
**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): November 1, 2023

G1 THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38096
(Commission
File Number)

26-3648180
(IRS Employer
Identification No.)

**700 Park Offices Drive
Suite 200
Research Triangle Park, NC**
(Address of principal executive offices)

27709
(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 November 1, 2023, G1 Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the third quarter ended September 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 November 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/ John W. Umstead V
John W. Umstead V
Chief Financial Officer

Date: November 1, 2023



G1 Therapeutics Provides Third Quarter 2023 Financial Results and Operational Highlights

- Recognized Total Revenue of \$12.3 million, Including \$10.8 million in Net COSELA® (trilaciclib) Revenue; Vial Volume Grew 3% Over Prior Quarter -
 - Confirmed Expectation of Interim Overall Survival (OS) Analysis for Pivotal Phase 3 PRESERVE 2 Trial in Metastatic Triple Negative Breast Cancer (TNBC) in the First Quarter of 2024 -
 - Reiterated Expectation of Initial OS Results from Phase 2 Trial of Trilaciclib in Combination with an Antibody-Drug Conjugate (ADC) in the First Quarter of 2024 -
 - COSELA Recommended in Updated American Society of Clinical Oncology (ASCO) Small Cell Lung Cancer (SCLC) Guidelines -
- Management to Host Webcast and Conference Call today at 8:30 AM ET -

RESEARCH TRIANGLE PARK, NC, November 1, 2023 – G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today provided a corporate and financial update for the third quarter ended September 30, 2023.

"Despite the impact of the ongoing platinum-based chemotherapy shortage, we continue to be encouraged by the mounting real-world evidence confirming the benefit of COSELA and the support of organizations like ASCO through their recent SCLC guideline update recommending its use; we believe these are indicative of the potential of COSELA," said Jack Bailey, Chief Executive Officer of G1 Therapeutics. "Beyond that, our focus remains on establishing our leadership position in TNBC. As we approach OS readouts from our ongoing trials, including most importantly the interim OS analysis of our pivotal Phase 3 TNBC trial, there is palpable excitement among clinicians regarding the potential for trilaciclib to improve survival. If successful in the interim analysis, we look forward to working closely with the U.S. Food and Drug Administration to expand the indication of this important drug."

Third Quarter 2023 and Recent Highlights

Financial

- **Recognized \$10.8 million in Net COSELA Revenue:** G1 recognized total revenues of \$12.3 million for the third quarter of 2023. Vial volume grew 3% over the second quarter of 2023 despite the impact of an ongoing platinum-based chemotherapy shortage.
- **Ended the Third Quarter of 2023 with Cash, Cash Equivalents, and Marketable Securities of \$94.4 million.** The Company's current financial position is now expected to be sufficient to fund G1's operations and capital expenditures beyond the third quarter of 2024.

Clinical

- **Confirmed Expectation of Interim OS Analysis of Pivotal Phase 3 Clinical Trial (PRESERVE 2) in Patients with mTNBC in the First Quarter of 2024:** 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, expected later in 2024. If the results of the interim OS analysis are 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.

- **Reiterated Expectation of Timing for Initial OS Results from Phase 2 Trial of Trilaciclib in Combination with the ADC Sacituzumab Govitecan-Hziy:** The Company expects to report these results in the first quarter of 2024.
- **Phase 2 Bladder Cancer Trial (PRESERVE 3) To Be Concluded in the Fourth Quarter of 2023; OS Trend Favoring Trilaciclib Observed in Maintenance Phase:** G1 intends to conclude the trial this quarter following the next protocol defined analyses of survival and report the results at a future medical meeting. PRESERVE 3 is a signal finding study designed to assess the potential additive contribution of trilaciclib to anti-cancer therapy, including in combination with the immune checkpoint inhibitor avelumab alone without chemotherapy during the maintenance part of the study. To date, an overall survival trend in favor of the trilaciclib plus avelumab arm in the maintenance phase was observed, suggesting a potential additive benefit when used in combination with a checkpoint inhibitor, which will inform future studies in G1's core areas of focus.

