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): March 5, 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 (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 March 5, 2018, G1 Therapeutics, Inc. issued a press release announcing topline data from its Phase 2a trial evaluating trilaciclib in patients undergoing chemotherapy for 1st-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.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of G1 Therapeutics, Inc., dated March 5, 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 thereunto duly authorized.

G1 THERAPEUTICS, INC.

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

Date: March 5, 2018

G1 Therapeutics Announces Positive Trilaciclib Phase 2a Topline Data Showing Robust Myelopreservation Benefits in Patients with Small Cell Lung Cancer

- Statistically significant results highlight benefit of trilaciclib in several prospectively-defined parameters, including: Grade 4 neutropenia, G-CSF usage, and chemotherapy dose reductions and delays
- Clinically meaningful data favoring trilaciclib versus placebo, including: febrile neutropenia, Grade 3/4 anemia, and red blood cell transfusions
- Management to host webcast and conference call today at 8 a.m. EST

RESEARCH TRIANGLE PARK, N.C., March 5, 2018 – G1 Therapeutics, Inc. (Nasdaq: GTHX), a clinical-stage oncology company, today announced positive topline data from its Phase 2a trial evaluating trilaciclib in patients undergoing chemotherapy for first-line small cell lung cancer (SCLC). Trilaciclib is a potential first-in-class short-acting CDK4/6 inhibitor in development to preserve hematopoietic stem cells and enhance immune system function (myelopreservation) during chemotherapy.

“The data from this trial showed clear evidence that trilaciclib preserved bone marrow and immune system function from the damaging effects of chemotherapy,” said Raj Malik, M.D., Chief Medical Officer and Senior Vice President, R&D. “Moreover, the myelopreservation effects demonstrated by trilaciclib improved patient outcomes. Chemotherapy continues to be a cornerstone of cancer treatment, and trilaciclib has the potential to benefit many of these patients.”

Trial Design

This double-blind, placebo-controlled trial enrolled participants with a confirmed diagnosis of extensive-stage SCLC. The trial randomized 77 treatment-naïve participants in a 1:1 ratio, and 75 received trilaciclib or placebo administered intravenously prior to each dose of standard-of-care etoposide and carboplatin (EP) chemotherapy. Participants in both arms of the trial were able to receive standard supportive care as recommended by the trial investigator. Growth factors, including granulocyte colony-stimulating factor (G-CSF) and erythropoietin, and transfusion support were available to all participants. The statistical analysis plan prospectively defined several clinically-relevant hematologic endpoints.

Key Trial Findings

Data from this signal-generating Phase 2a trial demonstrated that trilaciclib reduced clinically relevant consequences of chemotherapy-induced myelosuppression versus placebo. Trilaciclib was well tolerated, with no Grade 3/4 trilaciclib-related treatment emergent adverse events (TEAEs) reported. Baseline demographics and disease characteristics were generally well balanced between the two arms. Key hematological results are shown in the table below.

Parameter	EP (1) + placebo Patients N = 37	EP + trilaciclib Patients N = 38	% Reduction	P-value (2)
Patients with Gr 3/4 Hematologic TEAEs	27 (73.0%)	9 (23.7%)	67.5%	<0.0001
Patients with Gr 3/4 Neutropenia	30 (81.1%)	15 (39.5%)	51.3%	0.0002
Patients with Gr 4 Neutropenia	16 (43.2%)	2 (5.3%)	87.7%	0.0001
Patients with Gr 4 Neutropenia in Cycle 1	13 (35.1%)	1 (2.6%)	92.6%	0.0003
Cycles with Febrile Neutropenia	5	1	80.8%	0.1542
Patients with Febrile Neutropenia	3 (8.1%)	1 (2.6%)	67.9%	0.2773
Patients with G-CSF Administration	24 (64.9%)	4 (10.5%)	83.8%	<0.0001
Patients with Chemotherapy Cycle Delays	25 (67.6%)	15 (39.5%)	41.6%	0.0170
Patients with Chemotherapy Dose Reductions	13 (35.1%)	3 (7.9%)	77.5%	0.0033

(1) etoposide and carboplatin
(2) significance testing at two-sided alpha = 0.2 per prospectively defined analysis plan

The trilaciclib arm also showed favorable trends with reduced Grade 3 anemia, red blood cell transfusions, and Grade 3 thrombocytopenia versus placebo. There was no Grade 4 anemia or thrombocytopenia in either arm.

