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 2, 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 August 2, 2023, G1 Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 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 August 2, 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/ John W. Umstead V*
John W. Umstead V
Chief Financial Officer

Date: August 2, 2023

G1 Therapeutics Provides Second Quarter 2023 Financial Results and Operational Highlights

- Recognized Total Revenue of $42.4 million, Including $11.1 million in Net COSELA® (trilaciclib) Revenue -

- Reiterated Expectation for Interim Overall Survival (OS) Analysis of Pivotal Phase 3 Trial in Metastatic Triple Negative Breast Cancer (TNBC) in the First Quarter of 2024 -

- Presented New Phase 2 Results Confirming Benefit of Trilaciclib in Reducing Adverse Events Associated with an Antibody-Drug Conjugate (ADC) in Triple Negative Breast Cancer (TNBC) -

- Provided Phase 2 Mechanism of Action Trial Results Clarifying Trilaciclib's Role in Enhancing Immune Surveillance and Efficacy as Measured by Long Term Endpoints like Overall Survival (OS) -

- Improved Financial Strength By Amending Hercules Debt Facility and Receiving Payment from Simcere for Relief of Future Royalties; Cash Runway Extends Beyond Expected Clinical Trial Readouts in Early 2024 -

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

RESEARCH TRIANGLE PARK, NC, August 2, 2023 – G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today provided a corporate and financial update for the second quarter ended June 30, 2023.

“We know the impact that trilaciclib can have on the lives of people battling cancer; we see it every day in patients with extensive stage small cell lung cancer who receive COSELA prior to their chemotherapy. And, we’ve made good progress in further developing the potential of the drug in clinical trials for additional indications,” said Jack Bailey, Chief Executive Officer of G1 Therapeutics. “As such, our focus remains on driving depth of COSELA usage and adoption in our top accounts, despite a national platinum-based chemotherapy shortage. We are also preparing for multiple important data readouts expected early next year, and ensuring our continued financial strength."

Second Quarter 2023 and Recent Highlights

Financial

- **Recognized $11.1 million in Net COSELA Revenue:** Results represent a 6% increase in net sales over the first quarter of 2023. G1 recognized total revenues of $42.4 million for the second quarter of 2023.
- **Received Net Proceeds of $27.0 million for Relief of Future Royalty Payments from Simcere:** An additional $18.0 million would be due to G1 upon filing and approval of COSELA in mainland China for patients with TNBC. All other aspects of the strategic collaboration remain in place. G1 retains the rights to trilaciclib throughout the rest of the world, other than Greater China.
- **Ended the Second Quarter of 2023 with Cash, Cash Equivalents, and Marketable Securities of $104.2 million.** The Company’s current financial position is expected to be sufficient to fund G1’s operations and capital expenditures well beyond its clinical trial readouts in the first quarter of 2024.
- **Amended Debt Facility With Hercules Capital:** In June 2023, the debt facility was mutually amended, providing G1 with additional financial flexibility. As of June 30, 2023, the total loan amount outstanding is $50.0 million.

Clinical

- **Confirmed Expected Timing for Initial Results from Pivotal Phase 3 Clinical Trial of Trilaciclib in Patients with mTNBC; Interim Overall Survival (OS) Analysis Expected in the First Quarter of 2024:** The primary endpoint of PRESERVE 2 is to evaluate the effect of trilaciclib on OS compared with placebo in patients receiving first-line gemcitabine/carboplatin. G1 expects the interim OS analysis to be conducted by its data monitoring committee in the first quarter of 2024. If the trial meets the interim analysis stopping rule, it will be unblinded and G1 will report the top line results. If it does not, the trial will continue to the final analysis. If positive, the Company intends to meet with the U.S. Food and Drug Administration to discuss filing a supplemental new drug application (sNDA) as soon as possible in 2024.

- **Presented Preliminary Phase 2 Results Confirming Benefit of Trilaciclib in Reducing Adverse Events Related to an ADC; OS Endpoints Expected in the First Quarter of 2024:** New results presented at the 2023 European Society of Medical Oncology (ESMO) Breast Cancer Congress showed a clinically meaningful on-target effect of trilaciclib to reduce (>50%) the rates of multiple adverse events compared to the previously published sacituzumab govitecan-hziy single agent safety profile**.** The Company expects to reach the OS endpoints in the first quarter of 2024. (press release here)

- **Presented Phase 2 Results Showing that Trilaciclib Increases the Pool of Memory T Cells in the Tumor Microenvironment that Could Contribute to Long Term Immune Surveillance and Efficacy:** New results presented at the American Society of Clinical Oncology (ASCO) Annual Meeting highlight the potential for trilaciclib to increase the pool of functional memory T cells that could contribute to long-term immune surveillance and efficacy, as measured by longer term endpoints like OS. (press release here)

- **Provided Initial Results from Phase 2 Bladder Cancer Trial of Trilaciclib (PRESERVE 3); OS Endpoints Expected in the First Quarter of 2024:** Data generated across multiple preclinical and clinical studies to date show that trilaciclib has the greatest effect on longer term endpoints including OS rather than earlier efficacy measures such as overall response rate (ORR) and progression free survival (PFS), consistent with other immunotherapies. As of the data cutoff on July 5, 2023, PFS is similar between patients receiving trilaciclib prior to gemcitabine/platinum + avelumab and patients receiving gemcitabine/platinum + avelumab alone (median PFS=6.0 months and 6.1 months, respectively; hazard ratio=1.07). Median PFS was also similar across arms in both PD-L1 subsets. Median duration of response (DOR) favored participants that received trilaciclib (7.0 months) compared to those that did not (6.0 months); median DOR also favored the trilaciclib arms in both PD-L1 subsets. The Company expects to reach the OS endpoints in the first quarter of 2024.

