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): February 28, 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 **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 2.02 Results of Operations and Financial Condition

On February 28, 2019, G1 Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth-quarter and full-year ended December 31, 2018. 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

Exhibit No.	Description
99.1	Press release dated February 28, 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 hereunto duly authorized.

G1 THERAPEUTICS, INC.

Date: February 28, 2019

/s/ Barclay A. Phillips
Barclay A. Phillips
Chief Financial Officer and
Senior Vice President of Corporate Development

G1 Therapeutics Reports Fourth Quarter and Full-Year 2018 Financial Results

- Reported positive findings in all four randomized Phase 2 clinical trials of trilaciclib in 2018
- Clinical program updates to be provided at Investor Day 2019 on March 6
- Management to host webcast and conference call today at 4:30 p.m. ET

RESEARCH TRIANGLE PARK, NC, February 28, 2019 – G1 Therapeutics, Inc. (Nasdaq: GTHX), a clinical-stage oncology company, today reported financial results for the fourth quarter and full-year ended December 31, 2018. The company also highlighted 2018 operational results and upcoming 2019 milestones.

“Data from four randomized Phase 2 trials showed the benefits of trilaciclib across different indications, lines of therapy and chemotherapy regimens,” said Raj Malik, M.D., Chief Medical Officer and Senior Vice President, R&D. “We have scheduled meetings with U.S. and European regulatory authorities in the first half of 2019 to discuss the totality of data and next steps for the development of trilaciclib. We will provide an update on these meetings in the second quarter.”

“We made substantial progress across our three clinical-stage product candidates in 2018. We reported positive results from all four Phase 2 trilaciclib trials, presented proof-of-concept data on lerociclib in breast cancer, initiated a trial of lerociclib in non-small cell lung cancer, and brought our oral selective estrogen receptor degrader G1T48 into the clinic,” said Mark Velleca, M.D., Ph.D., Chief Executive Officer. “These accomplishments will drive a number of important clinical and regulatory milestones in 2019 in the advancement of our pipeline.”

Corporate Highlights

- **Reported positive multi-lineage myelopreservation data from three randomized, double-blind, placebo-controlled Phase 2 trials of trilaciclib in small cell lung cancer (SCLC):** In the fourth quarter, the company presented additional data from its Phase 2 trial of trilaciclib in combination with chemotherapy in first-line SCLC at the European Society for Medical Oncology (ESMO) 2018 Congress, and reported preliminary data from Phase 2 trials in first-line SCLC in combination with chemotherapy/Tecentriq® (atezolizumab) and second/third-line SCLC in combination with chemotherapy. In these trials, patients receiving trilaciclib showed statistically significant improvements in duration and occurrence of severe neutropenia (primary endpoints) and clinically meaningful reductions in G-CSF administrations and red blood cell transfusions. Treatment was well tolerated and the safety profile of trilaciclib was consistent across the three trials.
- **Presented preliminary improved progression-free survival data from randomized Phase 2 trial of trilaciclib in combination with chemotherapy in patients with metastatic triple-negative breast cancer (mTNBC):** In December, the company presented data from its Phase 2 trial of trilaciclib in patients with mTNBC at the 2018 San Antonio Breast Cancer Symposium. Preliminary median progression-free survival (PFS) was 5.4 months in the chemotherapy arm, 8.8 months in the chemotherapy and trilaciclib (dosed the day of chemotherapy) arm (hazard ratio 0.52, p=0.0669), and 7.3 months in the chemotherapy and trilaciclib (dosed the day prior to and day of chemotherapy) arm (hazard ratio 0.49; p=0.0546). A combined analysis of trilaciclib-treated patients showed PFS of 5.4 months for the chemotherapy arm and 7.9 months for chemotherapy and trilaciclib (hazard ratio 0.50, p=0.0189). Patients on trilaciclib received more chemotherapy cycles than those in the control arm. The safety profile of trilaciclib was consistent with previously reported trials; no trilaciclib-related serious adverse events were reported.

