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 4, 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 November 4, 2020, G1 Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the third-quarter ended September 30, 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 November 4, 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: November 4, 2020

EXHIBIT 99.1

G1 Therapeutics Provides Third Quarter 2020 Corporate and Financial Update

- New Drug Application (NDA) for trilaciclib in small cell lung cancer accepted for Priority Review with a PDUFA action date of February 15, 2021
- Announced CEO succession plan in evolution to commercial-stage company
- Management to host webcast and conference call today at 4:30 p.m. ET

RESEARCH TRIANGLE PARK, N.C., November 4, 2020 – G1 Therapeutics, Inc. (Nasdaq: GTHX), a clinical-stage oncology company, today provided a corporate and financial update for the third quarter ended September 30, 2020.

"Since I joined G1 in 2014, the company has made tremendous progress in advancing trilaciclib from the lab to receiving Priority Review for our NDA and a PDUFA action date of February 15, 2021. We have built exceptional commercial and medical teams that are prepared for the potential approval of trilaciclib in the first quarter of next year. In addition, we have developed a comprehensive clinical and regulatory strategy to evaluate the use of trilaciclib in other solid tumors, including a registrational trial in metastatic colorectal cancer that is on track to start this quarter," said Mark Velleca, M.D., Ph.D., Chief Executive Officer. "It has been a privilege to work with the talented team at G1 to accomplish these goals, and I am equally fortunate to be handing the reins to Jack Bailey, our board member and incoming CEO. Jack is a superb leader with extensive experience launching novel therapeutics and managing product development to maximize benefit to patients."

Regulatory, Clinical and Corporate Highlights

- **NDA for trilaciclib in small cell lung cancer (SCLC) accepted by FDA and assigned Priority Review in August 2020.** The application was supported by positive data from three randomized clinical trials showing the myelopreservation benefits of trilaciclib in patients with SCLC being treated with chemotherapy. The FDA assigned a Prescription Drug User Fee Act (PDUFA) action date of February 15, 2021 (press release here). Trilaciclib has also received Breakthrough Therapy Designation by the FDA.
- **Additional analyses of trilaciclib SCLC trial results presented at North America Conference on Lung Cancer (NACLC).** A mini-oral session highlighted analysis of three randomized trials in patients with small cell lung cancer that showed trilaciclib significantly reduced hospitalizations caused by chemotherapy-induced myelosuppression or sepsis.
- **Completed enrollment in rintodestrant/palbociclib combination trial in October 2020.** The company expects preliminary safety, tolerability and efficacy data from 40 patients enrolled in this Phase 2 trial to be presented in the second quarter of 2021. The trial is comparing a treatment regimen of rintodestrant plus palbociclib (known commercially as Ibrance®) to fulvestrant plus palbociclib in patients with ER+, HER2- breast cancer.
- **CEO succession plan announced in September 2020.** Effective January 1, 2021, Mark Velleca, M.D., Ph.D., will transition to the role of senior advisor and continue to serve as a member of the G1 Board of Directors. John ("Jack") Bailey, a member of the company's board, has been named as CEO (press release here).

"I'm excited to have the opportunity to lead G1 through its next chapter as a commercial company," said Jack Bailey, incoming CEO. "Our top priorities remain the successful execution of our launch strategy for trilaciclib in small cell lung cancer and advancing the clinical development of trilaciclib in other tumor types. I've gotten to know the team at G1 since joining the board earlier this year, and have been struck by their desire to help patients. It's a privilege to join this group that shares a common passion for delivering better treatment options to people living with cancer."

