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): March 1, 2023

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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 o

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. o

Item 2.02 Results of Operations and Financial Condition.

On March 1, 2023, G1 Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth-quarter and full-year ended December 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	Earnings Press Release dated March 1, 2023
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: March 1, 2023

G1 Therapeutics Provides Fourth Quarter and Full Year 2022 Financial Results and Operational Highlights

- Achieved $31.3 million in Net Revenue from Sales of COSELA® (trilaciclib) for Full Year 2022, Representing 182% Growth Over 2021; Provided 2023 Net COSELA Revenue Guidance of $50 to $60 Million -

- Announced Top Line Results from Pivotal Phase 3 Trial of Trilaciclib in Patients Receiving FOLFOXIRI + Bevacizumab for Metastatic Colorectal Cancer (CRC) (PRESERVE 1) -

- Provided Initial Results from Two Phase 2 Trials in Triple Negative Breast Cancer (TNBC) Demonstrating Potential of Trilaciclib to Reduce (>50%) the Rates of Adverse Events Related to an Antibody-Drug Conjugate (ADC) and Favorably Alter the Tumor Microenvironment -

- Announced Executive Succession Plan: Chief Financial Officer Jennifer Moses to Resign Effective March 15, 2023, and Remain as Senior Advisor; G1 Controller John W. Umstead V Appointed to CFO Role -

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

RESEARCH TRIANGLE PARK, NC, March 1, 2023 – 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, 2022.

“Since the start of 2022, the G1 team has achieved the milestones we put forth at the beginning of the year and did so with the resolve expected of a company focused on the needs of the cancer patients we seek to treat,” said Jack Bailey, Chief Executive Officer of G1 Therapeutics. “Since announcing the results of PRESERVE 1 last month, we’ve moved forward with urgency on the rest of the business. First, we remain confident in the small cell lung cancer business and have returned growth to COSELA sales through February 2023. Second, we are aggressively executing on our ongoing clinical trials, including the Phase 2 ADC and MOA trials in TNBC, each of which provided compelling initial results late in 2022 and have additional readouts expected in the second quarter of this year. And third, we have moved quickly to make necessary reductions to the organization and our expenses to extend our cash runway through each of our ongoing clinical trials."

Continued Bailey, “On behalf of the G1 team, I’d also like to express my gratitude to Jen Moses for her dedication to our company, our vision, and the patients we seek to treat. Jen has been with G1 since 2015 and became our Chief Financial Officer in 2019; her financial leadership throughout that period has been exceptional. We wish her continued success in her next professional chapter.”

Fourth Quarter 2022 and Recent Highlights

Financial

- **Achieved $8.9 million and $31.3 million in Net COSELA Revenue for the Fourth Quarter and Full Year 2022:** Results represent a 102% increase and a 182% increase over the corresponding periods in 2021. G1 recognized total revenues of $10.3 million and $51.3 million for the fourth quarter and full year of 2022, respectively.

- **Completed Public Offering Resulting in $52.0 million in Net Proceeds**: In November 2022, G1 closed an underwritten public offering of its common stock at a public offering price of $6.50 per share.

- **Ended the Fourth Quarter 2022 with Cash, Cash Equivalents, and Marketable Securities of $145.1 million.**

Clinical

- **Announced Top Line Results from Pivotal Phase 3 Trial of Trilaciclib in Patients Receiving FOLFOXIRI + Bevacizumab for Metastatic Colorectal Cancer (CRC) (PRESERVE 1):** G1 announced top line results from its pivotal Phase 3 PRESERVE 1 trial showing that the trial achieved its co-primary endpoints related to severe neutropenia with statistical significance ($p<0.001$). These results further validate the myeloprotection benefit of trilaciclib. Despite the achievement of the co-primary endpoints and other secondary measures of myeloprotection and tolerability, early anti-tumor efficacy data, including overall response rate, favored patients receiving placebo compared to trilaciclib. Given the differential in these anti-tumor efficacy metrics and the low likelihood of achieving the progression-free survival and overall survival (OS) endpoints, G1 has discontinued PRESERVE 1. (Press release here)

- **Completed Enrollment in Pivotal Phase 3 Clinical Trial of Trilaciclib in Patients with mTNBC:** Enrollment in PRESERVE 2 is complete at 187 patients receiving first line trilaciclib or placebo prior to gemcitabine and carboplatin (GC). The primary endpoint is to evaluate the effect of trilaciclib on OS compared with placebo in patients receiving first-line GC (press release here). The interim OS analysis will be conducted by its data monitoring committee at 70% of events. Based on recent evaluations, the number of actual events appears to be occurring more slowly than predicted. As a result, G1 now expects the interim OS analysis to be conducted in the first half of 2024. If the trial meets the interim analysis stopping rule, it will terminate, and G1 will report the top line results. If it does not, the trial will continue to the final analysis.

