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 1, 2024

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 1, 2024, G1 Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the first-quarter ended March 31, 2024. 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 1, 2024
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/ John W. Umstead V*
John W. Umstead V
Chief Financial Officer

Date: May 1, 2024

G1 Therapeutics Provides First Quarter 2024 Financial Results and Operational Highlights

- Achieved $14.1 Million in Net Revenue from Sales of COSELA® (trilaciclib) for First Quarter 2024 -

- Reaffirmed 2024 Net COSELA Revenue Guidance of $60 to $70 Million -

- Announced That Updated Efficacy Results from Phase 2 Trial of Trilaciclib in Combination with a TROP2 Antibody-Drug Conjugate (ADC) Will Be Presented at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting -

- Announced That Final Analysis of Phase 3 PRESERVE 2 Trial Evaluating Overall Survival in 1L Metastatic Triple Negative Breast Cancer (mTNBC) Is Expected to Occur in Late Second Quarter of 2024 -

- Cash Runway Expected to Extend into the Third Quarter of 2025 -

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

RESEARCH TRIANGLE PARK, NC, May 1, 2024 – G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today provided a corporate and financial update for the first quarter ended March 31, 2024.

“Our focus for 2024 is on developing trilaciclib toward potential category leadership in triple negative breast cancer and maximizing the uptake of COSELA in its first indication in extensive stage small cell lung cancer; we've made progress on both in the first four months of the year,” said Jack Bailey, Chief Executive Officer of G1 Therapeutics. “Regarding our clinical progress, we have two important readouts later this year, the first of which is an ASCO poster presentation in early June on the mature results from our Phase 2 trial of trilaciclib in combination with a TROP2 ADC. This will be followed by the readout of our Phase 3 PRESERVE 2 1L mTNBC trial late in the second quarter of this year. Regarding COSELA for extensive stage small cell lung cancer, we remain confident in our annual net sales guidance of $60 to $70 million."

First Quarter 2024 and Recent Highlights

Financial

- **Recognized $14.1 Million in Net COSELA Revenue:** Vial volume grew four percent in the first quarter of 2024 over the prior quarter.

- **Cash Runway Extends into the Third Quarter of 2025:** G1 ended the first quarter of 2024 with cash, cash equivalents, and marketable securities of $65.2 million.

Clinical

- **Updated Efficacy Results from Phase 2 Trial of Trilaciclib in Combination with an ADC Accepted for Poster Presentation at the 2024 ASCO Annual Meeting:** In January 2024, the Company provided preliminary data from this Phase 2 trial in combination with the TROP2 ADC sacituzumab govitecan (SG) in patients with mTNBC suggesting clinically meaningful improvements in overall survival among patients receiving trilaciclib with SG compared to SG alone using historical data from the ASCENT study. Updated efficacy results will be presented in a poster at the 2024 ASCO Meeting, which is being held from May 31 to June 4, 2024.

- **Final Analysis of the Phase 3 PRESERVE 2 Trial in 1L mTNBC is Estimated to Occur in Late Second Quarter 2024:** The final analysis will be conducted on the intent-to-treat (ITT) population, which includes the survival events from patients enrolled in the Ukraine. Based on recent interactions with the U.S. Food and Drug Administration regarding the inclusion of these events, the final analysis is now expected late in the second quarter of 2024. If the pivotal results are positive, the Company will engage the U.S. Food and Drug Administration ahead of a supplemental New Drug Application (sNDA) filing for this indication.

Corporate

- **Announced License Agreement for Lerociclib with Pepper Bio, Inc. ("Pepper Bio"):** Pepper Bio will gain exclusive rights to develop, manufacture, and commercialize lerociclib for all indications except for certain radioprotectant uses in the US, Europe, Japan, and all other global markets, excluding the Asia-Pacific region. Under the terms of the agreement, G1 is expected to receive upfront payments totaling mid-single digit millions within 12 months and is eligible to receive a maximum of $135M upon achievement of development and commercial milestones in up to three indications. In addition, Pepper Bio will pay G1 a double-digit royalty on aggregate annual net sales of lerociclib. (See May 1, 2024 press release here)

First Quarter 2024 Financial Results

As of March 31, 2024, cash, cash equivalents and marketable securities totaled $65.2 million, compared to $82.2 million as of December 31, 2023. The Company believes that its current cash runway is sufficient to fund its operations into the third quarter of 2025.