Third Quarter 2020 Financial Highlights and 2020 Guidance

- **Cash Position:** Cash and cash equivalents totaled $238.3 million as of September 30, 2020, compared to $269.2 million as of December 31, 2019.
- **License Revenue:** License revenues were $26.6 million for the third quarter of 2020, mostly related to the upfront cash payments from license agreements of $20.0 million and $6.0 million from EQRx, Inc. and Genor Biopharma, Inc., respectively.
- **Operating Expenses:** Operating expenses were $36.3 million for the third quarter of 2020, compared to $34.0 million for the third quarter of 2019. GAAP operating expenses include stock-based compensation expense of $4.9 million for the third quarter of 2020, compared to $4.4 million for the third quarter of 2019.
- **Research and Development Expenses:** Research and development (R&D) expenses for the third quarter of 2020 were $17.9 million, compared to $22.9 million for the third quarter of 2019. The decrease in R&D expenses was primarily due to a decrease of $4.6 million in costs for manufacturing active pharmaceutical ingredients, as well as a decrease of $1.6 million in external costs related to discovery and pre-clinical costs development. The decrease is partially offset by an increase of $1.2 million in spend for clinical trials.
- **General and Administrative Expenses:** General and administrative (G&A) expenses for the third quarter of 2020 were $18.4 million, compared to $11.1 million for the third 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, and an increase in professional fees and other administrative costs necessary to support our commercial operations.
- **Net Loss:** G1 reported a net loss of $11.7 million for the third quarter of 2020, compared to $32.4 million for the third quarter of 2019.
- **2020 Guidance:** The company has updated its cash and cash equivalents guidance provided in the second quarter, and now expects to end 2020 with cash and cash equivalents of $200-$205 million (previous guidance of $185-$200 million). This guidance does not include consideration of potential additional proceeds from partnerships, collaboration activities and/or other sources of capital.

Key Anticipated 2020/2021 Milestones

- Initiation of Phase 3 trilaciclib metastatic colorectal cancer clinical trial in November/December 2020.
- Presentation of additional Phase 2 data of trilaciclib in triple-negative breast cancer at the San Antonio Breast Cancer Summit (SABCS) in December 2020.
- Presentation of additional rintodestrant monotherapy data at SABCS in December 2020.
- Pending FDA approval, commercial launch of trilaciclib in SCLC in 1Q21.
- Presentation of rintodestrant/palbociclib Phase 2 data in 2Q21.

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 2020 ended September 30, 2020. The live call may be accessed by dialing 866-763-6020 (domestic) or 210-874-7713 (international) and entering the conference code: 6634419. 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 next generation therapies that improve the lives of those affected by cancer. The company is developing and advancing two novel therapies: trilaciclib is a first-in-class therapy designed to improve outcomes for patients being treated with chemotherapy; rintodestrant is a potential best-in-class oral selective estrogen receptor degrader (SERD) for the treatment of ER+ breast cancer. In 2020, the company out-licensed global development and commercialization rights to its differentiated oral CDK4/6 inhibitor, lerociclib.

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, our reliance on partners to develop and commercial licensed products, 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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Contact:

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

	September 30, 2020	December 31, 2019
Cash and cash equivalents	$ 238,342	$ 269,208
Working capital	$ 212,635	$ 251,234
Total assets	$ 258,232	$ 284,831
Accumulated deficit	$ (410,760)	$ (336,853)
Total stockholders' equity	$ 197,472	$ 255,527

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
License revenue	$ 26,599	$ —	$ 28,739	$ —
Operating expenses:				
Research and development	17,932	22,941	56,897	64,510
General and administrative	18,412	11,083	44,230	27,979
Total operating expenses	36,344	34,024	101,127	92,489
Loss from operations	(9,745)	(34,024)	(72,388)	(92,489)
Other income (expense):				
Interest income	50	1,660	922	5,469
Interest expense	(757)	—	(1,022)	—
Other income (expense)	(291)	—	(488)	14
Total other income (expense), net	(998)	1,660	(588)	5,483
Loss before income taxes	(10,743)	(32,364)	(72,976)	(87,006)
Income tax expense	931	—	931	—
Net Loss	$ (11,674)	$ (32,364)	$ (73,907)	$ (87,006)
Net loss per share, basic and diluted	$ (0.31)	$ (0.86)	$ (1.95)	$ (2.32)
Weighted average common shares outstanding, basic and diluted	38,009,204	37,540,380	37,819,071	37,469,952