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 4, 2022

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 4, 2022, G1 Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the first-quarter ended March 31, 2022. 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 4, 2022
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 4, 2022

G1 Therapeutics Provides First Quarter 2022 Financial Results and Operational Highlights

- Achieved $6.9 Million in Total Revenue in the First Quarter of 2022, Including $5.5 Million in Net Revenue from Sales of COSELA™ (trilaciclib) -

- Fully Deployed G1's COSELA Sales Team as of Mid-February 2022 -

- Confirmed Expected Timelines for Initial Results of Ongoing Phase 2 and Pivotal Phase 3 Clinical Trials of Trilaciclib -

- Presented Real-World Data Showing Impact of Trilaciclib on Hospitalizations and Burden of Myelosuppression in Patients with Extensive-Stage Small Cell Lung Cancer (ES-SCLC) Undergoing Chemotherapy -

- Management to Host Webcast and Conference Call today at 8:30 AM ET -

RESEARCH TRIANGLE PARK, NC, May 4, 2022 – G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today provided a corporate and financial update for the first quarter ended March 31, 2022.

"The first quarter of 2022 was a period of transition and execution across the G1 business," said Jack Bailey, Chief Executive Officer of G1 Therapeutics. "In March of this year, we entered a new phase for COSELA promotion as we transitioned fully away from our commercial launch partner Boehringer Ingelheim and put the promotion of COSELA into the hands of our newly deployed G1 sales team; the strong month over month sales performance in March adds to the evidence of good early access to key accounts by our team. Our sales and commercial teams are now fully engaged in driving depth in key top organizations. Regarding our clinical programs, we are approaching a data-rich period, as we currently expect initial results from each of our ongoing Phase 2 and Phase 3 trials over the coming 18 months, starting with data from our three Phase 2 trials in the fourth quarter of this year."

First quarter 2022 and Recent Highlights

Financial

- **Achieved Total Revenue of $6.9 Million:** G1 recognized total revenues of $6.9 Million in the first quarter of 2021, including $5.5 million in net product revenue from sales of COSELA.

- **Ended the First Quarter 2021 with Cash and Cash Equivalents of $183.0 Million:** The Company's current financial position is expected to be sufficient to fund G1's operations and capital expenditures into 2024.

Commercial

- **Fully Deployed COSELA Sales Team:** On March 2, 2022, the co-promotion agreement for COSELA between G1 and Boehringer Ingelheim was terminated. As of February 15, 2022, G1 had fully deployed its sales team into regions across the U.S. to accelerate sales activities and help maximize the adoption of COSELA.

Clinical

- **Reiterated Expectation of Initial Data in the Fourth Quarter of 2022 from Three Phase 2 Trials of Trilaciclib:** G1 has reiterated that it expects to release initial data from multiple ongoing Phase 2 clinical trials of trilaciclib in the fourth quarter of 2022. These trials include a Phase 2 trial of trilaciclib in combination with avelumab in bladder cancer; a Phase 2 trial in combination with the antibody-drug conjugate (ADC) Trodelvy® (sacituzumab govitecan-hziy) in patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC); and a Phase 2 trial designed to confirm the mechanism of action of trilaciclib in modulating the anti-tumor immune response with and without a checkpoint inhibitor in early stage TNBC.
- **Reiterated Expectation of Initial Data in 2023 from Two Phase 3 Trials of Trilaciclib:** G1 expects to release data from two ongoing pivotal Phase 3 clinical trials of trilaciclib in 2023. Initial results including myeloprotection and Objective Response Rate (ORR) endpoints from PRESERVE 1, our ongoing line extension trial of trilaciclib in patients with colorectal cancer (CRC) receiving first line trilaciclib or placebo administered prior to FOLFOXIRI and bevacizumab, are expected in the first quarter of 2023. Initial results including interim results for Overall Survival (OS) from PRESERVE 2, our ongoing line extension trial of trilaciclib in PD-L1 positive and negative patients with TNBC receiving first line gemcitabine and carboplatin, are expected in the second half of 2023.

