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): August 7, 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

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	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 2.02 Results of Operations and Financial Condition.

On August 7, 2019, G1 Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the second-quarter ended June 30, 2019. The full text of the press release was posted on the Company's internet website and is furnished as Exhibit 99.1 hereto and incorporated herein by reference.

Pursuant to General Instruction B.2 of Current Report on Form 8-K, the information contained in, or incorporated into, Item 2.02, including the press release attached as Exhibit 99.1, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any registration statement or other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference to such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated August 7, 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/ Jennifer Moses*
Jennifer Moses
Chief Financial Officer

Date: August 7, 2019

G1 Therapeutics Provides Second Quarter 2019 Corporate and Financial Update

– FDA grants Breakthrough Therapy Designation for trilaciclib based on myelopreservation data in small cell lung cancer patients
– First clinical data on oral SERD G1T48 in breast cancer to be presented at ESMO 2019 Congress
– Management to host webcast and conference call today at 4:30 p.m. ET

RESEARCH TRIANGLE PARK, NC, August 7, 2019 – G1 Therapeutics, Inc. (Nasdaq: GTHX), a clinical-stage oncology company, today provided a corporate and financial update for the second quarter ended June 30, 2019.

"Our most advanced investigational therapy, trilaciclib, has demonstrated significant benefits for people being treated with chemotherapy for small cell lung cancer and triple-negative breast cancer. We are pleased that the FDA has granted Breakthrough Therapy Designation based on myelopreservation data in small cell lung cancer, an important step toward making trilaciclib available to these patients. We look forward to working with the FDA during our pre-NDA meeting next month. We have also initiated parallel discussions with the FDA regarding promising data in metastatic triple-negative breast cancer, which showed improved overall survival," said Mark Velleca, M.D., Ph.D., Chief Executive Officer. "In addition, we continue to make rapid progress across our pipeline, with emerging data suggesting that all three investigational therapies – trilaciclib, lerociclib and G1T48 – have the potential to improve outcomes for women with breast cancer and be used in early stages of their disease."

Raj Malik, M.D., Chief Medical Officer and Senior Vice President, R&D, added, "We will present new data on trilaciclib, lerociclib and G1T48 at the upcoming ESMO congress. Of note, we will report the first clinical data from approximately 25 patients in a Phase 1 trial of G1T48, our oral selective estrogen receptor degrader. Based on data from this trial, we are planning to initiate a pivotal trial in 2020 with G1T48 for the treatment of ER+, HER2- breast cancer in combination with a CDK4/6 inhibitor."

Clinical, Regulatory and Corporate Updates

- **Breakthrough Therapy Designation (BTD) granted for trilaciclib based on myelopreservation data in small cell lung cancer (SCLC) patients; U.S. and European regulatory filings on track for 2020:** The company has received BTD from the U.S. Food and Drug Administration (FDA) based on positive myelopreservation data in small cell lung cancer patients from three randomized Phase 2 clinical trials. The BTD program is designed to expedite development and review of drugs intended for serious or life-threatening conditions. The company expects to submit marketing applications in the U.S. and Europe in 2020.
- **Preliminary overall survival (OS) results from randomized Phase 2 trial demonstrated women with metastatic triple-negative breast cancer (mTNBC) lived significantly longer when receiving trilaciclib and chemotherapy compared with women receiving chemotherapy alone:** 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) (press release here). In June 2019, the company reported updated anti-tumor efficacy results that showed women receiving trilaciclib and a chemotherapy regimen of gemcitabine/carboplatin had a statistically significant improvement in OS compared with those receiving gemcitabine/carboplatin alone (press release here). Detailed data from this trial will be presented at a medical meeting later this year.

- **Data on all three clinical-stage programs accepted for presentation at ESMO 2019 Congress:** New clinical data on trilaciclib, lerociclib and G1T48 have been accepted for presentation at the European Society for Medical Oncology (ESMO) 2019 Congress, being held Sept. 27-Oct. 1. Presentations include the first clinical data on G1T48, an oral selective estrogen receptor degrader (SERD), myelopreservation and efficacy data from the Phase 2 trilaciclib + chemotherapy + Tecentriq® (atezolizumab) small cell lung cancer trial, and safety and tolerability data from the Phase 1b/2a lerociclib + Tagrisso® (osimertinib) non-small cell lung cancer trial. The company will host a webcast on Sunday, Sept. 29 to review the data and provide an overview of development and commercial plans across the pipeline.
- **Additional data on trilaciclib reported at ASCO and MASCC/ISOO annual meetings:** The company reported additional data from trilaciclib SCLC clinical trials at both the American Society of Clinical Oncology (ASCO) and the Multinational Association of Supportive Care in Cancer (MASCC)/International Society of Oral Oncology (ISOO) 2019 annual meetings. Pooled myelopreservation and patient-reported outcomes (PRO) data from all three trilaciclib SCLC trials presented at MASCC 2019 showed significant multilineage benefits across neutrophils, red blood cells and platelets, and significantly improved symptoms and function across multiple parameters over time compared to placebo.
- **Executive team update:** In July, the company announced the appointment of Mark Avagliano as Chief Business Officer. Prior to joining G1, Mr. Avagliano was Vice President, Corporate Development at Pfizer Inc., where he was responsible for the evaluation, planning and execution of significant corporate level transactions and oversaw the Mergers and Acquisitions, Transactions and Valuations, and Out-licensing groups (press release here).
- **Board of Directors update:** In June, current board member Garry Nicholson was named board chair, succeeding former chair Seth Rudnick, M.D. Additionally, Dr. Rudnick, Sir Andrew Witty and Fredric Eshelman, Pharm.D. were re-elected to the company's Board of Directors.

