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 19, 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**	**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))

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 19, 2018, G1 Therapeutics, Inc. issued a press release announcing positive topline results from a randomized Phase 2 trial of trilaciclib showing multi-lineage myelopreservation benefits in 2nd /3rd line small cell lung 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 19, 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 19, 2018

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

Exhibit 99.1

G1 Therapeutics Announces Positive Topline Results from Randomized Phase 2 Trial of Trilaciclib Showing Multi-Lineage Myelopreservation Benefits in 2nd-/3rd-Line Small Cell Lung Cancer

- Achieved both primary endpoints: statistically significant reductions in the duration and occurrence of Grade 4 neutropenia
- Clinically meaningful reductions in rates of granulocyte-colony stimulating factor (G-CSF) usage and red blood cell (RBC) transfusions
- Safety profile consistent with previously reported trials
- Management to host webcast and conference call today at 4:30 p.m. ET

RESEARCH TRIANGLE PARK, N.C., December 19, 2018 – G1 Therapeutics, Inc. (Nasdaq: GTHX), a clinical-stage oncology company, today announced positive topline data showing multi-lineage myelopreservation benefits in its randomized, double-blind, placebo-controlled Phase 2 trial evaluating trilaciclib in combination with topotecan as a treatment for 2nd-/3rd-line small cell lung cancer (2/3L SCLC).

“This is the third positive Phase 2 trial of trilaciclib in small cell lung cancer showing significant reductions in the duration and occurrence of Grade 4 neutropenia, and lower rates of G-CSF administrations and red blood cell transfusions. Small cell lung cancer is difficult to treat, particularly in later lines of therapy, and trilaciclib has shown potential to improve outcomes for these patients,” said Raj Malik, M.D., Chief Medical Officer and Senior Vice President, R&D. “We now have four randomized Phase 2 trials showing trilaciclib’s multi-lineage myelopreservation benefits. We plan to meet with U.S. and European regulatory authorities in 2019 to discuss the totality of trilaciclib data and pathways to approval.”

Trial Design

The Phase 1 dose finding portion of this trial enrolled 32 patients. The randomized, double-blind, placebo-controlled Phase 2 portion of the trial enrolled 91 patients with SCLC who had received 1-2 prior lines of therapy. In the three-arm trial, all patients received a chemotherapy regimen of topotecan. Patients were randomized to receive topotecan (1.5 mg/m^2) + placebo, or one of two approved doses of topotecan (1.5 mg/m^2 or 0.75 mg/m^2) + trilaciclib (240 mg/m^2). Treatment for all three arms was administered intravenously on Days 1 through 5 of a 21-day cycle.

The standard therapeutic dose of topotecan is 1.5 mg/m^2; the 0.75 mg/m^2 dose was also included in this trial in order to define the appropriate combination regimen of topotecan and trilaciclib. There were no unexpected safety signals observed at either topotecan dose level. It was determined that 1.5 mg/m^2 is the appropriate dose of topotecan when administered in combination with trilaciclib, and key trial findings reported below compare the 1.5 mg/m^2 topotecan + placebo arm to the 1.5 mg/m^2 topotecan + trilaciclib arm. Data are presented from the intent-to-treat population, with the exception of response rate which is based on the response-evaluable population.

Key Trial Findings

Data from this trial demonstrated that trilaciclib reduced clinically relevant consequences of myelosuppression versus placebo when administered in combination with topotecan.

- Achieved both primary endpoints after multiplicity adjustment: the trilaciclib arm demonstrated statistically significant reductions in both the duration of Grade 4 neutropenia in cycle 1 (mean 8 days vs. 2 days; adjusted 1-sided $p < 0.0001$) and occurrence of Grade 4 neutropenia (75.9% vs. 40.6%; adjusted 1-sided p=0.0160) compared to the placebo arm.
- There were seven events of febrile neutropenia (five patients) in the placebo arm compared to two events of febrile neutropenia (two patients) in the trilaciclib arm.
- The total number of patients receiving G-CSF was similar between the placebo (n=19/29, 65.5%) and trilaciclib (n=16/32, 50.0%) arms. Trilaciclib treatment resulted in a 45.0% reduction in number of G-CSF administrations per cycle compared to placebo (G-CSF/cycles of chemotherapy: placebo: 66/112; trilaciclib: 44/136).
- The total number of patients requiring RBC transfusions (on/after week 5) was similar between the placebo (n=12/29, 41.4%) and trilaciclib (n=10/32, 31.3%) arms. Trilaciclib treatment resulted in a 58.7% reduction in number of RBC transfusions (on/after week 5) per week compared to placebo (transfusions/weeks of therapy: placebo: 27/428; trilaciclib: 13/500).
- Exposures of topotecan and duration of therapy were comparable across the two groups.
- Objective response rate (ORR) (placebo: n=6/26, 23.1%; trilaciclib: n=4/30, 13.3%), clinical benefit rate (CBR) (placebo: n=16/26, 61.5%; trilaciclib: n=18/30, 60.0%) and median progression-free survival (PFS) (placebo: 4.2 months; trilaciclib: 4.2 months; hazard ratio=0.83) were comparable between the two groups. These findings are consistent with historical data[1, 2] (ORR: 16.9% and 10.1%; CBR: 61.5% and 73.4%; median PFS: 3.5 and 3.0 months).
- Overall survival (OS) data is immature and will be reported when available.
- Consistent with previous trilaciclib Phase 2 trials, treatment was well tolerated and there were fewer Grade ^{3} 4 treatment emergent adverse events (TEAEs) in the trilaciclib arm compared to the placebo arm.

“We have observed positive, multi-lineage myelopreservation benefits across different tumor types, lines of therapy and chemotherapy regimens in four randomized Phase 2 trials,” said Mark Velleca, M.D., Ph.D., Chief Executive Officer. “The totality of the data demonstrates trilaciclib’s potential to become a standard of care with chemotherapy and improve patient outcomes.”

Webcast and Conference Call

The management team will host a webcast and conference call at 4:30 p.m. ET today to provide an overview of the trial findings and next steps for the trilaciclib development program. The live call may be accessed by dialing 866-763-6020 (domestic) or 210-874-7713 (international) and entering the conference code: 5489226. A live and archived webcast will be available on the Events & Presentations page of the company’s website: www.g1therapeutics.com.

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1 von Pawel et al. J Clin Oncol 2014 32:4012-4019.

2 Evans et al. J Thorac Oncol 2015; 10: 1221–1228

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 all of these trials in 2018. Two trials showed myelopreservation benefits in treatment-naive SCLC patients. In one of the first-line SCLC trials, 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 another first-line SCLC 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 improved progression-free survival and multi-lineage myelopreservation benefits were presented at the San Antonio Breast Cancer Symposium on December 5, 2018. The company issued a press release announcing positive topline data from a trial in combination with chemotherapy in previously treated SCLC (NCT02514447) on December 19, 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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