Medical

- **COSELA Recommended as a Myeloid Supportive Agent in the Updated ASCO SCLC Guidelines:** Multidisciplinary panels of experts, including patient advocates, develop ASCO's clinical practice guidelines. The SCLC guidelines provide evidence-based recommendations to practicing clinicians on the management of patients with SCLC. (press release [here](#))
- **Presented Four Posters During the 2023 ASCO Quality Care Symposium:** These posters provide new real-world evidence indicating that trilaciclib administered prior to chemotherapy in patients with ES-SCLC lowers the rate of hospitalization and cytopenia events and may improve survival. In addition, multiple analyses indicate the consistent impact of chemotherapy-induced myelosuppressive events, including severe neutropenia, thrombocytopenia, and anemia, on patients with ES-SCLC being treated with chemotherapy as well as the resulting impact on healthcare resource utilization. The posters are available on the G1 Therapeutics website. (press release [here](#))
- **Announced New Publication Highlighting the Real-World Impact of Trilaciclib on Myelosuppressive Events in Patient with ES-SCLC:** Real-world outcomes data from published and new unpublished studies indicate the potential of trilaciclib to reduce single and multilineage myelosuppressive events associated with chemotherapy, cytopenia-related healthcare utilization, and hospitalizations. This review of real-world experience with trilaciclib was published in *Advanced Therapy*. (press release [here](#))

Third Quarter 2023 Financial Results

As of September 30, 2023, cash and cash equivalents and marketable securities totaled \$94.4 million, compared to \$145.1 million as of December 31, 2022.

Total revenues for the third quarter of 2023 were \$12.3 million, including \$10.8 million in net product sales of COSELA and license revenue of \$1.5 million, primarily related to supply and manufacturing services from Simcere and patent and clinical trial costs reimbursed primarily by EQRx and Simcere, compared to \$23.6 million in total revenues in the third quarter of 2022.

On August 1, 2023, the Company received formal notice from EQRx of their intent to terminate the lerociclib license agreement as part of their proposed acquisition by Revolution Medicines, Inc. G1 received a payment of \$1.6 million during the quarter ended September 30, 2023 for the remainder of the costs to wind down the lerociclib study. No milestones have been achieved through September 30, 2023, and as a result of the termination, the Company will not receive any further milestone payments or future royalties from EQRx.

Operating expenses for the third quarter of 2023 were \$28.7 million, compared to \$45.1 million for the third quarter of 2022. GAAP operating expenses include stock-based compensation expense of \$3.7 million for the third quarter of 2023, compared to \$4.8 million for the third quarter of 2022.

Cost of goods sold expense for the third quarter of 2023 was \$3.1 million, compared to \$1.1 million for the third quarter of 2022, primarily due to an increase in sales volume and a one-time inventory reserve for potential product obsolescence.

Research and development (R&D) expenses for the third quarter of 2023 were \$8.8 million, compared to \$19.6 million for the third 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 third quarter of 2023 were \$16.8 million, compared to \$24.4 million for the third quarter of 2022. The decrease in SG&A expenses was primarily due to decreases in commercialization activities, personnel costs, and medical affairs.

The net loss for the third quarter of 2023 was \$18.2 million, compared to \$25.3 million for the third quarter of 2022. The basic and diluted net loss per share for the third quarter of 2023 was \$(0.35), compared to \$(0.59) for the third quarter of 2022.

2023 Financial Guidance

As a result of the ongoing shortage of platinum-based chemotherapy, G1 today lowered its full year 2023 net revenue guidance. The Company expects to generate between \$44 million and \$47 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 third quarter ended September 30, 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](https://twitter.com/G1Therapeutics) and [LinkedIn](https://www.linkedin.com/company/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. 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 successfully 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)

	September 30, 2023	December 31, 2022
Cash and cash equivalents and Marketable securities	\$94,352	\$145,070
Working Capital	\$92,450	\$143,912
Total Assets	\$133,097	\$187,965
Accumulated deficit	\$(769,107)	\$(732,018)
Total stockholders' equity	\$43,022	\$68,747

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues				
Product sales, net	\$ 10,839	\$ 8,269	\$ 32,422	\$ 22,467
License revenue	1,461	15,307	35,216	18,584
Total revenues	12,300	23,576	67,638	41,051
Operating expenses				
Cost of goods sold	3,076	1,111	5,939	2,756
Research and development	8,811	19,581	36,331	66,729
Selling, general and administrative	16,781	24,432	55,966	76,857
Total operating expenses	28,668	45,124	98,236	146,342
Loss from operations	(16,368)	(21,548)	(30,598)	(105,291)
Other income (expense)				
Interest income	585	211	1,944	270
Interest expense	(2,115)	(2,764)	(7,914)	(7,436)
Other income (expense)	599	48	1,692	(234)
Total other income (expense), net	(931)	(2,505)	(4,278)	(7,400)
Loss before income taxes	(17,299)	(24,053)	(34,876)	(112,691)
Income tax expense	905	1,219	2,213	1,219
Net loss	\$ (18,204)	\$ (25,272)	\$ (37,089)	\$ (113,910)
Net loss per share, basic and diluted	\$ (0.35)	\$ (0.59)	\$ (0.72)	\$ (2.67)
Weighted average common shares outstanding, basic and diluted	51,777,731	42,799,342	51,697,989	42,731,826

