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): February 28, 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 February 28, 2024, G1 Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and full-year ended December 31, 2023. 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 February 28, 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: February 28, 2024

G1 Therapeutics Provides Fourth Quarter and Full Year 2023 Financial Results and Operational Highlights

- Achieved $46.3 Million in Net Revenue from Sales of COSELA® (trilaciclib) for Full Year 2023, Representing 48% Growth Over 2022; Provided 2024 Net COSELA Revenue Guidance of $60 to $70 Million -

- Net COSELA Revenue Grew 29% in the Fourth Quarter of 2023 to $13.9 Million -

- Announced That Final Analysis of Phase 3 PRESERVE 2 Trial Evaluating Overall Survival in Metastatic Triple Negative Breast Cancer is Estimated to Occur in the Third Quarter of 2024 -

- Presented New Analyses Indicating that Patients Who Previously Received Trilaciclib in a Clinical Trial Setting Experienced Improved Overall Survival with Subsequent Anticancer Therapies -

- Provided Initial Results from Phase 2 Trial in Combination with a TROP2 Antibody-Drug Conjugate Indicating Improvements in Overall Survival for Patients Receiving Trilaciclib -

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

RESEARCH TRIANGLE PARK, NC, February 28, 2024 – G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today provided a corporate and financial update for the fourth quarter and full year ended December 31, 2023.

“The strong fourth quarter 2023 vial volume growth of COSELA, which has continued through the beginning of 2024, highlights not only the importance of this unique drug to oncologists treating people living with extensive-stage small cell lung cancer, but also the significant addressable market still available to us as we drive continued penetration and growth,” said Jack Bailey, Chief Executive Officer of G1 Therapeutics. “Looking ahead, our primary clinical focus is on completing our ongoing trials of trilaciclib in metastatic triple negative breast cancer, including our pivotal PRESERVE 2 trial. We remain confident in the potential of trilaciclib in this trial given the robust long term survival benefit observed in prior trials and the increased statistical power for the final analysis. If successful, we would work closely with the U.S. Food and Drug Administration to expeditiously file for label expansion and bring this therapy to patients as quickly as possible."

Fourth Quarter 2023 and Recent Highlights

Financial

- **Recognized $13.9 Million and $46.3 Million in Net COSELA Revenue for the Fourth Quarter and Full Year 2023:** Net COSELA revenue and vial volume grew 29% and 19%, respectively, during the fourth quarter over the third quarter of 2023 despite the impact of a platinum-based chemotherapy shortage. G1 recognized total revenues of $14.9 million and $82.5 million for the fourth quarter and full year of 2023, respectively.

- **Cash Runway Extends into 2025:** G1 ended 2023 with cash, cash equivalents, and marketable securities of $82.2 million.

Clinical

- **Final Analysis of the Phase 3 PRESERVE 2 Trial in Metastatic Triple Negative Breast Cancer (mTNBC) is Estimated to Occur in the Third Quarter of 2024:** G1 announced that the Independent Data Monitoring Committee (DMC) recommended continuation of the Phase 3 PRESERVE 2 trial, evaluating trilaciclib in combination with gemcitabine and carboplatin for 1L treatment of mTNBC, to the final analysis. The DMC did not express any concerns or recommend any other changes to the study. The final analysis will be conducted on the intent-to-treat (ITT) population. G1 remains blinded to all data. (See February 12, 2024 press release here)

- **Initial Efficacy Results from Ongoing Phase 2 Antibody-Drug Conjugate (ADC) Trial Suggest Improved Overall Survival (OS) Among Patients Receiving Trilaciclib in Combination with a TROP2 ADC:** The preliminary data provided in January 2024 from the ongoing Phase 2 trial of trilaciclib in combination with the ADC sacituzumab govitecan (SG) in patients with mTNBC patients suggested clinically meaningful improvements in OS among patients receiving trilaciclib in combination with SG compared to SG alone (using historical data from the ASCENT study), including (1) median OS of 17.9 months with trilaciclib versus 12.1 months for SG alone and (2) estimated 12-month survival of 59% of patients receiving trilaciclib in combination with SG, representing a ~20% improvement over SG alone. The Company expects to provide updated OS results from this study mid-2024. (See January 8, 2024 J.P. Morgan update press release here)

Medical

- **Presented New Post Hoc Analyses Indicating that Patients Who Previously Received Trilaciclib Experienced Improved OS with Subsequent Anticancer Therapies (SACT):** G1 presented new data at the 2023 San Antonio Breast Cancer Symposium (SABCS) from patients with mTNBC who participated in G1's Phase 2 trial. These data indicate that patients who received trilaciclib with their cytotoxic chemotherapy during the trial and then received SACT after trilaciclib discontinuation exhibit statistically significant and clinically meaningful improvements in median OS (32.7 months versus 12.8 months; p=0.001). Additionally, median OS for patients who received prior trilaciclib was improved from the time they started their first SACT compared to patients who did not receive prior trilaciclib (14.0 months versus 5.8 months; p=0.001). (See December 5, 2023 SABCS press release here)

- **Presented Four Posters During the 2023 ASCO Quality Care Symposium:** These provide new real-world evidence indicating that trilaciclib administered prior to chemotherapy in patients with extensive-stage small cell lung cancer (ES-SCLC) lowers the rate of hospitalization and cytopenia events and may improve survival. (See October 27, 2023 ASCO Quality Care Symposium press release here)

- **COSELA Recommended as a Myeloid Supportive Agent in the Updated ASCO SCLC Guidelines:** The SCLC guidelines provide evidence-based recommendations to practicing clinicians on the management of patients with SCLC. (See October 18, 2023 ASCO Guidelines press release here)

Fourth Quarter and Full Year 2023 Financial Results

As of December 31, 2023, cash, cash equivalents and marketable securities totaled $82.2 million, compared to $145.1 million as of December 31, 2022.

