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 26, 2020

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 February 26, 2020, G1 Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth-quarter and full-year ended December 31, 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 February 26, 2020
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: February 26, 2020

G1 Therapeutics Provides Fourth Quarter and Full-Year 2019 Corporate and Financial Update

- New Drug Application (NDA) submission for trilaciclib in small cell lung cancer on track for 2Q20
- Trilaciclib selected for inclusion in I-SPY 2 breast cancer trial
- Rintodestrant (G1T48) combination trial with palbociclib expected to initiate in 2Q20
- Management to host webcast and conference call today at 4:30 p.m. ET

RESEARCH TRIANGLE PARK, NC, February 26, 2020 – G1 Therapeutics, Inc. (Nasdaq: GTHX), a clinical-stage oncology company, today provided a corporate and financial update for the fourth quarter and full-year ended December 31, 2019.

“We achieved significant clinical and regulatory milestones across our pipeline in 2019. In 2020, our primary focus is the execution of our U.S. and European regulatory filings for trilaciclib for patients with small cell lung cancer and preparation for its commercial launch in the U.S.,” said Mark Velleca, M.D., Ph.D., Chief Executive Officer. “We believe trilaciclib has the potential to improve outcomes for patients receiving chemotherapy across a broad range of tumor types. In 2020, we will initiate a Phase 3 trial in colorectal cancer and evaluate trilaciclib in the I-SPY 2 breast cancer trial.”

Fourth Quarter Regulatory, Clinical and Corporate Highlights

- **Initiated rolling NDA submission for trilaciclib in small cell lung cancer (SCLC) in 4Q19 and expect to complete the filing in 2Q20.** Certain portions of the NDA, including preclinical data, were submitted to the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2019. The company plans to complete the filing in the second quarter of 2020.
- **Trilaciclib included in I-SPY 2 neoadjuvant breast cancer trial based on compelling overall survival (OS) findings in Phase 2 triple-negative breast cancer (TNBC) trial.** At the European Society for Medical Oncology (ESMO) 2019 Congress, the company presented preliminary data from its randomized, open-label Phase 2 trial of trilaciclib in TNBC showing that the addition of trilaciclib to chemotherapy resulted in a significant increase in OS compared to chemotherapy alone (press release here). These findings contributed to trilaciclib being selected for inclusion in the ongoing Phase 2 I-SPY 2 TRIAL™. Two new investigational treatment arms of the trial will evaluate trilaciclib in neoadjuvant treatment of locally advanced breast cancer. The study will generate data that will allow the company to evaluate trilaciclib in combination with several broadly-used chemotherapy classes, an anti-PD-1 immunotherapy, and a range of breast cancer subtypes (press release here).
- **Findings from Phase 1/2a rintodestrant monotherapy trial in patients with ER+, HER2- breast cancer support initiation of combination trials with CDK4/6 inhibitors.** The company announced preliminary safety, tolerability and efficacy data on rintodestrant (formerly G1T48), its oral selective estrogen receptor degrader (SERD), at the 2019 European Society of Medical Oncology Congress in September (press release here). Based on these findings, G1 plans to

initiate an additional arm of its ongoing Phase 1/2a trial in the second quarter of 2020 to explore the combination regimen of rintodestrant and the CDK4/6 inhibitor Ibrance® (palbociclib) as a treatment for ER+, HER2- breast cancer. Palbociclib will be provided by Pfizer Inc. under a non-exclusive clinical supply agreement.

- **Reported additional data from Phase 1b/2a clinical trial of lerociclib in combination with fulvestrant for the treatment of ER+, HER2- breast cancer.** Updated findings presented at the 2019 San Antonio Breast Cancer Symposium showed lerociclib, dosed without a drug holiday, has a differentiated safety and tolerability profile than observed in clinical trials with currently marketed CDK4/6 inhibitors. Preliminary efficacy findings were consistent with other CDK4/6 inhibitors used in combination with fulvestrant. Additional safety and efficacy data are expected in the third quarter of 2020.

