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 23, 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 February 23, 2022, G1 Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth-quarter and full-year ended December 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 February 23, 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: February 23, 2022

G1 Therapeutics Provides Fourth Quarter and Full Year 2021 Financial Results and Operational Highlights

- Achieved $5.8 Million in Total Revenue in the Fourth Quarter of 2021, Including $4.4 Million in Net Revenue from Sales of COSELA™ (trilaciclib) -

- Completed Hiring, Training, and Deployment of G1's COSELA Sales Team -

- Announced That Initial Results from Phase 3 Trial of Trilaciclib in Colorectal Cancer (PRESERVE 1) Are Now Expected Early in the First Quarter of 2023 -

- Initiated Two New Phase 2 Trials to Confirm the Immune-Based Mechanism of Action (MOA) of Trilaciclib and to Help Clarify the Potential Synergistic Effects of Trilaciclib and an Antibody-Drug Conjugate (ADC) -

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

RESEARCH TRIANGLE PARK, NC, February 23, 2022 – 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, 2021.

"2021 was an important foundational year for G1; but I expect 2022 to be a year of strong execution across the Company and value creation for our shareholders and the people living with cancer we seek to serve," said Jack Bailey, Chief Executive Officer of G1 Therapeutics. "I'm very excited with the quality and experience of the members of our new COSELA sales team, who are already hired and fully deployed across the U.S., leveraging our exceptional reimbursement coverage, working to convert high intention-to-use into actual usage and uptake by promoting COSELA with prescribing oncologists, and fostering clinical advocacy – all with the goal of rapidly improving COSELA usage and adoption in 2022. Further, we expect to provide initial results from three clinical trials in the second half of this year, including the ADC combination, MOA, and bladder cancer Phase 2 trials, with pivotal
colorectal cancer trial data expected soon thereafter, early in the first quarter of 2023. We remain confident in the potential for COSELA in its first indication and, as our pipeline evolves, look forward to delivering on our goal of improving the lives of as many people living with cancer as possible."

Fourth Quarter 2021 and Recent Highlights

Financial

- **Achieved Total Revenue of $5.8 Million:** G1 recognized total revenues of $5.8 million in the fourth quarter of 2021, including $4.4 million in net product revenue from sales of COSELA.
- **Ended the Fourth Quarter 2021 with Cash and Cash Equivalents of $221.2 million:** The Company's current financial position is expected to be sufficient to fund G1's operations and capital expenditures into 2024.

Commercial

- **Completed Hiring, Training, and Deployment of G1's COSELA Sales Team:** G1 and Boehringer Ingelheim terminated the co-promotion agreement for COSELA, effective March 2, 2022. G1 has hired and fully deployed its sales team, including the Vice President of Sales, four Regional Sales Directors, and a total of 34 Oncology Sales Account Managers (OSAMs). The G1 sales team is targeting all U.S. accounts to accelerate sales activities and help maximize the adoption of COSELA. (Press release here)

- **Received Permanent J-code for COSELA Effective October 1, 2021:** The permanent J-code that was issued in July 2021 by the Centers for Medicare & Medicaid Services (CMS) is effective as of October 1, 2021, for provider billing for all sites of care. (Press release here)