Total revenues for the fourth quarter of 2023 were $14.9 million, including $13.9 million in net product sales of COSELA and license revenue of $1.0 million, primarily related to supply and manufacturing services from Simcere and patent and clinical trial costs reimbursed primarily by EQRx and Simcere, compared to $10.3 million in total revenues in the fourth quarter of 2022. Total revenues for the full year 2023 were $82.5 million, including net product revenue of $46.3 million from sales of COSELA and license revenue of $36.2 million, compared to total revenues of $51.3 million in the prior year.

Operating expenses for the fourth quarter of 2023 were $23.8 million, compared to $41.1 million for the fourth quarter of 2022. GAAP operating expenses include stock-based compensation expense of $3.2 million for the fourth quarter of 2023, compared to $4.4 million for the fourth quarter of 2022. Operating expenses for the full year 2023 were $122.0 million, compared to $187.5 million for the prior year. Stock-based compensation expense for the full year 2023 was $14.5 million, compared to $20.6 million for the prior year.

Cost of goods sold expense for the fourth quarter of 2023 was $1.3 million, compared to $1.0 million for the fourth quarter of 2022, primarily due to an increase in product sales. Cost of goods sold expense for the full year 2023 was $7.2 million, compared to $3.7 million for the prior year.

Research and development (R&D) expenses for the fourth quarter of 2023 were $7.4 million, compared to $16.6 million for the fourth quarter of 2022. The decrease in R&D expenses was primarily due to a decrease in the Company's clinical program costs. R&D expenses for the full year 2023 were $43.7 million, compared to $83.3 million for the prior year.

Selling, general, and administrative (SG&A) expenses for the fourth quarter of 2023 were $15.2 million, compared to $23.6 million for the fourth quarter of 2022. The decrease in SG&A expenses was primarily due to decreases in commercialization activities, personnel costs, and medical affairs. SG&A expenses for the full year 2023 were $71.1 million, compared to $100.4 million for the prior year.

The net loss for the fourth quarter of 2023 was $10.9 million, compared to $33.6 million for the fourth quarter of 2022. Net loss for the full year 2023 was $48.0 million, compared to a net loss of $147.6 million for the prior year. The basic and diluted net loss per share for the fourth quarter of 2023 was $(0.21), compared to $(0.73) for the fourth quarter of 2022. The basic and diluted net loss per share for the full year 2023 was $(0.93) compared to $(3.38) for the prior year.

2024 Financial Guidance

G1 today provided 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 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 fourth quarter and full year ended December 31, 2023.

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 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 development plan evaluating trilaciclib in a variety of solid tumors, including 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 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 potential of trilaciclib in the Phase 3 PRESERVE 2 trial for reasons including the robust long term survival benefit observed in prior trials and the increased statistical power for the final analysis, 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.

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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)

	December 31, 2023	December 31, 2022
Cash and cash equivalents and Marketable securities	$82,156	$145,070
Working Capital	$85,232	$143,912
Total Assets	$121,540	$187,965
Accumulated deficit	$(779,985)	$(732,018)
Total stockholders' equity	$35,386	$68,747

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
Revenues	*(unaudited)*			
Product sales, net	$ 13,922	$ 8,870	$ 46,344	$ 31,337
License revenue	951	1,380	36,167	19,964
Total revenues	14,873	10,250	82,511	51,301
Operating expenses				
Cost of goods sold	1,256	992	7,195	3,748
Research and development	7,380	16,587	43,711	83,316
Selling, general and administrative	15,166	23,558	71,132	100,415
Total operating expenses	23,802	41,137	122,038	187,479
Loss from operations	(8,929)	(30,887)	(39,527)	(136,178)
Other income (expense)				
Interest income	529	478	2,473	748
Interest expense	(2,124)	(2,996)	(10,038)	(10,432)
Other income (expense)	548	237	2,240	3
Total other income (expense), net	(1,047)	(2,281)	(5,325)	(9,681)
Loss before income taxes	(9,976)	(33,168)	(44,852)	(145,859)
Income tax expense	902	481	3,115	1,700
Net loss	$ (10,878)	$ (33,649)	$ (47,967)	$ (147,559)
Net loss per share, basic and diluted	$ (0.21)	$ (0.73)	$ (0.93)	$ (3.38)
Weighted average common shares outstanding, basic and diluted	51,838,834	46,279,808	51,733,487	43,626,113