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): August 3, 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:

- 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 August 3, 2022, G1 Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the second-quarter ended June 30, 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	Press Release dated August 3, 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: August 3, 2022

G1 Therapeutics Provides Second Quarter 2022 Financial Results and Operational Highlights

- Achieved $8.7 Million in Net Revenue from Sales of COSELA® (trilaciclib) in the Second Quarter of 2022 and $10.6 Million in Total Revenue -

- Completed Patient Enrollment in Pivotal Phase 3 Trial of Trilaciclib in Metastatic Colorectal Cancer (mCRC) (PRESERVE 1) -

- Completed Patient Enrollment in Phase 2 Mechanism of Action Trial of Trilaciclib in Neoadjuvant Triple Negative Breast Cancer (TNBC) -

- Achieved Target Enrollment in Phase 2 Trial of Trilaciclib in Bladder Cancer (mUC) (PRESERVE 3) -

- Announced Approval of COSELA (trilaciclib hydrochloride for injection) with Simcere in China -

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

RESEARCH TRIANGLE PARK, NC, August 3, 2022 – G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today provided a corporate and financial update for the second quarter ended June 30, 2022.

“The second quarter of 2022 was a period of continued momentum across the G1 organization toward our mission of improving the lives of those impacted with cancer,” said Jack Bailey, Chief Executive Officer of G1 Therapeutics. “For the first time, our sales team was in full control of COSELA, interacting with prescribers and driving usage and uptake. Thanks to the quality of these engagements, we experienced nearly 60 percent vial volume growth quarter over quarter - our highest quarterly growth rate since the initial launch period. In addition, our clinical team continued to execute on each of our ongoing clinical trials, including achieving important enrollment milestones in our Phase 3 trial of trilaciclib in patients with colorectal cancer and in our Phase 2 bladder cancer and mechanism of action trials.”

Second Quarter 2022 and Recent Highlights

Financial

- **Achieved $8.7 Million in Net COSELA Revenue:** G1 recognized total revenues of $10.6 million in the second quarter of 2022, including $8.7 million in net product revenue from sales of COSELA.

- **Ended the Second Quarter 2022 with Cash and Cash Equivalents of $144.0 Million:** The Company’s current financial position is expected to be sufficient to fund G1’s operations and capital expenditures into 2024.

Clinical

- **Completed Enrollment in Pivotal Phase 3 Clinical Trial of Trilaciclib in Patients with mCRC:** Enrollment in PRESERVE 1 is complete at 326 randomized patients; the trial was over-enrolled by approximately 10 percent to compensate for potential loss to follow up at trial sites in Ukraine. The primary endpoint is myeloprotection as measured by duration of severe neutropenia and the occurrence of severe neutropenia during induction. Key secondary endpoints include the effects of trilaciclib on chemotherapy-induced fatigue compared with placebo and the effect of trilaciclib on progression free survival and overall survival compared with placebo. Initial data including the primary endpoint of myeloprotection are expected in the first quarter of 2023. (Press release here)

- **Completed Enrollment in Phase 2 Clinical Trial Assessing the Mechanism of Action (MOA) of Trilaciclib in Neoadjuvant Breast Cancer:** Enrollment is complete at 24 patients in the Phase 2 trial in early stage TNBC to confirm the mechanism of action of trilaciclib in modulating the anti-tumor immune response. The primary endpoints will assess the immune-based MOA, including the impact of trilaciclib on CD8+ T cells and regulatory T cells, or Tregs, in the tumor microenvironment. Secondary endpoints include pathological complete response (pCR), immune response, and profiling measures. Initial data from the primary endpoint are expected in the fourth quarter of 2022.