Clinical

- **Announced that Initial Data from Pivotal Phase 3 Trial of Trilaciclib in Colorectal Cancer (CRC) (PRESERVE 1) Are Now Expected Early in the First Quarter of 2023:** This Phase 3 multi-center, randomized, placebo-controlled trial is designed to confirm the benefit of trilaciclib in combination with 5-FU-based regimens. PRESERVE 1 is being conducted in approximately 300 mCRC patients being treated with first line FOLFOXIRI, a highly efficacious but highly myelosuppressive chemotherapy frequently used in this setting. The primary endpoint of this trial is myeloprotection, with survival measures including progression free survival (PFS) and overall survival (OS) also being assessed as secondary endpoints. G1 expects to announce the initial results from this Phase 3 trial including myeloprotection and objective response rate (ORR) endpoints early in the first quarter of 2023, earlier than previously stated.
- **Initiated New Phase 2 Trial of Trilaciclib in Combination with an Antibody-Drug Conjugate (ADC) in Triple-Negative Breast Cancer:** The Company initiated a Phase 2, single arm, open-label trial of trilaciclib to study the potential synergistic effects of trilaciclib and the antibody-drug conjugate (ADC) Trodelvy® (sacituzumab govitecan-hziy) in patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC). The primary objective is to evaluate the anti-tumor efficacy of trilaciclib when administered prior to sacituzumab govitecan-hziy as measured by PFS. Data from this trial will help determine future ADC combinations. Initial results including ORR and myeloprotection endpoints are expected in the fourth quarter of 2022. (Press release here)
- **Initiated New Phase 2 Trial of Trilaciclib to Support its Immune-based Mechanism of Action:** G1 initiated a Phase 2, single arm, open-label trial of trilaciclib in patients with early-stage TNBC designed to confirm the mechanism of action of trilaciclib in modulating the anti-tumor immune response with and without a checkpoint inhibitor. This trial is replacing I-SPY2 neoadjuvant breast trial in G1's pipeline given the landscape shift from chemotherapy only to chemotherapy + I/O. The primary endpoint is to evaluate the immune-based mechanism of action of trilaciclib after a single-dose as measured by the change in the ratio of effector CD8+ tumor-infiltrating lymphocytes (TILs) to suppressor regulatory T cell (Tregs) in the tumor microenvironment. Data from this trial will inform design of future pivotal studies across multiple tumor types and treatment combinations. Initial results including immune endpoints (e.g., CD8+ TIL / Treg ratio) are expected in the fourth quarter of 2022. (Press release here)
- **Reiterated Expectation of Initial Data in the Second Half of 2023 from Pivotal Phase 3 Trial of Trilaciclib in 1L TNBC (PRESERVE 2); Changes in Market Landscape Drive Strategic Decision to Discontinue 2L Arm:** The treatment landscape is shifting rapidly in 2L TNBC given the expanded indication and rapid uptake of Trodelvy® (sacituzumab govitecan-hziy) in 2L/3L TNBC, creating significant barriers to enrollment in this cohort and dramatically reducing the future market opportunity in 2L. As such, the Company has made the strategic decision to discontinue the 2L arm of the trial and will continue to enroll and focus on 1L mTNBC, an area of high unmet medical need. G1 has also modified the protocol to include post-checkpoint patients in the 1L arm to develop clinical experience in this setting. The Company has confirmed that it expects initial results from this pivotal trial, including interim overall survival, in the second half of 2023.

Medical

- **Announced Publication of Data Showing That Proactive Use of Trilaciclib Prior To Chemotherapy in Certain Patients Significantly Reduced the Use of Reactive Supportive Care Therapies After Chemotherapy:** Results from a retrospective analysis of the pooled results of three randomized trilaciclib studies were published in *Cancer Medicine*, demonstrating that patients with extensive-stage small-cell lung cancer (ES-SCLC) who received trilaciclib prior to each chemotherapy treatment had significantly lower use of supportive care therapies—including G-CSFs, ESAs, and RBC transfusions— for chemotherapy-induced myelosuppression than patients who received placebo. (Press release here)
- **Presented Data at the 36th Annual Meeting of The Society for Immunotherapy of Cancer (SITC) Demonstrating that Trilaciclib Enhanced Patients' T Cell Immune Function:** Results from an immunologic analysis of Phase 2 study data showed that trilaciclib enhanced both CD4 and CD8 T cell function in certain patients with metastatic TNBC when administered prior to chemotherapy. Patients who received trilaciclib prior to gemcitabine/carboplatin (GCb) had fewer immune suppressing cells (myeloid derived suppressor cells; MDSCs) than patients who received GCb alone, whether they were responders or non-responders to treatment, and showed increased T cell function. (Press release here)
- **Published Data in the Journal of Medical Economics Showing Cost Savings Associated with Trilaciclib Use Prior To Chemotherapy in Patients with Extensive-Stage Small Cell Lung Cancer:** Data show that the use of trilaciclib prior to first-line chemotherapy resulted in cost savings due to fewer myelosuppressive adverse events and their associated treatment costs in patients with ES-SCLC suggesting that trilaciclib could provide both clinical and economic benefits for the treatment of these patients.

Fourth Quarter and Full Year 2021 Financial Results

As of December 31, 2021, cash and cash equivalents totaled $221.2 million, compared to $207.3 million as of December 31, 2020. On November 1, 2021, G1 and Hercules Capital amended Hercules' loan terms to provide total commitments of $150.0 million, of which $100.0 million was fully available as of amendment closing. To date, G1 has drawn $75 million on this facility. An additional $25.0 million of debt facility is currently available but not yet drawn.