Fourth Quarter/Full-Year 2019 Financial Highlights and 2020 Guidance

- **Cash Position:** Cash and cash equivalents totaled $269.2 million as of December 31, 2019, compared to $369.3 million as of December 31, 2018.
- **Operating Expenses:** Operating expenses were $36.6 million for the fourth quarter of 2019, compared to $26.1 million for the fourth quarter of 2018. GAAP operating expenses include stock-based compensation expense of $4.5 million for the fourth quarter of 2019, compared to $3.3 million for the fourth quarter of 2018. Operating expenses for the full-year 2019 were $129.0 million, compared to $89.3 million for the prior year. Stock-based compensation expense for the full-year 2019 was $16.4 million, compared to $10.2 million for the prior year.
- **Research and Development Expenses:** Research and development (R&D) expenses for the fourth quarter of 2019 were $24.5 million, compared to $19.1 million for the fourth quarter of 2018. R&D expenses for the full-year 2019 were $89.0 million, compared to $70.7 million for the prior year. The increase in R&D expenses 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 fourth quarter of 2019 were $12.1 million, compared to $7.0 million for the fourth quarter of 2018. G&A expenses for the full-year 2019 were $40.0 million, compared to $18.6 million for the prior year. The increase in G&A expenses 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 $35.4 million for the fourth quarter of 2019, compared to $24.1 million for the fourth quarter of 2018. Net loss for the full-year 2019 was $122.4 million, compared to a net loss of $85.3 million for the prior year.
- **2020 Guidance:** The company expects to end 2020 with $110-$130 million in cash and cash equivalents, prior to the consideration of potential proceeds from partnerships, collaboration activities, and/or other sources of capital. The company expects year-end 2019 cash and cash equivalents of $269.2 million to be sufficient to fund its operating expenses and capital expenditure requirements into the second half of 2021.

Key Anticipated 2020 Milestones

- Complete NDA submission for trilaciclib in SCLC in 2Q20 and Marketing Authorization Application to the European Medicines Agency in 4Q20.
- Begin enrollment in I-SPY 2 clinical trial of trilaciclib in neoadjuvant breast cancer in 2Q20.
- Initiate additional arm of rintodestrant Phase 1/2a trial to evaluate combination with Ibrance® (palbociclib) in 2Q20; additional Phase 1/2a monotherapy data expected in 4Q20.
- Initiate Phase 3 clinical trial of trilaciclib in colorectal cancer in 4Q20.

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 fourth quarter and full-year 2019 ended December 31, 2019. The live call may be accessed by dialing 866-763-6020 (domestic) or 210-874-7713 (international) and entering the conference code: 4188787. 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. Trilaciclib has received Breakthrough Therapy Designation from the FDA; a rolling NDA submission for small cell lung cancer is expected to be completed in the second quarter of 2020. Rintodestrant (formerly G1T48) is a potential best-in-class oral selective estrogen receptor degrader (SERD) for the treatment of ER+ breast cancer. Lerociclib is a differentiated oral CDK4/6 inhibitor designed to enable more effective combination treatment strategies.

G1 Therapeutics 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, those relating to the therapeutic potential of trilaciclib, rintodestrant and lerociclib, the timing of marketing applications in the U.S. and Europe for trilaciclib in SCLC, the planned initiation of the additional arm of the rintodestrant trial to evaluate combination with Ibrance® (palbociclib), and lerociclib's differentiated safety and tolerability profile over other marketed CDK4/6 inhibitors 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; 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.

###

Contact:

Jeff Macdonald
Senior Director, Investor Relations & Corporate Communications
919-213-9835
jmacdonald@g1therapeutics.com

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

	December 31, 2019	December 31, 2018
Cash and cash equivalents	$ 269,208	$ 369,290
Working capital	$ 251,234	$ 357,771
Total assets	$ 284,831	$ 371,270
Accumulated deficit	$ (336,853)	$ (214,406)
Total stockholders' equity	$ 255,527	$ 358,820

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
Revenue	$ —	$ —	$ —	$ —
Operating expenses				
Research and development	24,492	19,077	89,002	70,683
General and administrative	12,061	7,009	40,039	18,603
Total operating expenses	36,553	26,086	129,041	89,286
Operating loss	(36,553)	(26,086)	(129,041)	(89,286)
Other income (expense)				
Other income	1,112	1,994	6,594	3,998
Total other income, net	1,112	1,994	6,594	3,998
Net loss	$ (35,441)	$ (24,092)	$ (122,447)	$ (85,288)
Net loss per share, basic and diluted	$ (0.94)	$ (0.65)	$ (3.27)	$ (2.56)
Weighted average common shares outstanding, basic and diluted	37,586,218	37,203,233	37,499,256	33,316,719