- **Achieved Target Patient Enrollment in Phase 2 Clinical Trial of Trilaciclib in Combination with Chemotherapy and Avelumab in Patients with Bladder Cancer (mUC):** Target enrollment of 90 patients was achieved in PRESERVE 3; the last few consented patients are expected to enroll shortly. The trial builds on the strong rationale for trilaciclib in combination with chemotherapy and a checkpoint inhibitor (anti-PD-L1); preclinical and published data to date suggest potential for a synergistic effect in known immunogenic tumors. The primary endpoint is progression-free survival. Key secondary endpoints include overall survival, overall response rate, duration of response, and myeloprotection. Initial data including top line response rate and myeloprotection data are expected in the fourth quarter of 2022 followed by data on the primary endpoint of progression free survival in 2023.

- **Confirmed Expectation for Initial Data from Pivotal Phase 3 Trial of Trilaciclib in Triple Negative Breast Cancer (mTNBC) in the Second Half of 2023:** Initial results including interim results for Overall Survival from PRESERVE 2, the Company's ongoing line extension trial of trilaciclib in approximately 170 patients with PD-L1 positive and negative metastatic TNBC receiving first line gemcitabine and carboplatin, are expected in the second half of 2023. If the trial meets the interim analysis stopping rule, it will terminate, and we will report the topline results. If it does not, the trial will continue to the final analysis.

- **Confirmed Expectation for Initial Data in the Fourth Quarter of 2022 from Phase 2 Trial of Trilaciclib in Combination with an Antibody-Drug Conjugate (ADC):** G1 has reiterated that it expects to release preliminary safety data in the fourth quarter of 2022 from a Phase 2 trial in combination with the antibody-drug conjugate (ADC) Trodelvy® (sacituzumab govitecan-hziy) in patients with unresectable locally advanced or metastatic TNBC.

Medical

- **Presented Data at the 2022 ASCO Annual Meeting Showing that Trilaciclib Helps Protect Patients with Extensive-Stage Small Cell Lung Cancer (ES-SCLC) Against Single- and Multilineage Myelosuppressive Events When Used Prior to Chemotherapy:** Results of the analysis showed that throughout cycles one through four of first-line therapy, fewer patients with ES-SCLC treated with trilaciclib experienced single-lineage (neutrophil, red blood cell or platelet lineages) and multilineage myelosuppressive events (severe neutropenia, severe anemia, and severe thrombocytopenia)—and fewer events occurred per person—than patients who received placebo. (Press release here)

- **Presented Data at the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Describing the Economic Impact of Trilaciclib for Chemotherapy-Induced Myelosuppression in ES-SCLC):** Data showed that from both the US provider and patient-caregiver perspectives, the use of trilaciclib prior to chemotherapy in patients with ES-SCLC is associated with fewer myelosuppressive AEs and less healthcare resource use, translating into lower total cost of care. (Poster available here)

Corporate

- **Announced Approval of COSELA with Simcere in China:** The China National Medical Products Administration (NMPA) has conditionally approved COSELA (trilaciclib hydrochloride for injection), which was jointly developed for use in Greater China by Simcere and G1. As a result of receiving approval in China, G1 will receive a $13 million milestone payment. In total, G1 may receive up to $156M in total milestones, and double-digit royalties on annual net sales of COSELA in China (Press release here)

- **Announced Appointments of Norman E. "Ned" Sharpless, M.D. and Jacks Lee to Board of Directors:** Dr. Sharpless, the former Director of the National Cancer Institute (NCI) of the National Institutes of Health, is an accomplished oncologist and seasoned public servant who has treated cancer patients, investigated the biologic basis of cancer, and has led academic institutions and government agencies including the NCI. (Press release here). Mr. Lee, the Senior Vice President – Manufacturing & Supply of Merck & Co., brings more than 30 years of experience in manufacturing and supply chain management in the life sciences industry, spanning across technical, operational, and strategic leadership roles in science-technology, engineering, quality, supply chain, and manufacturing. (Press release here)

Second Quarter 2022 Financial Results

As of June 30, 2022, cash and cash equivalents totaled $144.0 million, compared to $221.2 million as of December 31, 2021.