- **Announced Initial Results from Phase 2 Trial of Trilaciclib in Combination with an Antibody-Drug Conjugate:** Initial Phase 2 safety data suggest on-target effect of trilaciclib to reduce (>50%) the rates of adverse events associated with the ADC sacituzumab govitecan-hziy, including myelosuppression and diarrhea, relative to the previously published sacituzumab single agent safety profile. The Company anticipates disclosure of a more comprehensive data set including safety and initial efficacy results at a medical meeting in the second quarter 2023. (Press release here)

- **Confirmed that Initial Results Including the Primary Endpoint of Progression Free Survival from Phase 2 Bladder Cancer Trial of Trilaciclib (PRESERVE 3) Are Anticipated Midyear 2023:** G1 has reiterated that additional safety and efficacy results, including results from the primary endpoint of Progression Free Survival, are expected from PRESERVE 3 midyear 2023. (Press release here)

Medical

- **Presented Results from Phase 2 Mechanism of Action Trial at the San Antonio Breast Cancer Symposium (SABCS) Showing That Trilaciclib Favorably Alters the Tumor Microenvironment:** G1 provided initial results from a 24 patient Phase 2 mechanism of action (MOA) trial showing favorable alterations in the tumor microenvironment from a single dose of trilaciclib monotherapy as measured by increases in the proportions of CD8+ T cells compared to T regulatory cells (Tregs) in patients with early-stage triple negative breast cancer (TNBC). (Press release here)

- **Presented Nonclinical Study Results at the 2022 Society for Immunotherapy of Cancer (SITC) Conference Elucidating Immune Effects of Trilaciclib:** New nonclinical data show that trilaciclib upregulates key processes within the cancer immunity cycle including that trilaciclib enhances the differentiation of CD8+ T cells into effector memory and central memory T cell populations. In addition, trilaciclib can increase antigen presentation on tumor cells by upregulating HMC Class I and II, and promote T cell recruitment to tumor cells. (Press release here)

Corporate

- **Reduced Headcount and Associated Expenses to Extend Cash Runway Beyond Clinical Trial Readouts:** G1 completed a reduction in force of approximately 30%, though the COSELA sales team remains intact. As a result of this and other reductions in spend, G1 currently expects its 2023 operating expense to be 20% to 30% lower than that of 2022. With these adjustments to operating expenses, the top line guidance provided, and other assumptions around partner revenue, the Company believes this extends its cash runway through its upcoming readouts from its ongoing clinical trials.

- **Announced Executive Succession Plan:** Jen Moses, G1's Chief Financial Officer, will resign as of March 15, 2023, and will remain a senior advisor to the organization for one year. As of the date of her departure, G1's Controller John W. Umstead V will be appointed to the role of CFO. Mr. Umstead has been with the Company since 2018. Prior to joining the Company, Mr. Umstead worked for PricewaterhouseCoopers LLP serving clients in various industries ranging from small private companies to large publicly traded corporations in a number of roles of increasing responsibility.

Fourth Quarter and Full Year 2022 Financial Results

As of December 31, 2022, cash and cash equivalents and marketable securities totaled $145.1 million, compared to $221.2 million as of December 31, 2021. This includes $52.0 million in net proceeds from a fourth quarter 2022 underwritten public offering of its common stock at a public offering price of $6.50 per share. Cowen and Raymond James acted as joint book-running managers for the offering. Needham & Company and Wedbush PacGrow acted as lead managers for the offering.

Total revenues for the fourth quarter of 2022 were $10.3 million, including $8.9 million in net product sales of COSELA and license revenue of $1.4 million, primarily related to clinical trial reimbursements from EQRx and Simcere, compared to a total of $5.8 million in total revenues in the fourth quarter of 2021. Total revenues for the full year 2022 were $51.3 million, including net product revenue of $31.3 million from sales of COSELA and license revenue of $20.0 million, compared to total revenues of $31.5 million for the prior year.