Medical

- **Presented Real World Data Confirming Consistent Risk of Myelosuppression Across Patients Receiving Chemotherapy for Small Cell Lung Cancer (SCLC):** Results presented at the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 2023 meeting showed that grade ≥3 myelosuppression (neutropenia, anemia, thrombocytopenia) occurred in 61% of patients included in the overall population of studied patients. No significant associations between patient characteristics and myelosuppression were identified. (press release here)

- **Announced New Publication Describing the Immune-Based Mechanism of Trilaciclib**: G1's manuscript entitled, "Investigating Potential Immune Mechanisms of Trilaciclib Administered Prior to Chemotherapy in Patients with Metastatic Triple-Negative Breast Cancer" has been published in the Journal of *Breast Cancer Research* and Treatment. (publication here)

Corporate

- **Appointed Monica Roberts Thomas as General Counsel and Chief Compliance Officer:** Mrs. Thomas brings nearly two decades of leadership experience in securities filings and corporate governance, global regulatory engagement, and all aspects of legal support for commercial organizations. (press release here)

Second Quarter 2023 Financial Results

As of June 30, 2023, cash and cash equivalents and marketable securities totaled $104.2 million, compared to $145.1 million as of December 31, 2022. On June 6, 2023, G1 and Hercules Capital Inc. amended their loan and security agreement. The amended terms modified certain tranche advances, lowered the minimum cash covenant, and removed the existing minimum revenue covenant and replaced it with a conditional borrowing base limit, beginning with the financial reporting for the period ending June 30, 2023. On closing, G1 paid down the loan by $25.0 million, resulting in a total loan amount outstanding of $50.0 million as of June 30, 2023.

Total revenues for the second quarter of 2023 were $42.4 million, including $11.1 million in net product sales of COSELA and license revenue of $31.3 million, primarily related to the one-time payment for the relief of future royalties from Simcere, supply and manufacturing services and royalty revenue from Simcere, and clinical trial reimbursements from EQRx and Simcere, compared to $10.6 million in total revenues in the second quarter of 2022.

Operating expenses for the second quarter of 2023 were $30.9 million, compared to $47.5 million for the second quarter of 2022. GAAP operating expenses include stock-based compensation expense of $3.8 million for the second quarter of 2023, compared to $5.6 million for the second quarter of 2022.

Cost of goods sold expense for the second quarter of 2023 was $1.4 million compared to $1.0 million for the second quarter of 2022, primarily due to an increase in product sales.

Research and development (R&D) expenses for the second quarter of 2023 were $12.0 million, compared to $20.8 million for the second quarter of 2022. 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 second quarter of 2023 were $17.4 million, compared to $25.7 million for the second quarter of 2022. The decrease in SG&A expenses was primarily due to decreases in commercialization activities, personnel costs, and medical affairs.

The net income for the second quarter of 2023 was $8.7 million, compared to a net loss of $39.4 million for the second quarter of 2022. The basic and diluted net income per share for the second quarter of 2023 was $0.17 and $0.14, respectively, compared to a basic and diluted net loss per share of $(0.92) for the second quarter of 2022.

2023 Financial Guidance

G1 today reiterated its full year 2023 net revenue guidance. The Company expects to generate between $50 million and $60 million in COSELA net revenue in 2023. G1's product revenue guidance was initially provided in its fourth quarter and full year 2022 financial results and business update, and 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 second quarter ended June 30, 2023.

Please note the 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 drive growth of COSELA among our top accounts, our ability to obtain approvals for and commercialize additional indications of COSELA (trilaciclib), our ability to complete our ongoing clinical trials on time, our ability to minimize the impact of a national platinum-based chemotherapy shortage, and our reliance on partners to develop licensed products. If we are not in compliance with 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.
Condensed Balance Sheet Data (unaudited)
(in thousands)

	June 30, 2023	December 31, 2022
Cash and cash equivalents and Marketable securities	$104,231	$145,070
Working Capital	$106,524	$143,912
Total Assets	$147,891	$187,965
Accumulated deficit	$(750,903)	$(732,018)
Total stockholders' equity	$57,548	$68,747

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenues				
Product sales, net	$ 11,091	$ 8,718	$ 21,583	$ 14,198
License revenue	31,301	1,855	33,755	3,277
Total revenues	42,392	10,573	55,338	17,475
Operating expenses				
Cost of goods sold	1,404	976	2,863	1,645
Research and development	12,040	20,843	27,520	47,148
Selling, general and administrative	17,432	25,716	39,185	52,425
Total operating expenses	30,876	47,535	69,568	101,218
Income (loss) from operations	11,516	(36,962)	(14,230)	(83,743)
Other income (expense)				
Interest income	643	50	1,359	59
Interest expense	(2,710)	(2,407)	(5,799)	(4,672)
Other income (expense)	569	(127)	1,093	(282)
Total other income (expense), net	(1,498)	(2,484)	(3,347)	(4,895)
Income (loss) before income taxes	10,018	(39,446)	(17,577)	(88,638)
Income tax expense	1,308	—	1,308	—
Net income (loss)	$ 8,710	$ (39,446)	$ (18,885)	$ (88,638)
Earnings per share attributable to common stockholders:				
Basic	$ 0.17	$ (0.92)	$ (0.37)	$ (2.08)
Diluted	$ 0.14	$ (0.92)	$ (0.37)	$ (2.08)
Weighted average common shares outstanding:				
Basic	51,667,099	42,707,703	51,657,456	42,697,508
Diluted	61,040,507	42,707,703	51,657,456	42,697,508