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 5, 2021

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 5, 2021, G1 Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the first-quarter ended March 31, 2021. 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 5, 2021
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 5, 2021

G1 Therapeutics Provides First Quarter 2021 Financial Results and Operational Highlights

- G1's COSELA™ (trilaciclib), the Only FDA-Approved Proactive Multilineage Myeloprotection Therapy, Approved on February 12, 2021 and Commercially Available as of March 2, 2021 -

- Strong Total Revenue of $14.2 Million Included $0.6 Million from Initial Sales of COSELA in First Four Weeks of Product Availability -

- COSELA Added to Two National Comprehensive Cancer Network® (NCCN) Guidelines Which Inform Reimbursement and Formulary Decisions -

- Pivotal Phase 3 Trial of COSELA in Metastatic Triple-Negative Breast Cancer Underway to Evaluate the Survival Benefit of COSELA Compared with Placebo -

- Management to Host Webcast and Conference Call today at 4:30 PM ET -

RESEARCH TRIANGLE PARK, NC, May 5, 2021 – G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today provided a corporate and financial update for the first quarter ended March 31, 2021.

"The first quarter of 2021 was a transformational period for G1 as the approval and availability of COSELA provided extensive-stage small cell lung cancer patients undergoing chemotherapy with the first proactive multilineage myeloprotection therapy to help prevent myelosuppression," said Jack Bailey, Chief Executive Officer of G1 Therapeutics. "COSELA represents an opportunity to shift the treatment paradigm away from reactive treatments with multiple different single lineage therapeutic interventions. Our commercial team has demonstrated that we can effectively launch and deliver the drug during a very challenging time. Further, though very early in the launch period, leading and lagging indicators from the first four weeks of availability are encouraging and suggest that the awareness and interest in COSELA is strong, that it is being accepted by oncologists and oncology nurses, and that it is being well covered by payers. Another important step during the quarter was the inclusion of COSELA in two sets of NCCN Guidelines, which are the standard resource for determining best course of treatment and supportive care for people living with cancer. We also maintained clinical momentum in our tumor-agnostic development program for COSELA, including the initiation of PRESERVE 2, our Phase 3 registrational trial in triple-negative breast cancer."

First Quarter 2021 and Recent Highlights

Commercial

- **COSELA Approved by U.S. Food and Drug Administration (FDA)**: On February 12, 2021, the FDA approved COSELA for injection 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 (ES-SCLC). (Press release here)
- **COSELA Now Available in the U.S.:** On March 2, 2021, G1 and its commercial partner Boehringer Ingelheim announced that COSELA was available through G1's specialty distributors Amerisource Specialty Distribution, Oncology Supply, McKesson Plasma and Biologics, McKesson Specialty and Cardinal Specialty. (Press release here)

Medical

- **COSELA Added to Two National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®):** On March 25, 2021, G1 announced that COSELA had been added to the Treatment Guidelines for Small Cell Lung Cancer and to the Supportive Care Guidelines for Hematopoietic Growth Factors. These guidelines document evidence-based, consensus-driven management to ensure that all patients receive preventive, diagnostic, treatment, and supportive services that are most likely to lead to optimal outcomes. (Press release here)
- **Presented New Budget Impact Data for COSELA at the Academy of Managed Care Pharmacy (AMCP) Meeting:** These data described a model that compared ES-SCLC treatment scenarios with and without COSELA. The incremental cost of COSELA to a third-party payer is projected to be entirely offset by a reduction in the costs of managing adverse events related to myelosuppression. Therefore, the use of COSELA is estimated to provide cost savings.

Clinical

- **Initiated Pivotal Trial of COSELA in Patients Receiving First or Second Line Gemcitabine and Carboplatin Chemotherapy for Locally Advanced Unresectable or Metastatic Triple-Negative Breast Cancer (mTNBC):** Patient enrollment is underway in PRESERVE 2, a randomized, double-blind, placebo-controlled Phase 3 registrational trial of COSELA in patients receiving first- or second-line gemcitabine/carboplatin (GC) chemotherapy for locally advanced unresectable or metastatic TNBC. (Press release here)
- **Entered Clinical Trial Collaboration for Upcoming First Line Locally Advanced or Metastatic Bladder Cancer (mUC) Trial of COSELA:** G1 entered a clinical trial collaboration with the alliance between Merck KGaA, Darmstadt, Germany and Pfizer whereby the alliance will contribute clinical supply of the checkpoint inhibitor avelumab to the G1-sponsored and funded first-line mUC trial.
- **On Track to Initiate Two Phase 2 Trials of COSELA in First Line Metastatic Bladder Cancer (mUC) and Second Line / Third Line Non-Small Cell Lung Cancer (NSCLC) in the Second Quarter of 2021:** The Company expects to initiate Phase 2 trials of COSELA in first-line treatment of locally advanced or metastatic bladder cancer (locally advanced or metastatic urothelial carcinoma, or mUC) and second- and third-line treatment of NSCLC, both of which are known immunogenic tumors, in the second quarter of 2021. Both trials are designed to evaluate the anti-tumor efficacy of COSELA.