Total revenues for the fourth quarter of 2021 were $5.8 million, including $4.4 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. Total revenues for the full-year 2021 were $31.5 million, consisting of license revenue of $20.4 million and net product revenue of $11.1 million from sales of COSELA.

Operating expenses for the fourth quarter of 2021 were $43.4 million, compared to $40.6 million for the fourth quarter of 2020. GAAP operating expenses include stock-based compensation expense of $5.2 million for the fourth quarter of 2021, compared to $4.8 million for the fourth quarter of 2020. Operating expenses for the full-year 2021 were $173.9 million, compared to $141.8 million for the prior year. Stock-based compensation expense for the full-year 2021 was $22.3 million, compared to $18.8 million for the prior year.

Cost of goods sold expense for the fourth quarter of 2021 were $0.4 million compared to $0 for the fourth quarter of 2020. 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. Cost of goods sold expense for the full-year 2021 were $2.0 million.

Research and development (R&D) expenses for the fourth quarter of 2021 were $19.8 million, compared to $16.4 million for the fourth quarter of 2020. The increase in R&D expenses was primarily due to an increase in clinical trial spend, which is partially offset by a decrease in costs associated with the manufacturing of active pharmaceutical ingredients and drug product to support clinical trials. R&D expenses for the full-year 2021 were $76.2 million, compared to $73.3 million for the prior year.

Selling, general, and administrative (SG&A) expenses for the fourth quarter of 2021 were $23.2 million, compared to $24.3 million for the fourth quarter of 2020. The decrease in SG&A expenses was largely due to a decrease in spend on commercialization activities and medical affairs, partially offset by an increase in personnel costs due to increases in headcount. SG&A expenses for the full-year 2021 were $95.7 million, compared to $68.5 million for the prior year.

The net loss for the fourth quarter of 2021 was $40.0 million, compared to $25.3 million for the fourth quarter of 2020. Net loss for the full-year 2021 was $148.4 million, compared to a net loss of $99.3 million for the prior year. The basic and diluted net loss per share for the fourth quarter of 2021 was $(0.94) compared to $(0.67) for the fourth quarter of 2020. The basic and diluted net loss per share for the full-year 2021 was $(3.54) compared to $(2.62) for the full-year 2020.

Financial Guidance

G1 also expects its current financial position 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 fourth quarter and full year 2021 ended December 31, 2021. The live call may be accessed by dialing (866) 763-6020 (domestic) or (409) 216-0626 (international) and entering the conference code: 5256086. 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)

	December 31, 2021	December 31, 2020
Cash and cash equivalents	$ 221,186	$ 207,306
Working capital	$ 215,952	$ 192,949
Total assets	$ 254,094	$ 228,552
Accumulated deficit	$ (584,459)	$ (436,107)
Total stockholders' equity	$ 143,541	$ 177,351

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

	Three months ended December 31,		Twelve months ended December 31,	
	2021	2020	2021	2020
Revenues:				
Product sales, net	$ 4,403	$ —	$ 11,120	$ —
License revenue	1,393	16,546	20,356	45,285
Total revenues	5,796	16,546	31,476	45,285
Operating expenses:				
Cost of goods sold	374	—	2,016	—
Research and development	19,790	16,374	76,225	73,271
Selling, general and administrative	23,218	24,260	95,692	68,490
Total operating expenses	43,382	40,634	173,933	141,761
Loss from operations	(37,586)	(24,088)	(142,457)	(96,476)
Other income (expense):				
Interest income	8	30	43	952
Interest expense	(2,058)	(756)	(4,667)	(1,778)
Other income (expense)	(138)	(54)	(346)	(542)
Total other income (expense), net	(2,188)	(780)	(4,970)	(1,368)
Loss before income taxes	(39,774)	(24,868)	(147,427)	(97,844)
Income tax expense	246	479	925	1,410
Net loss	$ (40,020)	$ (25,347)	$ (148,352)	$ (99,254)
Net loss per share, basic and diluted	$ (0.94)	$ (0.67)	$ (3.54)	$ (2.62)
Weighted average common shares outstanding, basic and diluted	42,544,321	38,053,609	41,943,417	37,878,026