Medical

- **Presented New Real-World Data at the Annual Conference of the National Comprehensive Cancer Network (NCCN) Showing the Impact of Trilaciclib on Hospitalizations and the Burden of Myelosuppression in Patients with ES-SCLC Treated with Chemotherapy:** Results showed that the use of trilaciclib prior to chemotherapy was associated with a 50% reduction in the percent of patients with grade ≥ 3 myelosuppressive hematologic adverse events in at least one blood cell lineage and a 74% reduction in the percent of all-cause hospitalizations (days 1 to 21 after treatment), compared to patients who received chemotherapy alone. The analyses were derived using structured, real-world, de-identified clinical patient level data from the Integra Connect oncology warehouse. (Press release here)
- **Published Data in *Cancer Treatment and Research Communications* Showing Treatment Patterns and the Burden of Myelosuppression for Patients with Small Cell Lung Cancer (SCLC):** Results of this retrospective study showed that 42 percent of small-cell lung cancer patients failed to complete the recommended number of chemotherapy cycles, and 74 percent of patients were admitted to the hospital due to a myelosuppressive event, thus underscoring the burden of myelosuppression. Additionally, health care resource utilization associated with myelosuppression was prominent, suggesting a substantial burden on older patients with SCLC. These data were derived from a descriptive, retrospective study of patients with SCLC aged ≥65 years, identified from linked Surveillance, Epidemiology, and End Results (SEER)-Medicare data. (Publication available here)

Corporate

- **Strategic Decision Made to Discontinue the Rintodestrant Program:** After completing our evaluation of the rintodestrant partnering options and recent data in the highly competitive oral SERD space, G1 has made the strategic decision to discontinue the program, including all clinical and partnering efforts. G1 will responsibly wind down all remaining clinical efforts for rintodestrant by the end of this year and revert the rights back to the originator (University of Illinois Chicago); there are no additional financial obligations due to the originator resulting from the reversion.

First Quarter 2022 Financial Results

As of March 31, 2022, cash and cash equivalents totaled $183.0 million, compared to $221.2 million as of December 31, 2021.

Total revenues for the first quarter of 2022 were $6.9 million, including $5.5 million in net product sales of COSELA and license revenue of $1.4 million. This license revenue is primarily related to clinical trial reimbursements from EQRx and Simcere.

Operating expenses for the first quarter of 2022 were $53.7 million, compared to $39.8 million for the first quarter of 2021. GAAP operating expenses include stock-based compensation expense of $5.8 million for the first quarter of 2022, compared to $5.9 million for the first quarter of 2021.

Cost of goods sold expense for the first quarter of 2022 were $0.7 million compared to $0.2 for the first quarter of 2021. The increase is related to the Company's period costs for the sales of COSELA, including third-party logistics costs for the sales of COSELA, inventory overhead costs, and personnel costs.

Research and development (R&D) expenses for the first quarter of 2022 were $26.3 million, compared to $16.5 million for the first quarter of 2021. The increase in R&D expenses was driven by an increase in clinical trial spend related to increased activity in all of our clinical trials including an acceleration of enrollment in our Phase 3 CRC trial, which is partially offset by a decrease in costs associated with the manufacturing of active pharmaceutical ingredients and drug product to support clinical trials.

Selling, general, and administrative (SG&A) expenses for the first quarter of 2022 were $26.7 million, compared to $23.0 million for the first quarter of 2021. The increase in SG&A expenses was largely due to an increase in personnel costs due to increased headcount, and an increase in professional services, insurance and other administrative costs.

The net loss for the first quarter of 2022 was $49.2 million, compared to $26.4 million for the first quarter of 2021. The basic and diluted net loss per share for the first quarter of 2022 was $(1.15) compared to $(0.65) for the first quarter of 2021.