Anticipated Milestones for 2019

- Meet with U.S. and European regulatory authorities in the first half of 2019 and announce the next steps for trilaciclib development in the second quarter of 2019.
- Initiate additional randomized trials for trilaciclib in the second half of 2019, pending feedback from regulatory authorities.
- Report additional data from all four randomized Phase 2 trilaciclib clinical trials.
- Present additional data from the Phase 1b clinical trial of lerociclib/Faslodex® (fulvestrant) in ER+, HER2- breast cancer in the second half of 2019.
- Present preliminary dose-escalation data from the Phase 1b clinical trial of lerociclib/Tagrisso® (osimertinib) in non-small cell lung cancer in the second half of 2019.
- Present preliminary dose-escalation data from the Phase 1 clinical trial of G1T48, an oral selective estrogen receptor degrader (SERD), in ER+ breast cancer in the second half of 2019.

Fourth Quarter and Full-Year 2018 Financial Highlights

- **Cash Position:** Cash, cash equivalents and short-term investments totaled $369.3 million as of December 31, 2018, compared to $390.5 million as of September 30, 2018, and $103.8 million as of December 31, 2017.
- **Operating Expenses:** Operating expenses were $26.1 million for the fourth quarter of 2018, compared to $17.3 million for the fourth quarter of 2017. GAAP operating expenses include stock-based compensation expense of $3.3 million for the fourth quarter of 2018, compared to $1.0 million for the fourth quarter of 2017. Operating expenses for the full-year 2018 were $89.3 million, compared to $61.0 million for the prior year. Stock-based compensation expense for the full-year 2018 was $10.2 million, compared to $3.4 million for the prior year.
- **Research and Development Expenses:** Research and development (R&D) expenses for the fourth quarter of 2018 were $19.1 million, compared to $15.1 million for the fourth quarter of 2017. The increase in expense was due to an increase in clinical program costs, drug manufacturing costs to support clinical programs, external research studies and personnel costs due to additional headcount. R&D expenses for the full-year 2018 were $70.7 million, compared to $53.9 million for the prior year.
- **General and Administrative Expenses:** General and administrative (G&A) expenses for the fourth quarter of 2018 were $7.0 million, compared to $2.2 million for the fourth quarter of 2017. The increase in expense was largely due to an increase in professional fees and personnel-related costs. G&A expenses for the full-year 2018 were $18.6 million, compared to $7.1 million for the prior year.
- **Net Loss:** G1 reported a net loss of $24.1 million for the fourth quarter of 2018, compared to $17.0 million for the fourth quarter of 2017. Net loss for the full-year 2018 was $85.3 million, compared to a net loss of $60.1 million for the prior year.

Webcast and Conference Call

The management team will host a webcast and conference call at 4:30 p.m. ET today to provide a financial update for the fourth quarter and full-year of 2018. The live call may be accessed by dialing 866-763-6020 (domestic) or 210-874-7713 (international) and entering the conference code: 2698949. 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.

Clinical program updates will be provided at the Investor Day 2019 meeting on March 6.

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 also has an active discovery program focused on cyclin-dependent kinases 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 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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G1 Therapeutics, Inc.
Balance Sheet Data
(in thousands)

	December 31, 2018	December 31, 2017
Cash and cash equivalents	$ 369,290	$ 103,812
Working capital	$ 357,771	$ 92,957
Total assets	$ 371,270	$ 105,171
Accumulated deficit	$ (214,406)	$ (129,118)
Total stockholders' equity	$ 358,820	$ 93,388

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

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Revenue	$ —	$ —	$ —	$ —
Operating expenses				
Research and development	19,077	15,076	70,683	53,881
General and administrative	7,009	2,206	18,603	7,087
Total operating expenses	26,086	17,282	89,286	60,968
Operating loss	(26,086)	(17,282)	(89,286)	(60,968)
Other income (expense)				
Other income	1,994	301	3,998	888
Change in fair value in warrant liability and other liabilities	—	—	—	(41)
Total other income, net	1,994	301	3,998	847
Net loss	$ (24,092)	$ (16,981)	$ (85,288)	$ (60,121)
Accretion of redeemable convertible preferred stock	—	—	—	(4,757)
Net loss attributable to common stockholders	$ (24,092)	$ (16,981)	$ (85,288)	$ (64,878)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.65)	$ (0.60)	$ (2.56)	$ (3.57)
Weighted average common shares outstanding, basic and diluted	37,203,233	28,362,323	33,316,719	18,197,970