Total revenues for the first quarter of 2024 were $14.5 million, including $14.1 million in net product sales of COSELA and license revenue of $0.4 million, related to patent and clinical trial costs reimbursed by EQRx, Simcere, and Genor, compared to $12.9 million in total revenues in the first quarter of 2023.

Operating expenses for the first quarter of 2024 were $23.5 million, compared to $38.7 million for the first quarter of 2023. GAAP operating expenses include stock-based compensation expense of $2.5 million for the first quarter of 2024, compared to $3.8 million for the first quarter of 2023.

Cost of goods sold expense for the first quarter of 2024 was $1.1 million, compared to $1.5 million for the first quarter of 2023, the decrease was primarily due to a cancellation fee recognized during the quarter ended March 31, 2023.

Research and development (R&D) expenses for the first quarter of 2024 were $7.3 million, compared to $15.5 million for the first quarter of 2023. The decrease in R&D expenses was primarily due to a decrease in the Company's clinical program costs.

Selling, general, and administrative (SG&A) expenses for the first quarter of 2024 were $15.1 million, compared to $21.8 million for the first quarter of 2023. The decrease in SG&A expenses was primarily due to decreases in personnel costs, commercialization activities, and medical affairs.

The net loss for the first quarter of 2024 was $10.2 million, compared to $27.6 million for the first quarter of 2023. The basic and diluted net loss per share for the first quarter of 2024 was $(0.20), compared to $(0.53) for the first quarter of 2023.

2024 Financial Guidance

G1 today reaffirmed its full year 2024 financial guidance. The Company expects to generate between $60 million and $70 million in COSELA net revenue in 2024. G1's product revenue guidance is based on expectations for continued acceleration of sales performance of COSELA in the U.S. Additionally, the Company believes that its current cash runway is sufficient to fund its operations into the third quarter of 2025.

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 ended March 31, 2024.

Please note the following process to access the call via telephone: To register and receive a dial in number and unique PIN to access the live conference call, please follow this link to register online. While not required, it is recommended to join 10 minutes prior to the start of the event. 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 oncology biopharmaceutical company whose mission is to develop and deliver next-generation therapies that improve the lives of those affected by cancer, including the Company's first commercial product, COSELA® (trilaciclib). The Company is also evaluating therapies in combination with cytotoxic therapies and/or immunotherapy in areas of high unmet need including triple-negative breast cancer and extensive stage small cell lung cancer. G1's goal is to provide innovative therapeutic advances for people living with cancer. For additional information, please visit www.g1therapeutics.com and follow us on X (formerly known as Twitter) @G1Therapeutics and LinkedIn.

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," "could", "believe," "goal", "projections," "estimate," "intend," "indicate," "potential," "opportunity," "suggest," 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 related to the timing of results from G1's ongoing clinical trials and developing trilaciclib toward potential category leadership in triple negative breast cancer and maximizing the uptake of COSELA in its first indication in extensive stage small cell lung cancer, 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 dependence on the commercial success of COSELA (trilaciclib); the development and commercialization of new drug products is highly competitive; 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 commercial-stage company; chemotherapy shortages and market conditions. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties. 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.

###

G1 Therapeutics Contacts:

John W. Umstead V
Chief Financial Officer
919-747-8419
jumstead@g1therapeutics.com

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

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

	March 31, 2024	December 31, 2023
Cash and cash equivalents and Marketable securities	$65,186	$82,156
Working Capital	$63,236	$85,232
Total Assets	$102,026	$121,540
Accumulated deficit	$(790,204)	$(779,985)
Total stockholders' equity	$27,739	$35,386

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

	Three Months Ended March 31,	
	2024	2023
Revenues	*(unaudited)*	
Product sales, net	$ 14,079	$ 10,492
License revenue	397	2,454
Total revenues	14,476	12,946
Operating expenses		
Cost of goods sold	1,079	1,459
Research and development	7,318	15,480
Selling, general and administrative	15,127	21,753
Total operating expenses	23,524	38,692
Loss from operations	(9,048)	(25,746)
Other income (expense)		
Interest income	281	716
Interest expense	(1,978)	(3,089)
Other income (expense)	526	524
Total other income (expense), net	(1,171)	(1,849)
Loss before income taxes	(10,219)	(27,595)
Income tax expense	—	—
Net loss	$ (10,219)	$ (27,595)
Net loss per share, basic and diluted	$ (0.20)	$ (0.53)
Weighted average common shares outstanding, basic and diluted	52,171,684	51,647,934