Financial Guidance

G1 expects its current cash position of $183.0 million to be sufficient to fund its operations and capital expenditures into 2024.

Webcast and Conference Call

G1 will host a webcast and conference call at 8:30 a.m. ET today to provide a corporate and financial update for the first quarter 2022 ended March 31, 2022. The live call may be accessed by dialing (866) 763-6020 (domestic) or (409) 216-0626 (international) and entering the conference code: 2229795. 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 COSELA™ (trilaciclib) for Injection

COSELA (trilaciclib) was approved by the U.S. Food and Drug Administration on February 12, 2021.

Indication

COSELA™ (trilaciclib) is indicated to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer.

Important Safety Information

COSELA is contraindicated in patients with a history of serious hypersensitivity reactions to trilaciclib.

Warnings and precautions include injection-site reactions (including phlebitis and thrombophlebitis), acute drug hypersensitivity reactions, interstitial lung disease (pneumonitis), and embryo-fetal toxicity.

The most common adverse reactions (>10%) were fatigue, hypocalcemia, hypokalemia, hypophosphatemia, aspartate aminotransferase increased, headache, and pneumonia.

This information is not comprehensive. Please click here for full Prescribing Information. https://www.g1therapeutics.com/cosela/pi/

To report suspected adverse reactions, contact G1 Therapeutics at 1-800-790-G1TX or call FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

About G1 Therapeutics

G1 Therapeutics, Inc. is a commercial-stage biopharmaceutical company focused on the development and commercialization of next generation therapies that improve the lives of those affected by cancer, including the Company's first commercial product, COSELA™ (trilaciclib). G1 has a deep clinical pipeline and is executing a tumor-agnostic development plan evaluating trilaciclib in a variety of solid tumors, including colorectal, breast, lung, and bladder cancers. G1 Therapeutics is based in Research Triangle Park, N.C. For additional information, please visit www.g1therapeutics.com and follow us on Twitter @G1Therapeutics.

G1 Therapeutics™ and the G1 Therapeutics logo and COSELA™ and the COSELA logo are trademarks of G1 Therapeutics, Inc.

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 expectations for the commercial launch of COSELA (trilaciclib), the therapeutic potential of COSELA (trilaciclib), our ability to generate data to maximize trilaciclib's applicability to future treatment paradigms, and our reliance on partners to develop licensed products. In addition, COSELA (trilaciclib) may fail to achieve the degree of market acceptance for commercial success, 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 a successful commercial launch for COSELA (trilaciclib); the company's ability to complete clinical trials for, obtain approvals for and commercialize additional indications of COSELA and any of its product candidates other than COSELA (trilaciclib); 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 commercial-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, 2022	December 31, 2021
Cash and cash equivalents	$ 183,020	$ 221,186
Working Capital	$ 173,353	$ 215,952
Total Assets	$ 218,239	$ 254,094
Accumulated deficit	$(633,651)	$ (584,459)
Total stockholders' equity	$ 100,132	$ 143,541

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

	Three months ended March 31,	
	2022	2021
Revenues:		
Product sales, net	$ 5,480	$ 609
License revenue	1,422	13,609
Total revenues	6,902	14,218
Operating expenses:		
Cost of goods sold	669	243
Research and development	26,305	16,540
Selling, general and administrative	26,709	22,970
Total operating expenses	53,683	39,753
Loss from operations	(46,781)	(25,535)
Other income (expense):		
Interest Income	9	19
Interest Expense	(2,265)	(748)
Other income (expense)	(155)	(40)
Total other income (expense), net	(2,411)	(769)
Loss before income taxes	(49,192)	(26,304)
Income tax expense	—	138
Net loss	$ (49,192)	$ (26,442)
Net loss per share, basic and diluted	$ (1.15)	$ (0.65)
Weighted average common shares outstanding, basic and diluted	42,687,201	40,700,827