Operating expenses for the fourth quarter of 2022 were $41.1 million, compared to $43.4 million for the fourth quarter of 2021. GAAP operating expenses include stock-based compensation expense of $4.4 million for the fourth quarter of 2022, compared to $5.2 million for the fourth quarter of 2021. Operating expenses for the full year 2022 were $187.5 million, compared to $173.9 million for the prior year. Stock-based compensation expense for the full year 2022 was $20.6 million, compared to $22.3 million for the prior year.

Cost of goods sold expense for the fourth quarter of 2022 was $1.0 million compared to $0.4 million for the fourth quarter of 2021, primarily due to an increase in product sales. Cost of goods sold expense for the full year 2022 was $3.7 million, compared to $2.0 million for the prior year.

Research and development (R&D) expenses for the fourth quarter of 2022 were $16.6 million, compared to $19.8 million for the fourth quarter of 2021. 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 2022 were $83.3 million, compared to $76.2 million for the prior year.

Selling, general, and administrative (SG&A) expenses for the fourth quarter of 2022 were $23.6 million, compared to $23.2 million for the fourth quarter of 2021. The increase in SG&A expenses was due to increases in personnel costs and was offset by a decrease in payments to Boehringer Ingelheim and decreased professional and administrative expenses. SG&A expenses for the full year 2022 were $100.4 million, compared to $95.7 million for the prior year.

The net loss for the fourth quarter of 2022 was $33.6 million, compared to $40.0 million for the fourth quarter of 2021. Net loss for the full year 2022 was $147.6 million, compared to a net loss of $148.4 million for the prior year. The basic and diluted net loss per share for the fourth quarter of 2022 was $(0.73) compared to $(0.94) for the fourth quarter of 2021. The basic and diluted net loss per share for the full year 2022 was $(3.38) compared to $(3.54) for the prior year.

2023 Financial Guidance

G1 today provided full year 2023 financial guidance. The Company expects to generate between $50 million and $60 million in COSELA net revenue in 2023. G1's product revenue guidance is based on expectations for continued acceleration of sales performance of COSELA in the U.S.

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, 2022.

Please note that there is a new 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 that you 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 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 sales of COSELA (trilaciclib), the therapeutic potential of COSELA (trilaciclib), our full year 2023 financial guidance, our ability to generate data to maximize trilaciclib's applicability to future treatment paradigms, our ability to obtain approvals for and commercialize additional indications of COSELA (trilaciclib), and our reliance on partners to develop licensed products. If we are not in compliance with our monthly net revenue covenants or the minimum cash covenant with our debt facility, we may be subject to the acceleration clauses in our loan agreement, and the lender may call the debt, resulting in our immediate need for additional funds. 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). Each of these forward-looking statements is based on the company's expectations and assumptions as of the date of this press release and 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 commercialize COSELA (trilaciclib); the company's ability to complete clinical trials for, obtain approvals for and commercialize additional indications of 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)

	December 31, 2022	December 31, 2021
Cash and cash equivalents and Marketable securities	$145,070	$221,186
Working Capital	$143,912	$215,952
Total Assets	$187,965	$254,094
Accumulated deficit	$(732,018)	$(584,459)
Total stockholders' equity	$68,747	$143,541

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
Revenues				
Product sales, net	$ 8,870	$ 4,403	$ 31,337	$ 11,120
License revenue	1,380	1,393	19,964	20,356
Total revenues	10,250	5,796	51,301	31,476
Operating expenses				
Cost of goods sold	992	374	3,748	2,016
Research and development	16,587	19,790	83,316	76,225
Selling, general and administrative	23,558	23,218	100,415	95,692
Total operating expenses	41,137	43,382	187,479	173,933
Loss from operations	(30,887)	(37,586)	(136,178)	(142,457)
Other income (expense)				
Interest income	478	8	748	43
Interest expense	(2,996)	(2,058)	(10,432)	(4,667)
Other income (expense)	237	(138)	3	(346)
Total other income (expense), net	(2,281)	(2,188)	(9,681)	(4,970)
Loss before income taxes	(33,168)	(39,774)	(145,859)	(147,427)
Income tax expense	481	246	1,700	925
Net loss	$ (33,649)	$ (40,020)	$ (147,559)	$ (148,352)
Net loss per share, basic and diluted	$ (0.73)	$ (0.94)	$ (3.38)	$ (3.54)
Weighted average common shares outstanding, basic and diluted	46,279,808	42,544,321	43,626,113	41,943,417