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): December 7, 2018 (December 4, 2018)

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 (Address of principal executive offices)	27709 (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))

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

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 Results of Operations and Financial Condition

On December 4, 2018, G1 Therapeutics, Inc. issued a press release announcing preliminary results from a randomized phase 2 trial of trilaciclib in combination with chemotherapy in patients 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

Exhibit No.	Description
99.1	Press release dated December 4, 2018

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 hereunto duly authorized.

G1 THERAPEUTICS, INC.

Date: December 7, 2018

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

Preliminary Results from Randomized Phase 2 Trial Demonstrate Trilaciclib Improved Progression-Free Survival in Combination with Chemotherapy in Patients with Metastatic Triple-Negative Breast Cancer

- Patients on trilaciclib received more chemotherapy cycles than those in the control arm
- Trilaciclib showed multi-lineage myelopreservation benefits when adjusting for longer duration of treatment
- Safety profile consistent with previously reported trials; no trilaciclib-related serious adverse events reported

RESEARCH TRIANGLE PARK, N.C., December 4, 2018 – G1 Therapeutics, Inc. (Nasdaq: GTHX), a clinical-stage oncology company, today announced preliminary anti-tumor efficacy and myelopreservation data from its randomized, open-label Phase 2 trial evaluating trilaciclib in combination with chemotherapy as a treatment for metastatic triple-negative breast cancer (mTNBC). These data will be presented on Wednesday, December 5 at a poster discussion Spotlight Session at the 2018 San Antonio Breast Cancer Symposium (SABCS), being held in San Antonio, Texas.

The poster is now available on the Publications page of the company's website.

"In settings such as metastatic triple-negative breast cancer where chemotherapy is dosed until disease progression, trilaciclib has the potential to deliver both multi-lineage myelopreservation and anti-tumor efficacy benefits to patients," said Raj Malik, M.D., Chief Medical Officer and Senior Vice President, R&D. "In this trial, we observed promising early progression-free survival results favoring trilaciclib, as well as myelopreservation benefits across neutrophils, red blood cells, platelets, and lymphocytes."

Trial Design

This randomized, open-label Phase 2 clinical trial 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 and 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 (GC/Tx1) or trilaciclib administered the day prior to and the day of chemotherapy (GC/Tx2).

Key Trial Findings

- Preliminary median progression-free survival (PFS) was 5.4 months in the GC arm, 8.8 months in the GC/Tx1 arm (hazard ratio 0.52, p=0.0669) and 7.3 months in the GC/Tx2 arm (hazard ratio 0.49; p=0.0546). A combined analysis of trilaciclib-treated patients showed PFS of 5.4 months for the GC arm and 7.9 months for trilaciclib (hazard ratio 0.50, p=0.0189).
- Preliminary objective response rate (ORR) was 29.2% in the GC arm, 43.3% in the GC/Tx1 arm and 36.7% in the GC/Tx2 arm.
- PFS and ORR in the control arm were consistent with historical data[1].
- Overall survival (OS) data is immature. OS and updated PFS and ORR will be reported when available.

1 J Clin Oncol 32:3840-3847

- Patients in both trilaciclib groups remained on therapy for a longer duration of time compared to GC only (median weeks: GC=14.4; GC/Tx1=20.0 weeks; GC/Tx2=19.0 weeks).
- On a per-patient basis, the number of patients experiencing myelosuppression events was similar across the three arms. When adjusted for the duration of chemotherapy, the trial demonstrated that patients receiving trilaciclib experienced multi-lineage myelopreservation benefits.
- Consistent with previous trilaciclib Phase 2 trials, treatment was well tolerated with no trilaciclib-related serious adverse events reported.

Poster Information

Title: Trilaciclib (T), a CDK4/6 inhibitor, dosed with gemcitabine (G), carboplatin (C) in metastatic triple negative breast cancer (mTNBC) patients: Preliminary phase 2 results
Abstract Number: 1191
Presentation Number: PD1-01
Session Title: Developmental Therapeutics
Date / Time / Location: December 5, 5-7 p.m. CST/6-8 p.m. EST, Stars at Night Ballroom 1&2, Henry B. Gonzalez Convention Center
Presenter: Joyce O'Shaughnessy, M.D. (Texas Oncology-Baylor Charles A. Sammons Cancer Center)

For more information about the 2018 San Antonio Breast Cancer Symposium, please visit https://www.sabcs.org.

About Trilaciclib

Trilaciclib is a first-in-class myelopreservation therapy designed to improve outcomes of patients who receive chemotherapy by preserving hematopoietic stem and progenitor cell (HSPC) and immune system function. Trilaciclib is a short-acting intravenous CDK4/6 inhibitor administered prior to chemotherapy.

Trilaciclib is being evaluated in four randomized Phase 2 clinical trials. G1 has reported positive results from three of these trials in 2018. Two trials showed myelopreservation benefits in newly diagnosed, treatment-naive SCLC patients. In the first trial, trilaciclib was administered in combination with a chemotherapy regimen of etoposide and carboplatin (NCT02499770); topline data were released in March and additional data were reported at the European Society of Medical Oncology 2018 Congress. In the second trial, trilaciclib was administered in combination with the same chemotherapy regimen and the checkpoint inhibitor Tecentriq® (atezolizumab) (NCT03041311); topline data were reported in November. Results from a trial in combination with chemotherapy in metastatic triple-negative breast cancer (NCT02978716) showing enhanced progression-free survival and multi-lineage myelopreservation benefits are being presented at the San Antonio Breast Cancer Symposium on December 5, 2018. The company plans to release topline data from a trial in combination with chemotherapy in previously treated SCLC (NCT02514447) by the end of 2018.

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, lerociclib and G1T48, that are designed to enable more effective combination treatment strategies and improve patient outcomes across multiple oncology indications.

G1 is based in Research Triangle Park, NC. 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 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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