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): May 6, 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 May 6, 2020, G1 Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the first-quarter ended March 31, 2020. 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 May 6, 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: May 6, 2020

G1 Therapeutics Provides First Quarter 2020 Corporate and Financial Update

- New Drug Application (NDA) submission for trilaciclib in small cell lung cancer on track for 2Q20
- Rintodestrant 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, May 6, 2020 – G1 Therapeutics, Inc. (Nasdaq: GTHX), a clinical-stage oncology company, today provided a corporate and financial update for the first quarter ended March 31, 2020.

"We have activated business continuity plans in response to the COVID-19 pandemic to ensure we can advance therapies that patients with cancer, their families, and healthcare providers are counting on to improve outcomes, and also taken actions to safeguard the well-being of our employees," said Mark Velleca, M.D., Ph.D., Chief Executive Officer. "We are on track to complete a New Drug Application filing for trilaciclib for patients with small cell lung cancer this quarter, and have initiated virtual medical education programs as we prepare for commercial launch in the U.S. We remain committed to evaluating the benefits of trilaciclib in other indications and expect to initiate the I SPY-2 breast cancer trial this quarter and a pivotal trial in colorectal cancer in the fourth quarter of 2020. Cancer patients experiencing chemotherapy-induced myelosuppression are an especially vulnerable population, and trilaciclib has the potential to be the first proactively administered myelopreservation therapy for these patients."

First Quarter Regulatory, Clinical and Corporate Highlights

- **NDA submission for trilaciclib in small cell lung cancer (SCLC) expected in 2Q20.** A rolling NDA submission to the U.S. Food and Drug Administration (FDA) began in the fourth quarter of 2019 and is expected to be completed this quarter.
- **Pivotal trial of trilaciclib in colorectal cancer expected to begin in 4Q20.** In 2Q20, the company discussed the design of a registrational clinical trial of trilaciclib in colorectal cancer with the FDA at a pre-Phase 3 meeting. The trial is on track to begin in the fourth quarter of 2020.
- **I-SPY 2 neoadjuvant breast cancer trial including trilaciclib on track for 2Q20 initiation.** Trilaciclib was selected for inclusion in the ongoing Phase 2 I-SPY 2 TRIAL™ based on compelling overall survival (OS) findings in a Phase 2 triple-negative breast cancer (TNBC) trial (press release here). The I-SPY trial will generate data across a range of breast cancer subtypes that will allow the company to evaluate trilaciclib in combination with several broadly-used chemotherapy classes and an anti-PD-1 immunotherapy.

- **Initiation of rintodestrant and Ibrance combination trial on track for 2Q20.** The company previously announced preliminary safety, tolerability and efficacy data on rintodestrant, its oral selective estrogen receptor degrader (SERD) (press release here) as monotherapy treatment for ER+, HER2- breast cancer. 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). Palbociclib will be provided by Pfizer Inc. under a non-exclusive clinical supply agreement.

- **Soma Gupta named as Chief Commercial Officer.** In March, the company appointed Soma Gupta as its Chief Commercial Officer (CCO) with responsibility for leading commercial preparations for the launch of trilaciclib in the U.S. Ms. Gupta and her team are focused on developing a patient access strategy that illustrates the value that trilaciclib can provide to patients and the healthcare system. Prior to joining G1, Ms. Gupta led the global commercial launch of Vyndaqel® (tafamidis meglumine) while serving as Vice President, Global Marketing for Amyloidosis and Cardiac Rare Disease at Pfizer Inc. Previously, she led the global commercial team responsible for Pfizer's oncology portfolio, including Ibrance® (palbociclib).

- **Changes to the Board of Directors.** In March, the company named Jack Bailey to its board of directors. Mr. Bailey most recently served as President – U.S. at GlaxoSmithKline (GSK) and is a past member of the board of directors of Pharmaceutical Research and Manufacturers of America (PhRMA). Sir Andrew Witty, who joined the G1 board in July 2017, has retired from this position. Sir Andrew recently took a leave of absence from his current role as president, UnitedHealth Group and CEO of Optum to co-lead the World Health Organization (WHO) COVID-19 vaccine program.

  "On behalf of our shareholders and associates, I want to thank Sir Andrew for his many contributions to G1. He has provided valuable insights and counsel, particularly related to patient access and the global reimbursement landscape," said Dr. Velleca. "We commend him for applying his considerable talents and experience to the WHO COVID-19 vaccine initiative."

- **COVID-19 impact on operations.** The company has implemented business continuity plans to address the COVID-19 pandemic and minimize disruptions on ongoing operations. The timeline for filing the trilaciclib NDA has not been impacted by COVID-19, and the company expects to complete the NDA submission in the second quarter of 2020. Initiation of two clinical trials, the rintodestrant/palbociclib combination trial and the I-SPY 2 trial, is on track to begin in 2Q20. Initial enrollment of these trials is likely to be impacted by COVID-19. The company does not anticipate significant supply chain delays or shortages as a result of the COVID-19 pandemic.

First Quarter 2020 Financial Highlights and 2020 Guidance

- **Cash Position:** Cash and cash equivalents totaled $242.4 million as of March 31, 2020, compared to $269.2 million as of December 31, 2019.
- **Operating Expenses:** Operating expenses were $31.8 million for the first quarter of 2020, compared to $25.9 million for the first quarter of 2019. GAAP operating expenses include stock-based compensation expense of $4.7 million for the first quarter of 2020, compared to $3.8 million for the first quarter of 2019.
- **Research and Development Expenses:** Research and development (R&D) expenses for the first quarter of 2020 were $20.4 million, compared to $18.1 million for the first quarter of 2019. 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 first quarter of 2020 were $11.4 million, compared to $7.8 million for the first quarter of 2019. 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 $31.0 million for the first quarter of 2020, compared to $24.0 million for the first quarter of 2019.
- **2020 Guidance:** The company is reiterating its previous financial guidance and 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 current cash and cash equivalents to be sufficient to fund its operating expenses and capital expenditure requirements into the fourth quarter of 2021.

Key Anticipated 2020 Milestones

- Complete NDA submission for trilaciclib in SCLC in 2Q20.
- Initiate 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 first quarter 2020 ended March 31, 2020. The live call may be accessed by dialing 866-763-6020 (domestic) or 210-874-7713 (international) and entering the conference code: 5669692. 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 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 press 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, trilaciclib's possibility to improve patient outcomes across multiple indications, rintodestrant's potential to be best-in-class oral SERD, lerociclib's differentiated safety and tolerability profile over other marketed CDK4/6 inhibitors and the impact of pandemics such as COVID-19 (coronavirus), 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.

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

	March 31, 2020	December 31, 2019
Cash and cash equivalents	$ 242,402	$ 269,208
Working capital	$ 225,141	$ 251,234
Total assets	$ 256,514	$ 284,831
Accumulated deficit	$(367,876)	$ (336,853)
Total stockholders' equity	$ 229,450	$ 255,527

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

	Three Months Ended March 31,	
	2020	2019
Revenue	$ —	$ —
Operating expenses		
Research and development	20,434	18,080
General and administrative	11,387	7,801
Total operating expenses	31,821	25,881
Operating loss	(31,821)	(25,881)
Other income (expense)		
Other income	798	1,929
Total other income, net	798	1,929
Net loss	$ (31,023)	$ (23,952)
Net loss per share, basic and diluted	$ (0.82)	$ (0.64)
Weighted average common shares outstanding, basic and diluted	37,659,722	37,396,980