase targets.

G1 is based in Research Triangle Park, N.C. For additional information, please visit www.g1therapeutics.com and follow us on Twitter @G1Therapeutics.

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,” “estimate,” “intend” 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 news release include, but are not limited to, the therapeutic potential of trilaciclib, lerociclib and G1T48 and the timing for next steps with regard to the trilaciclib marketing applications, and 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 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 development-stage company; the Company’s development of a CDK4/6 inhibitor to reduce chemotherapy-induced myelosuppression is novel, unproven and rapidly evolving and may never lead to a marketable product; and market conditions. 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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