In addition to demonstrating myelopreservation benefits across multiple hematopoietic lineages, trilaciclib showed favorable trends versus placebo for overall response rate (ORR), duration of response (DOR) and progression free survival (PFS). The survival data are still immature.

- ORR by blinded independent central review (BICR): trilaciclib 66.7%, placebo 62.2% (p=0.6759)
- Median DOR (BICR): trilaciclib 5.7 months, placebo 4.3 months (p=0.1449)
- PFS (investigator, including clinical progression) median: trilaciclib 6.2 months, placebo 5.0 months (hazard ratio 0.6, p=0.06)

The company plans to share these data with U.S. and European regulatory authorities this year and discuss next steps for the development of trilaciclib. The company also plans to present results from this trial, including updated data from the Phase 1b portion, at a medical meeting later this year.

G1 is currently conducting two additional clinical trials of trilaciclib to assess myelopreservation in second- / third-line SCLC and first- / second- / third-line triple-negative breast cancer, with preliminary data from both trials expected in the fourth quarter of 2018. In addition to myelopreservation, trilaciclib's effect on overall survival (OS) is being evaluated in a Phase 2a trial in first-line extensive stage SCLC as part of a combination regimen with Tecentriq® / carboplatin / etoposide. Enrollment of that trial was completed last month, two quarters ahead of schedule.

"The strength of this dataset provides us with a solid foundation to advance the development of trilaciclib and its ultimate commercialization," said Mark Velleca, M.D., Ph.D., Chief Executive Officer. "As shown by our non-exclusive collaboration with Genentech, there is significant interest in combining trilaciclib with checkpoint inhibitor / chemotherapy regimens. We believe that trilaciclib has the potential to become backbone therapy for multiple chemotherapeutic regimens across a variety of cancer types, delivering significant benefits to patients and creating a substantial long-term commercial opportunity."

Webcast and Conference Call

The G1 management team will host a conference call and webcast at 8 a.m. EST today. The live call may be accessed by dialing 866-763-6020 (domestic) or 210-874-7713 (international) and entering the conference code: 3098523. A live and archived webcast will be available in the Investors section of G1's website at www.g1therapeutics.com.

About Trilaciclib (G1T28)

Trilaciclib is a potential first-in-class short-acting CDK4/6 inhibitor in development to preserve hematopoietic stem cells and enhance immune system function during chemotherapy. Trilaciclib is administered intravenously prior to chemotherapy and has the potential to significantly improve treatment outcomes.

Trilaciclib is being evaluated in four randomized Phase 2 clinical trials: a trial in newly diagnosed, treatment-naive SCLC patients (NCT02499770), a trial in previously treated SCLC patients (NCT02514447), a trial in patients with triple-negative breast cancer (NCT02978716), and a trial in combination with Tecentriq® and chemotherapy in SCLC patients (NCT03041311).

About G1 Therapeutics

G1 Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the discovery and development of novel therapeutics for the treatment of cancer. G1's two clinical assets, trilaciclib and G1T38, are CDK4/6 inhibitors, a validated and promising class of targets for anti-cancer therapeutics. Trilaciclib and G1T38 have broad therapeutic potential in many forms of cancer and may serve as the backbone of multiple combination regimens. In addition, G1 is advancing G1T48, a potential first- / best-in-class oral selective estrogen receptor degrader, or SERD, which is targeted for the treatment of ER+ breast cancer.

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, G1T38 and G1T48, and are based on G1 Therapeutics' 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 G1 Therapeutics' actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in G1 Therapeutics' filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" sections contained therein and include, but are not limited to, the inherent uncertainties associated with developing new products or technologies and operating as a development-stage company; G1 Therapeutics' ability to complete clinical trials for, obtain approvals for and commercialize any of its product candidates; G1 Therapeutics' ability to recruit and enroll participants in its studies; competition in the industry in which G1 Therapeutics operates; and market conditions. Except as required by law, G1 Therapeutics 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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