First Quarter 2021 Financial Results

As of March 31, 2021, cash and cash equivalents totaled $279.0 million, compared to $207.3 million as of December 31, 2020. This includes $86.4 million in net proceeds in the first quarter from the “At the Market” offering with Cowen and Company, LLC. This ATM offering is now closed. In addition, the Company drew the additional $10M available in the first tranche of debt on its debt financing facility with Hercules Capital. The Company has access to an additional $70 million through this facility.

Total revenue for the first quarter of 2021 was $14.2 million, including approximately $0.6 million in initial net product sales of COSELA and license revenue of $13.6 million, primarily related to development milestone payments from the Company’s license agreement with Simcere and revenue from EQRx related to delivery of clinical drug supply and manufacturing services and reimbursement of clinical trial costs with EQRx. In addition, the Company recognized revenue related to achievement of a development milestone by Genor.

Operating expenses for the first quarter of 2021 were $39.8 million, compared to $31.8 million for the first quarter of 2020. GAAP operating expenses include stock-based compensation expense of $5.9 million for the first quarter of 2021, compared to $4.7 million for the first quarter of 2020.

Cost of goods sold expense for the first quarter of 2021 were $0.2 million, compared to $0 for first quarter of 2020. The increase related to the Company's period costs for the sales of COSELA.

Research and development (R&D) expenses for the first quarter of 2021 were $16.5 million, compared to $20.4 million for the first quarter of 2020. The decrease in R&D expenses was primarily due to a decrease in costs for manufacturing of active pharmaceutical ingredients and drug product to support clinical trials, as well as a decrease in external costs related to discovery and pre-clinical development.

Selling, general and administrative (SG&A) expenses for the first quarter of 2021 were $23.0 million, compared to $11.4 million for the first quarter of 2020. The increase in SG&A expenses was largely due to an increase in compensation due to increases in headcount and increased commercialization activities.

The net loss for the first quarter of 2021 was $26.4 million, compared to $31.0 million for the first quarter of 2020. The basic and diluted net loss per share for the first quarter of 2021 was $(0.65) compared to $(0.82) for the first quarter of 2020.

Financial Guidance

The Company expects its current financial position to be sufficient to fund its operations and capital expenditures into 2023.

Webcast and Conference Call

G1 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 2021 ended March 31, 2021. The live call may be accessed by dialing (866) 763-6020 (domestic) or (210) 874-7713 (international) and entering the conference code: 2509548. 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.

I**ndication**

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.

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 COSELA 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), COSELA's (trilaciclib) possibility to improve patient outcomes across multiple indications, our reliance on partners to develop and commercial licensed products, 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 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 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 Contacts:
Jen Moses
Chief Financial Officer
919-930-8506
jmoses@g1therapeutics.com

Will Roberts
Vice President, Investor Relations & Corporate Communications
919-907-1944
wroberts@g1therapeutics.com

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

	March 31, 2021	December 31, 2020
Cash and cash equivalents	$ 278,968	$ 207,306
Working Capital	$ 271,408	$ 192,949
Total Assets	$ 308,558	$ 228,552
Accumulated deficit	$(462,549)	$ (436,107)
Total stockholders' equity	$ 245,443	$ 177,351

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

	Three months ended March 31,	
	2021	2020
Revenues:		
Product sales, net	$ 609	$ —
License revenue	13,609	—
Total revenues	14,218	—
Operating expenses:		
Cost of goods sold	243	—
Research and development	16,540	20,434
Selling, general and administrative	22,970	11,387
Total operating expenses	39,753	31,821
Loss from operations	(25,535)	(31,821)
Other income (expense):		
Interest Income	19	780
Interest Expense	(748)	—
Other income (expense)	(40)	18
Total other income (expense), net	(769)	798
Loss before income taxes	(26,304)	(31,023)
Income tax expense	138	—
Net loss	$ (26,442)	$ (31,023)
Net loss per share, basic and diluted	$ (0.65)	$ (0.82)
Weighted average common shares outstanding, basic and diluted	40,700,827	37,659,722