Total revenues for the second quarter of 2022 were $10.6 million, including $8.7 million in net product sales of COSELA and license revenue of $1.9 million. This license revenue is primarily related to revenue recognized from amounts to be reimbursed by EQRx and Simcere for costs associated with clinical trials.

Operating expenses for the second quarter of 2022 were $47.5 million, compared to $44.8 million for the second quarter of 2021. GAAP operating expenses include stock-based compensation expense of $5.6 million for the second quarter of 2022, compared to $5.7 million for the second quarter of 2021.

Cost of goods sold expense for the second quarter of 2022 was $1.0 million compared to $0.8 million for the second quarter of 2021, primarily due to an increase in product sales.

Research and development (R&D) expenses for the second quarter of 2022 were $20.8 million, compared to $18.8 million for the second quarter of 2021. The increase in R&D expenses was primarily due to an increase in clinical trial costs offset by a decrease in costs for manufacturing of active pharmaceutical ingredients and drug product to support clinical trials.

Selling, general, and administrative (SG&A) expenses for the second quarter of 2022 were $25.7 million, compared to $25.2 million for the second quarter of 2021. The increase in SG&A expenses was due to increased personnel costs related to headcount and an increase in insurance and other administrative costs.

The increase is offset by a decrease in medical affairs costs, commercialization activities, professional and legal fees, and IT-related costs.

The net loss for the second quarter of 2022 was $39.4 million, compared to $39.4 million for the second quarter of 2021. The basic and diluted net loss per share for the second quarter of 2022 was $(0.92) compared to $(0.94) for the second quarter of 2021.

Financial Guidance

G1 expects its current cash and cash equivalents of $144.0 million 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 second quarter 2022 ended June 30, 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 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 sales of COSELA (trilaciclib), the therapeutic potential of COSELA (trilaciclib), our ability to generate data to maximize trilaciclib's applicability to future treatment paradigms, our reliance on partners to develop licensed products, and our expectation that we have sufficient cash to fund our operations into 2024. If we are not in compliance with our monthly net revenue covenants or the minimum cash covenant, 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 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; our ability to meet our monthly net revenue covenants or the minimum cash covenants, 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.

###

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

Rebecca Levine
Director, Corporate Communications and Public Relations
(919) 667-8711
rlevine@g1therapeutics.com

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

	June 30, 2022	December 31, 2021
Cash and cash equivalents	$143,957	$221,186
Working Capital	$139,848	$215,952
Total Assets	$186,879	$254,094
Accumulated deficit	$(673,097)	$(584,459)
Total stockholders' equity	$66,325	$143,541

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenues				
Product sales, net	$ 8,718	$ 2,532	$ 14,198	$ 3,141
License revenue	1,855	4,072	3,277	17,681
Total revenues	10,573	6,604	17,475	20,822
Operating expenses				
Cost of goods sold	976	808	1,645	1,051
Research and development	20,843	18,752	47,148	35,292
Selling, general and administrative	25,716	25,236	52,425	48,206
Total operating expenses	47,535	44,796	101,218	84,549
Loss from operations	(36,962)	(38,192)	(83,743)	(63,727)
Other income (expense)				
Interest income	50	9	59	28
Interest expense	(2,407)	(927)	(4,672)	(1,675)
Other income (expense)	(127)	(92)	(282)	(132)
Total other income (expense), net	(2,484)	(1,010)	(4,895)	(1,779)
Loss before income taxes	(39,446)	(39,202)	(88,638)	(65,506)
Income tax expense	—	220	—	358
Net loss	$ (39,446)	$ (39,422)	$ (88,638)	$ (65,864)
Net loss per share, basic and diluted	$ (0.92)	$ (0.94)	$ (2.08)	$ (1.59)
Weighted average common shares outstanding, basic and diluted	42,707,703	42,119,850	42,697,508	41,414,254