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): April 29, 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** **(Address of principal executive offices)**	**27709** **(zip code)**

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

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**

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 April 29, 2019, G1 Therapeutics, Inc. (the "Company") issued a press release announcing that it received positive feedback about trilaciclib at the end-of-phase 2 meeting with the U.S. Food and Drug Administration (FDA). Based on written feedback from the FDA and discussions with European regulatory authorities, the Company plans to submit marketing applications in the U.S. and Europe for trilaciclib for myelopreservation in small cell lung cancer. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of G1 Therapeutics, Inc., dated April 29, 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: April 29, 2019

Exhibit 99.1

G1 Therapeutics Announces Positive Feedback from Trilaciclib End-of-Phase 2 Meeting with FDA; Expects to File NDA in 2020

RESEARCH TRIANGLE PARK, N.C., APRIL 29, 2019 – G1 Therapeutics, Inc. (Nasdaq: GTHX), a clinical-stage oncology company, today provided a regulatory update on trilaciclib, a first-in-class myelopreservation agent designed to protect the bone marrow from damage by chemotherapy and improve patient outcomes.

Based on written feedback from its end-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) and discussions with European regulatory authorities, the company plans to submit marketing applications in the U.S. and Europe for trilaciclib for myelopreservation in small cell lung cancer (SCLC). These submissions will be based on currently available data from three randomized, double-blind, placebo-controlled SCLC clinical trials, as well as safety data collected across all completed and ongoing clinical trials.

"We are pleased with the feedback from our recent meetings with regulatory authorities. We look forward to continuing a collaborative dialogue regarding the marketing applications, as well as discussing further clinical development of trilaciclib," said Raj Malik, M.D., Chief Medical Officer. "We believe trilaciclib represents an important advance in the care of SCLC patients. We will also move forward with a robust development program to evaluate trilaciclib in multiple tumor types and chemotherapy regimens."

G1 will request a pre-New Drug Application (NDA) meeting with the FDA and anticipates it will be scheduled later this year. The company will provide further details regarding the NDA submission and timeline following that meeting. The company plans to submit a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) subsequent to an NDA filing.

Chemotherapy is an effective and important weapon against cancer. However, chemotherapy does not differentiate between healthy cells and cancer cells and kills both, including important stem cells in the bone marrow that produce white blood cells, red blood cells and platelets. This chemotherapy-induced bone marrow damage is known as myelosuppression. When white blood cells, red blood cells and platelets become depleted, chemotherapy patients are at increased risk of infection, experience anemia and fatigue, and are at increased risk of bleeding. Myelosuppression often requires the administration of rescue interventions such as growth factors and blood or platelet transfusions, and may also result in chemotherapy dose delays and reductions.

"In clinical trials, trilaciclib demonstrated the ability to protect bone marrow from chemotherapy damage and meaningfully reduced the need for supportive care interventions, such as G-CSF and transfusions," said Jared Weiss, M.D., Associate Professor, University of North Carolina Lineberger Comprehensive Cancer Center, and trilaciclib clinical trial investigator. "By providing a proactive approach to reduce myelosuppression, trilaciclib improves the patient experience during chemotherapy

treatment, reducing side effects and the need for associated interventions commonly given to treat them."

About Trilaciclib

Trilaciclib is a first-in-class myelopreservation agent designed to protect the bone marrow from damage by chemotherapy and improve patient outcomes. Trilaciclib is being evaluated in four randomized Phase 2 clinical trials; G1 reported positive results from all these trials in 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 and lerociclib are designed to enable more effective combination treatment strategies and improve patient outcomes across multiple oncology indications. 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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