Second Quarter 2019 Financial Highlights

- **Cash Position:** Cash, cash equivalents and short-term investments totaled $324.9 million as of June 30, 2019, compared to $369.3 million as of December 31, 2018.
- **Operating Expenses:** Operating expenses were $32.6 million for the second quarter of 2019, compared to $21.7 million for the second quarter of 2018. GAAP operating expenses include stock-based compensation expense of $3.7 million for the second quarter of 2019, compared to $2.1 million for the second quarter of 2018.
- **Research and Development Expenses:** Research and development (R&D) expenses for the second quarter of 2019 were $23.5 million, compared to $18.4 million for the second quarter of 2018. The increase in R&D expense was primarily due to an increase in clinical program costs and personnel costs due to additional headcount.
- **General and Administrative Expenses:** General and administrative (G&A) expenses for the second quarter of 2019 were $9.1 million, compared to $3.3 million for the second quarter of 2018. The increase in G&A expense was largely due to an increase in compensation due to additional headcount, increase in pre-commercialization activities, and an increase in professional fees and other administrative costs necessary to support our operations as a public company.

- **Net Loss:** G1 reported a net loss of $30.7 million for the second quarter of 2019, compared to $20.9 million for the second quarter of 2018.
- **2019 Guidance:** the company expects to end the year with $260-$270 million in cash and cash equivalents.

Anticipated Milestones for 2H 2019

- Present new clinical results for trilaciclib, lerociclib and G1T48 at the ESMO 2019 Congress, being held Sept. 27-Oct. 1. The company will host an onsite event/webcast on Sunday, Sept. 29 to review the data.
- Complete meetings with the FDA and provide regulatory update for trilaciclib, including NDA filing timeline.
- Present preliminary OS findings from trilaciclib mTNBC trial at a medical meeting in 2H19.
- Present additional data from the Phase 1b/2a clinical trial of lerociclib + Faslodex® (fulvestrant) in ER+, HER2- breast cancer in 4Q19.
- In 4Q19, identify dose and schedule of lerociclib and G1T48 for pivotal trials in breast cancer in 2020.

Webcast and Conference Call

The management team will host a webcast and conference call at 4:30 p.m. ET today to provide a corporate and financial update for the second quarter 2019 ended June 30, 2019. The live call may be accessed by dialing 866-763-6020 (domestic) or 210-874-7713 (international) and entering the conference code: 7989125. A live and archived webcast will be available on the Events & Presentations page of the company's website: www.g1therapeutics.com. The webcast will be archived on the same page for 90 days following the event.

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 therapy 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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Contact:

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Exhibit 99.1

G1 Therapeutics, Inc.
Balance Sheet Data
(in thousands)

	June 30, 2019	December 31, 2018
Cash and cash equivalents	$ 324,911	$ 369,290
Working capital	$ 310,384	$ 357,771
Total assets	$ 331,653	$ 371,270
Accumulated deficit	$ (269,048)	$ (214,406)
Total stockholders' equity	$ 312,670	$ 358,820

G1 Therapeutics, Inc.
Condensed Statements of Operations
(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue	$ —	$ —	$ —	$ —
Operating expenses				
Research and development	23,489	18,385	41,569	35,732
General and administrative	9,094	3,268	16,896	6,646
Total operating expenses	32,583	21,653	58,465	42,378
Operating loss	(32,583)	(21,653)	(58,465)	(42,378)
Other income (expense)				
Other income	1,893	785	3,823	1,099
Total other income, net	1,893	785	3,823	1,099
Net loss	$ (30,690)	$ (20,868)	$ (54,642)	$ (41,279)
Net loss per share, basic and diluted	$ (0.82)	$ (0.64)	$ (1.46)	$ (1.33)
Weighted average common shares outstanding, basic and diluted	37,470,926	32,781,921	37,434,156	31,080,650