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): November 5, 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.)**

700 Park Offices Drive	
Suite 200	
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))

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 November 5, 2019, G1 Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the third-quarter ended September 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 November 5, 2019
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: November 5, 2019

G1 Therapeutics Provides Third Quarter 2019 Corporate and Financial Update

- Company to complete New Drug Application (NDA) submission for trilaciclib in small cell lung cancer in 2Q20
- Phase 2 trilaciclib data and Phase 1 G1T48 data presented at ESMO
- Management to host webcast and conference call today at 4:30 p.m. ET

RESEARCH TRIANGLE PARK, NC, November 5, 2019 – G1 Therapeutics, Inc. (Nasdaq: GTHX), a clinical-stage oncology company, today provided a corporate and financial update for the third quarter ended September 30, 2019.

"Based on written feedback from the FDA following our pre-NDA meeting in September, we will submit a New Drug Application for myelopreservation in small cell lung cancer. We expect to complete the submission in the second quarter of 2020," said Mark Velleca, M.D., Ph.D., Chief Executive Officer. "Our vision is for trilaciclib to become a new standard of care to mitigate myelosuppression in patients receiving chemotherapy. We are committed to making trilaciclib available to small cell lung cancer patients as quickly as possible, and are executing on a regulatory and development strategy to evaluate the myelopreservation benefits of trilaciclib in the most commonly used chemotherapy regimens. We expect to initiate a Phase 3 trial in colorectal cancer in the second half of 2020. In addition, we will continue to explore trilaciclib in triple-negative breast cancer, where preliminary data has demonstrated a survival benefit."

Third Quarter Regulatory and Clinical Highlights

- **The company plans to submit an NDA for trilaciclib in small cell lung cancer (SCLC) based on written feedback from FDA.** Based on written feedback from its pre-NDA meeting with the U.S. Food and Drug Administration (FDA) in September, the company will file an NDA for trilaciclib in SCLC. The company expects to complete the NDA submission in the second quarter of 2020. Earlier this year, trilaciclib received Breakthrough Therapy Designation (BTD) from the FDA based on positive myelopreservation data in SCLC 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.
- **ESMO presentations: data from Phase 2 clinical trials of trilaciclib in metastatic triple-negative breast cancer (mTNBC) and SCLC and data from Phase 1 clinical trial of G1T48 in ER+, HER2- breast cancer.** In an oral presentation on data from a randomized Phase 2 trial of trilaciclib, preliminary overall survival (OS) results demonstrated that women with mTNBC lived significantly longer when receiving trilaciclib and chemotherapy compared with women receiving chemotherapy alone. Data were published simultaneously in *The Lancet Oncology*. The company also presented updated Phase 2 results in SCLC patients receiving trilaciclib and chemotherapy in combination with Tecentriq® (atezolizumab) (press release here) and the first clinical data on its oral selective estrogen receptor degrader (SERD), G1T48. Preliminary results from the ongoing Phase 1/2a dose-escalation trial of G1T48 in patients with estrogen receptor-

positive, HER2-negative (ER+, HER2-) breast cancer showed G1T48 was well tolerated and demonstrated evidence of anti-tumor activity in heavily pre-treated patients. Based on safety and tolerability findings in the Phase 1b portion of this trial, the company selected the 600 mg and 1,000 mg doses of G1T48 for evaluation in the ongoing Phase 2a portion (press release here).

Third Quarter 2019 Financial Highlights

- **Cash Position:** Cash, cash equivalents and short-term investments totaled $299.9 million as of September 30, 2019, compared to $369.3 million as of December 31, 2018.
- **Operating Expenses:** Operating expenses were $34.0 million for the third quarter of 2019, compared to $20.8 million for the third quarter of 2018. GAAP operating expenses include stock-based compensation expense of $4.4 million for the third quarter of 2019, compared to $3.3 million for the third quarter of 2018.
- **Research and Development Expenses:** Research and development (R&D) expenses for the third quarter of 2019 were $22.9 million, compared to $15.9 million for the third quarter of 2018. The increase in R&D expense was primarily due to an increase in clinical program costs, costs for manufacturing pharmaceutical active ingredients, and personnel costs due to additional headcount.
- **General and Administrative Expenses:** General and administrative (G&A) expenses for the third quarter of 2019 were $11.1 million, compared to $4.9 million for the third 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, increase in medical affairs costs, and an increase in professional fees and other administrative costs necessary to support our operations.
- **Net Loss:** G1 reported a net loss of $32.4 million for the third quarter of 2019, compared to $19.9 million for the third quarter of 2018.
- **2019 Guidance:** The company expects to end the year with $265-$270 million in cash and cash equivalents.

Anticipated Milestones

- Begin rolling NDA submission for trilaciclib in SCLC in 4Q19, which the company expects to complete in 2Q20; submit Marketing Authorization Application to the European Medicines Agency in 2H20.
- Initiate clinical trials of trilaciclib in colorectal cancer and TNBC in 2020.
- Present additional data from the Phase 1b/2a clinical trial of lerociclib + Faslodex® (fulvestrant) at the 2019 San Antonio Breast Cancer Symposium (SABCS) on December 11, 2019.
- Identify dose and schedule of lerociclib and G1T48 for pivotal trials in ER+, HER2- breast cancer.

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 third quarter 2019 ended September 30, 2019. The live call may be accessed by dialing 866-763-6020 (domestic) or 210-874-7713 (international) and entering the conference code: 3374256. 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 an 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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G1 Therapeutics, Inc.
Balance Sheet Data
(in thousands)

	September 30, 2019	December 31, 2018
Cash and cash equivalents	$ 299,933	$ 369,290
Working capital	$ 281,758	$ 357,771
Total assets	$ 317,186	$ 371,270
Accumulated deficit	$ (301,412)	$ (214,406)
Total stockholders' equity	$ 286,119	$ 358,820

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue	$ —	$ —	$ —	$ —
Operating expenses				
Research and development	22,941	15,873	64,510	51,605
General and administrative	11,083	4,949	27,979	11,595
Total operating expenses	34,024	20,822	92,489	63,200
Operating loss	(34,024)	(20,822)	(92,489)	(63,200)
Other income (expense)				
Other income	1,660	904	5,483	2,003
Total other income, net	1,660	904	5,483	2,003
Net loss	$ (32,364)	$ (19,918)	$ (87,006)	$ (61,197)
Net loss per share, basic and diluted	$ (0.86)	$ (0.59)	$ (2.32)	$ (1.91)
Weighted average common shares outstanding, basic and diluted	37,540,380	33,829,437	37,469,952	32,006,978